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Summary Report on the statistics on the use of animals for scientific purposes in the Member States of the European Union and Norway in 2020

PART C:
MEMBER STATE DATA 2020
MEMBER STATE COMPARATIVE TABLES FOR 2020

MEMBER STATE DATA 2020 144
VI Member State narratives and data submissions 2020 144
Introduction 144
Austria 145
Austria: Narrative 2020 145
Austria: Statistical Data 2020 146
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 146
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 147
Section 3: Creation and maintenance of genetically altered animal lines 150
Belgium 152
Belgium: Narrative 2020 152
Belgium: Statistical Data 2020 157
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 157
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 159
Section 3: Creation and maintenance of genetically altered animal lines 163
Bulgaria 165
Bulgaria: Narrative 2020 165
Bulgaria: Statistical Data 2020 166
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 166
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 167
Section 3: Creation and maintenance of genetically altered animal lines 170
Croatia 171
Croatia: Narrative 2020 171
Croatia: Statistical Data 2020 177

Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 177
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 178
Section 3: Creation and maintenance of genetically altered animal lines 181
Cyprus 182
Cyprus: Narrative 2020 182
Cyprus: Statistical Data 2020 183
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 183
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 184
Section 3: Creation and maintenance of genetically altered animal lines 186
Czechia 187
Czechia: Narrative 2020 187
Czechia: Statistical Data 2020 188
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 188
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 190
Section 3: Creation and maintenance of genetically altered animal lines 194
Denmark 196
Denmark: Narrative 2020 196
Denmark: Statistical Data 2020 198
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 198
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 199
Section 3: Creation and maintenance of genetically altered animal lines 202
Estonia 204
Estonia: Narrative 2020 204
Estonia: Statistical Data 2020 205
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 205
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 206

Section 3: Creation and maintenance of genetically altered animal lines 208
Finland 209
Finland: Narrative 2020 209
Finland: Statistical Data 2020 210
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 210
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 211
Section 3: Creation and maintenance of genetically altered animal lines 214
France 216
France: Narrative 2020 216
France: Statistical Data 2020 219
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 219
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 221
Section 3: Creation and maintenance of genetically altered animal lines 225
Germany 227
Germany: Narrative 2020 227
Germany: Statistical Data 2020 230
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 230
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 232
Section 3: Creation and maintenance of genetically altered animal lines 236
Greece 238
Greece: Narrative 2020 238
Greece: Statistical Data 2020 240
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 240
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 241
Section 3: Creation and maintenance of genetically altered animal lines 244
Hungary 246
Hungary: Narrative 2020 246

Hungary: Statistical Data 2020 248
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 248
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 249
Section 3: Creation and maintenance of genetically altered animal lines 253
Ireland 254
Ireland: Narrative 2020 254
Ireland: Statistical Data 2020 257
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 257
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 259
Section 3: Creation and maintenance of genetically altered animal lines 262
Italy 264
Italy: Narrative 2020 264
Italy: Statistical Data 2020 268
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 268
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 270
Section 3: Creation and maintenance of genetically altered animal lines 274
Latvia 276
Latvia: Narrative 2020 276
Latvia: Statistical Data 2020 283
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 283
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 284
Section 3: Creation and maintenance of genetically altered animal lines 286
Lithuania 287
Lithuania: Narrative 2020 287
Lithuania: Statistical Data 2020 289
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 289

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 290
Section 3: Creation and maintenance of genetically altered animal lines 292
Luxembourg 293
Luxembourg: Narrative 2020 293
Luxembourg: Statistical Data 2020 294
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 294
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 296
Section 3: Creation and maintenance of genetically altered animal lines 298
Malta 299
Malta: Narrative 2020 299
Malta: Statistical Data 2020 299
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 299
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 300
Section 3: Creation and maintenance of genetically altered animal lines 302
Netherlands 303
Netherlands: Narrative 2020 303
Netherlands: Statistical Data 2020 304
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 304
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 306
Section 3: Creation and maintenance of genetically altered animal lines 310
Poland 312
Poland: Narrative 2020 312
Poland: Statistical Data 2020 313
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 313
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 315
Section 3: Creation and maintenance of genetically altered animal lines 319

Poland, corrected statistical data 2019 321
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes (corrected) 321
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes (corrected) 322
Section 3: Creation and maintenance of genetically altered animal lines (corrected) 326
Portugal 328
Portugal: Narrative 2020 328
Portugal: Statistical Data 2020 330
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 330
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 332
Section 3: Creation and maintenance of genetically altered animal lines 335
Romania 337
Romania: Narrative 2020 337
Romania: Statistical Data 2020 338
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 338
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 339
Section 3: Creation and maintenance of genetically altered animal lines 342
Slovakia 343
Slovakia: Narrative 2020 343
Slovakia: Statistical Data 2020 345
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 345
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 346
Section 3: Creation and maintenance of genetically altered animal lines 349
Slovenia 350
Slovenia: Narrative 2020 350
Slovenia: Statistical Data 2020 351
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 351

Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 352
Section 3: Creation and maintenance of genetically altered animal lines 355
Spain 356
Spain: Narrative 2020 356
Spain: Statistical Data 2020 362
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 362
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 363
Section 3: Creation and maintenance of genetically altered animal lines 367
Sweden 369
Sweden: Narrative 2020 369
Sweden: Statistical Data 2020 381
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 381
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 382
Section 3: Creation and maintenance of genetically altered animal lines 385
Norway 387
Noway: Narrative 2020 387
Norway: Statistical Data 2020 389
Section 1: Numbers of animals used for the first time for research, testing, routine production and educational (including training) purposes 389
Section 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes 390
Section 3: Creation and maintenance of genetically altered animal lines 393
VII Member State comparative tables for 2020 395
Introduction 395
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) (2020) 396
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) (2020) 397
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) (2020) 398

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) (2020) 399

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)] (2020) 400

Table 3.2: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, reuse and Member State[1)] (2020).....401

Corrected Member State comparative tables for 2019 402

Introduction.....402

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) 403

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) 404

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) 405

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) 406

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) 407

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).....408

MEMBER STATE DATA 2020

VI Member State narratives and data submissions 2020

Introduction

Member States submitted 2020 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 2020.

The submissions include data from all 27 Member States of the EU in 2020, 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.

Finally, the corrected Polish data for the year 2019 have been added after their 2020 data sets. Due to an error, the Polish data were duplicated for 2019. The Public ALURES Statistical EU database has also been updated with the corrected data.

Austria

Austria: Narrative 2020

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 2020 is 206,469 (2019: 246,315) which is a decrease of approx. 16% or in absolute numbers 39,846 animals.

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

A decrease is especially observed in the total number of mice used for scientific purposes from 205,858 animals in 2019 to 168,995 animals in 2020. Also the total number of fish (including zebra fish) used for scientific purposes decreased from 24,790 animals in 2019 to 19,858 animals in 2020.

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 and 8,327 in 2019 to 2,284 animals in 2020) and “Basic Research, Ethology/Animal Behaviour/ Animal Biology” (from 11,872 in 2019 to 3,393 animals in 2020), “Regulatory use and routine production type, Quality control, Batch safety testing” (from 16,839 in 2019 to 13,400 animals in 2020) and “Translational and applied research, Human infectious disorders” (from 56,601 in 2019 to 34,642 animals in 2020).

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

The proportion of severity "severe" increased from 8% to 11% compared to the previous year (in absolute numbers: from 20,438 animals to 22,137 animals).

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.

The Austrian Government promotes projects to further advance the development of alternative approaches which could use fewer animals or which entail less painful procedures or which do not involve the use of animals at all. Also the establishment of the national 3Rs centre is supported to promote alternative approaches and to disseminate information and implement 3R best practice.

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 and Sus scrofa, “Other birds” include i.a. Meleagris gallopavo, “Other fish” include i.a. Perca fluviatilis, Onchorhynchus mykiss, Squalius cephalus, Thymallus thymallus, Chondrostoma nasus and “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 2020

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	151,446	82.33%
Rats	3,369	1.83%
Guinea-Pigs	107	0.06%
Hamsters (Syrian)	242	0.13%
Mongolian gerbil	63	0.03%
Other rodents	22	0.01%
Rabbits	1,250	0.68%
Cats	7	0%
Dogs	143	0.08%
Horses, donkeys and cross-breeds	98	0.05%
Pigs	2,216	1.2%
Goats	21	0.01%
Sheep	103	0.06%
Cattle	558	0.3%
Other mammals	83	0.05%
Domestic fowl	3,658	1.99%
Other birds	519	0.28%
Xenopus	74	0.04%
Other amphibians	4,894	2.66%
Zebra fish	7,197	3.91%
Other fish	7,883	4.29%
Total	183,953	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	170,944	92.93%
Animals born in the EU but not at a registered breeder	10,831	5.89%
Animals born in rest of Europe	3	0%
Animals born in rest of world	2,175	1.18%
Total	183,953	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	151,446	272	151,718
Rats	3,369		3,369
Guinea-Pigs	107		107
Hamsters (Syrian)	242		242
Mongolian gerbil	63		63
Other rodents	22		22
Rabbits	1,250	28	1,278
Cats	7		7
Dogs	143	33	176
Horses, donkeys and cross-breeds	98	43	141
Pigs	2,216	3	2,219
Goats	21		21
Sheep	103		103
Cattle	558	9	567
Other mammals	83		83
Domestic fowl	3,658		3,658
Other birds	519	20	539
Xenopus	74	26	100
Other amphibians	4,894	27	4,921
Zebra fish	7,197		7,197
Other fish	7,883	15	7,898
Total	183,953	476	18,4429

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	94,262	51.11%
Translational and applied research	71,817	38.94%
Regulatory use and Routine production	15,349	8.32%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1,226	0.66%
Preservation of species	19	0.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1,756	0.95%
Total	184,429	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	19,137	20.3%
Cardiovascular Blood and Lymphatic System	4,997	5.3%
Nervous System	10,051	10.66%
Respiratory System	167	0.18%
Gastrointestinal System including Liver	2,522	2.68%
Musculoskeletal System	8,744	9.28%
Immune System	23,024	24.43%
Urogenital/Reproductive System	1,834	1.95%
Sensory Organs (skin, eyes and ears)	85	0.09%
Endocrine System/Metabolism	3,685	3.91%

Multisystemic	11,810	12.53%
Ethology / Animal Behaviour /Animal Biology	3,393	3.6%
Other basic research	4,813	5.11%
Total	94,262	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	18,894	26.31%
Human Infectious Disorders	34,642	48.24%
Human Cardiovascular Disorders	572	0.8%
Human Nervous and Mental Disorders	3,573	4.98%
Human Respiratory Disorders	144	0.2%
Human Gastrointestinal Disorders including Liver	107	0.15%
Human Musculoskeletal Disorders	162	0.23%
Human Immune Disorders	806	1.12%
Human Urogenital/Reproductive Disorders	576	0.8%
Human Sensory Organ Disorders (skin, eyes and ears)	353	0.49%
Human Endocrine/Metabolism Disorders	809	1.13%
Other Human Disorders	1,400	1.95%
Animal Diseases and Disorders	6,027	8.39%
Animal Welfare	3,033	4.22%
Diagnosis of diseases	653	0.91%
Non-regulatory toxicology and ecotoxicology	66	0.09%
Total	71,817	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	15,323	99.83%
Toxicity and other safety testing including pharmacology	26	0.17%
Total	15,349	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	802	5.23%
Batch potency testing	13,400	87.45%
Other quality controls	1,121	7.32%
Total	15,323	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	26	100.00%
Total	26	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	15,323	99.83%
Other legislation	26	0.17%
Total	15,349	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	15,349	100.00%
Total	15,349	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	183,953	99.74%
Yes	476	0.26%
Total	184,429	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	4,825	2.62%
Mild [up to and including]	90,643	49.15%
Moderate	66,981	36.32%
Severe	21,980	11.92%
Total	184,429	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	111,841	60.64%
Genetically altered without a harmful phenotype	54,802	29.71%
Genetically altered with a harmful phenotype	17,786	9.64%
Total	184,429	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	14,993		14,993
Zebra fish	4,513		4,513
Other fish	250		250
Total	197,56		19,756

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

Severity	Number of uses	Percentage
Mild [up to and including]	17,136	86.74%
Moderate	2,463	12.47%
Severe	157	0.79%
Total	19,756	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	3,565	18.05%
Genetically altered without a harmful phenotype	11,930	60.39%
Genetically altered with a harmful phenotype	4,261	21.57%
Total	197,56	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	9,024	45.88%
Cardiovascular Blood and Lymphatic System	141	0.72%
Nervous System	542	2.76%
Gastrointestinal System including Liver	587	2.98%
Immune System	1,237	6.29%
Endocrine System/Metabolism	787	4%
Multisystemic	3,631	18.46%
Other basic research	3,718	18.9%
Total	19,667	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 Immune Disorders	89	100.00%
Total	89	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	2,284		2,284
Total	2,284		2,284

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

Severity	Number of uses	Percentage
Mild [up to and including]	1,973	86.38%
Moderate	311	13.62%
Total	2,284	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	395	17.29%
Genetically altered without a harmful phenotype	837	36.65%
Genetically altered with a harmful phenotype	1,052	46.06%
Total	2,284	100.00%

Belgium

Belgium: Narrative 2020

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

Compared to 2019 (493,982 uses), there is a decrease of 11.48% in the number of uses in 2020 (437,275 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
556,271	493,982	437,275

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	551,601	489,814	434,085
Yes	4,670	4,168	3,190
Total uses	**556,271**	**493,982**	**437,275**

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	454,576	401,065	362,087
Birds	45,412	41,703	45,946
Fish	54,843	49,807	28,126

Amphibians	1,116	1,106	1,011
Reptiles	324	301	105
Cephalopods	0	0	0
Total uses	**556,271**	**493,982**	**437,275**

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 2,985 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 1,420 in 2019 to 2,329 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	348,937	299,038	251,913
Hamsters	772	886	2,985
Rabbits	61,575	63,094	70,761
Cattle	850	1,420	2,329

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	39,203	35,292	41,115
Other birds	6,209	6,411	4,831

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	25,904	39,115	22,804
Other Fish	28,939	10,692	5,322

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	251,704	222,946	168,821
Translational and applied research	121,645	130,724	120,505
Regulatory use and Routine production	140,896	115,267	127,262
Protection of the natural environment in the interests of the health or welfare of human beings or animals	359	798	743
Preservation of species	5,598	243	371
Higher education or training for the acquisition, maintenance or improvement of vocational skills	7,442	6,287	3,827
Forensic enquiries	0	0	0
Maintenance of colonies of established genetically altered animals, not used in other procedures	28,627	17,717	15,746
Non-EU Purpose	0	0	0
Total uses	**556,271**	**493,982**	**43,7275**

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	20,565	3.70%	14,074	2.85%	9,464	2.16%
Mild	311,660	56.03%	284,376	57.57%	241,487	55.23%
Moderate	154,633	27.80%	131,963	26.71%	139,284	31.85%
Severe	69,413	12.48%	63,569	12.87%	47,040	10.76%
Total uses	556,271	100.00%	493,982	100.00%	437,275	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	1,719
Oncorhynchus mykiss	1,135
Anguilla anguilla	1,029
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

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 alpestris* (3.7%).

Other amphibians	**Number of uses**
Lithobates catesbeianus	30
Triturus helveticus	22
Tristurus alpestris	2

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	2,825
Perdix perdix	1,037
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.

Belgium: Statistical Data 2020

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	216,117	54.98%
Rats	12,343	3.14%
Guinea-Pigs	11,656	2.97%
Hamsters (Syrian)	2,726	0.69%
Mongolian gerbil	14	0%
Other rodents	194	0.05%
Rabbits	70,724	17.99%
Cats	245	0.06%
Dogs	428	0.11%
Horses, donkeys and cross-breeds	162	0.04%
Pigs	5,549	1.41%

Goats	68	0.02%
Sheep	473	0.12%
Cattle	2,150	0.55%
Rhesus monkey	6	0%
Other mammals	55	0.01%
Domestic fowl	40,870	10.4%
Other birds	4,820	1.23%
Reptiles	14	0%
Xenopus	794	0.2%
Other amphibians	54	0.01%
Zebra fish	18,527	4.71%
Other fish	5,068	1.29%
Total	393,057	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	369,146	93.92%
Animals born in the EU but not at a registered breeder	20,891	5.32%
Animals born in rest of Europe	341	0.09%
Animals born in rest of world	2,673	0.68%
Total	393,051	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	4	66.67%
Animals born in America	2	33.33%
Total	6	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	6	100.00%
Total	6	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	216,117	565	216,682
Rats	12,343	137	12,480
Guinea-Pigs	11,656		11,656
Hamsters (Syrian)	2,726		2,726
Mongolian gerbil	14		14
Other rodents	194	19	213
Rabbits	70,724	37	70,761
Cats	245	8	253
Dogs	428	1,091	1,519
Horses, donkeys and cross-breeds	162	37	199
Pigs	5,549	218	5,767
Goats	68	1	69
Sheep	473	30	503
Cattle	2,150	179	2,329
Rhesus monkey	6	30	36
Other mammals	55	55	110
Domestic fowl	40,870	245	41,115
Other birds	4,820	11	4,831
Reptiles	14	91	105
Xenopus	794	163	957
Other amphibians	54		54
Zebra fish	18,527		18,527
Other fish	5,068	254	5,322
Total	393,057	3,171	396,228

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	143,830	36.3%
Translational and applied research	120,195	30.33%
Regulatory use and Routine production	127,262	32.12%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	743	0.19%
Preservation of species	371	0.09%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3,827	0.97%
Total	396,228	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	31,377	21.82%
Cardiovascular Blood and Lymphatic System	8,296	5.77%
Nervous System	18,066	12.56%
Respiratory System	5,090	3.54%
Gastrointestinal System including Liver	13,165	9.15%
Musculoskeletal System	4,827	3.36%
Immune System	38,338	26.66%
Urogenital/Reproductive System	4,191	2.91%

Sensory Organs (skin, eyes and ears)	1,787	1.24%
Endocrine System/Metabolism	6,478	4.5%
Multisystemic	3,732	2.59%
Ethology / Animal Behaviour /Animal Biology	2,430	1.69%
Other basic research	6,053	4.21%
Total	143,830	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	19,769	16.45%
Human Infectious Disorders	13,783	11.47%
Human Cardiovascular Disorders	1,738	1.45%
Human Nervous and Mental Disorders	22,225	18.49%
Human Respiratory Disorders	4,849	4.03%
Human Gastrointestinal Disorders including Liver	1,864	1.55%
Human Musculoskeletal Disorders	592	0.49%
Human Immune Disorders	3,413	2.84%
Human Urogenital/Reproductive Disorders	783	0.65%
Human Sensory Organ Disorders (skin, eyes and ears)	3,187	2.65%
Human Endocrine/Metabolism Disorders	1,524	1.27%
Other Human Disorders	1,242	1.03%
Animal Diseases and Disorders	27,406	22.8%
Animal Welfare	9,545	7.94%
Diagnosis of diseases	4,101	3.41%
Non-regulatory toxicology and ecotoxicology	4,174	3.47%
Total	120,195	100.00%

Regulatory uses and Routine production

Regulatory uses 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	127,262	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	4,786	10.47%
Batch potency testing	36,849	80.62%
Other quality controls	4,074	8.91%
Total	45,709	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	364	10.69%
Repeated dose toxicity	534	15.69%
Genotoxicity	81	2.38%
Neurotoxicity	22	0.65%
Kinetics	861	25.29%
Pharmaco-dynamics (incl safety pharmacology)	29	0.85%
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	3,404	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	74	20.33%
Non lethal methods	290	79.67%
Total	364	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	514	96.25%
29 - 90 days	20	3.75%
Total	534	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	596	100.00%
Total	596	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	43,399	64.33%
Legislation on medicinal products for veterinary use and their residues	22,848	33.87%
Medical devices legislation	277	0.41%
Food legislation including food contact material	60	0.09%
Feed legislation including legislation for the safety of target animals, workers and environment	20	0.03%
Other legislation	862	1.28%
Total	67,466	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	59,392	88.03%
Legislation satisfying Non-EU requirements only	8,074	11.97%
Total	67,466	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	59,728	99.89%
Other product types	68	0.11%
Total	59,796	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	393,057	99.2%
Yes	3,171	0.8%
Total	396,228	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	9,247	2.33%
Mild [up to and including]	209,170	52.79%
Moderate	130,960	33.05%
Severe	46,851	11.82%

Total	396,228	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	307,762	77.67%
Genetically altered without a harmful phenotype	76,090	19.2%
Genetically altered with a harmful phenotype	12,376	3.12%
Total	396,228	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	20,766		20,766
Rats	119		119
Hamsters (Syrian)	259		259
Zebra fish	4,157		4,157
Total	25,301		25,301

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

Severity	Number of uses	Percentage
Non-recovery	217	0.86%
Mild [up to and including]	16,913	66.85%
Moderate	8,093	31.99%
Severe	78	0.31%
Total	25,301	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	4,711	18.62%
Genetically altered without a harmful phenotype	16,142	63.8%
Genetically altered with a harmful phenotype	4,448	17.58%
Total	25,301	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	8,804	35.23%
Cardiovascular Blood and Lymphatic System	1,349	5.4%
Nervous System	4,042	16.17%
Gastrointestinal System including Liver	3,868	15.48%
Musculoskeletal System	805	3.22%
Immune System	2,490	9.96%
Urogenital/Reproductive System	217	0.87%
Sensory Organs (skin, eyes and ears)	2	0.01%
Endocrine System/Metabolism	1,955	7.82%
Multisystemic	1,371	5.49%
Other basic research	88	0.35%
Total	24,991	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	15	4.84%
Human Nervous and Mental Disorders	53	17.1%
Human Respiratory Disorders	219	70.65%
Diagnosis of diseases	23	7.42%
Total	310	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	14,448	17	14,465

Rats	1,159	2	1,161
Zebra fish	120		120
Total	15,727	19	15,746

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

Severity	Number of uses	Percentage
Mild [up to and including]	15,404	97.83%
Moderate	231	1.47%
Severe	111	0.7%
Total	15,746	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	1,152	7.32%
Genetically altered without a harmful phenotype	12,611	80.09%
Genetically altered with a harmful phenotype	1,983	12.59%
Total	15,746	100.00%

Bulgaria

Bulgaria: Narrative 2020

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

The total number of animals, used for 2020, compared to 2019 is reduced. The number of re-used animals is decreased. The used animals are only animals born in the EU at register breeder. The number of used rodents is slightly decreased, as the number of used rabbits and artiodactyla are reduced.

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 used for 2020 animals, compared to 2019 is reduced. In some cases, depending on the project type, the Ethic Commission made recommendations for reduction of the used animals. The project authorization is not given to projects, who do not consider with the recommendation. It was asked, some of the tests to be filmed.

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

There are no procedures with non-recovery severity. The number of procedures with moderate severity is increased.

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 decreased. 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 2020

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	407	5.02%
Rats	1,526	18.83%
Guinea-Pigs	16	0.2%
Other rodents	140	1.73%
Rabbits	203	2.5%
Cats	50	0.62%
Pigs	34	0.42%
Sheep	320	3.95%
Cattle	30	0.37%
Domestic fowl	4,000	49.35%
Other birds	144	1.78%
Rana	930	11.47%
Other amphibians	305	3.76%
Total	8,105	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	8,105	100.00%
Total	8,105	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	407		407
Rats	1,526		1,526
Guinea-Pigs	16		16
Other rodents	140		140
Rabbits	203	309	512
Cats	50		50
Pigs	34		34
Sheep	320		320
Cattle	30		30
Domestic fowl	4,000		4,000
Other birds	144		144
Rana	930		930
Other amphibians	305		305
Total	8,105	309	8,414

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	6,417	76.27%
Translational and applied research	196	2.33%
Regulatory use and Routine production	419	4.98%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1,382	16.43%
Total	8,414	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Nervous System	1,190	18.54%
Respiratory System	91	1.42%
Gastrointestinal System including Liver	33	0.51%
Musculoskeletal System	105	1.64%
Endocrine System/Metabolism	84	1.31%
Multisystemic	218	3.4%
Ethology / Animal Behaviour /Animal Biology	144	2.24%
Other basic research	4,552	70.94%
Total	6,417	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Endocrine/Metabolism Disorders	30	15.31%
Animal Diseases and Disorders	110	56.12%
Diagnosis of diseases	56	28.57%
Total	196	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	309	73.75%
Toxicity and other safety testing including pharmacology	110	26.25%

Total	419	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
Pyrogenicity testing	309	100.00%
Total	309	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)	110	100.00%
Total	110	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	110	26.25%
Legislation on medicinal products for veterinary use and their residues	309	73.75%
Total	419	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	419	100.00%
Total	419	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	8,105	96.33%
Yes	309	3.67%
Total	8,414	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]	6,702	79.65%
Moderate	1,712	20.35%
Total	8,414	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	8,414	100.00%
Total	8,414	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	2,800		2,800
Total	2,800		2,800

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

Severity	Number of uses	Percentage
Mild [up to and including]	2,800	100.00%
Total	2,800	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	2,800	100.00%
Total	2,800	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
Immune System	2,800	100.00%
Total	2,800	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

Croatia

Croatia: Narrative 2020

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 2020, 2019 and 2018:

Animal Species	**2020**		**2019**		**2018**	
	number	**%**	**number**	**%**	**number**	**%**
Mice	30,060	79.03	19,216	66.99	18,295	70.87
Rats	5,282	13.89	6,446	22.47	6,885	26.67
Guinea Pigs	122	0.32	107	0.37	17	0.07
Rabbits	148	0.39	12	0.04	250	0.97
Horses, donkeys & cross-breeds	16	0.04	18	0.06	18	0.07
Pigs	2	0.01	2	0.01	20	0.08
Sheep	30	0.08	15	0.05	22	0.09
Domestic fowl	2,335	6.14	2,840	9.90	275	1.07
Zebra fish	41	0.11	28	0.10	34	0.13
Summary	38,036	100	28,684	100	25,816	100

Compared to the data for 2018 and 2019, the data for 2020 shows:

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

Re-use vs first use

Data for 2020, 2019 and 2018:

Re-Use	**2020**		**2019**		**2018**	
	number	**%**	**number**	**%**	**number**	**%**
No	38,002	99,91	28,650	99.88	25,769	99.82
Yes	34	0,09	34	0.12	47	0.18
Total uses	38,036	100	28,684	100	25,816	100

Compared to the data for 2018 and 2019, the data for 2020 shows slightly decrease in the proportion of Re-use vs first use.

Genetically altered animals

Data for 2020, 2019 and 2018:

Genetic Status	**2020**		**2019**		**2018**	
	number	**%**	**number**	**%**	**number**	**%**
Not genetically altered	32,686	85.93	25,463	88.77	24,711	95.72
Genetically altered without a harmful phenotype	4,662	12.26	2,882	10,05	968	3.75
Genetically altered with a harmful phenotype	688	1.81	339	1,18	137	0.53
Summary	38,036	100	28,684	100	25,816	100

Compared to the data for 2018 and 2019, the data for 2020 shows:

- number of not genetically altered animals increased
- the number of genetically altered animals without a harmful phenotype in the three years period increased and
- an 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 during three years period shows:

- decrease in use not genetically altered type of animals and

- increase in use genetically altered animals without a harmful phenotype and genetically altered animals with a harmful phenotype.

Creation of New Genetically altered lines
Data for 2020, 2019 and 2018:

Creation of New GL	**2020**		**2019**		**2018**	
	number	**%**	**number**	**%**	**number**	**%**
No	37,628	98.93	28,656	99,90	25,782	99.87
Yes	408	1.07	28	0,10	34	0.13
Summary	38,036	100	28,684	100	25,816	100

Compared to the data from 2018 and 2019, the data for 2020 shows the increase of number of animals used for creation of new genetically altered lines.

Origins of animals
Data for 2020, 2019 and 2018:

Place of Birth	**2020**		**2019**		**2018**	
	number	**%**	**number**	**%**	**number**	**%**
Animals born in the EU at a registered breeder	37,937	99.83	28,618	99.89	25,739	99.88
Animals born in the EU but not at a registered breeder	64	0.17	32	0.11	30	0.12
Animals born in the rest of Europe	0	0	0	0	0	0
Animals born in the rest of world	1	0	0	0	0	0
Summary	38,036	100	28,650	100	28,431	100

Compared to the data for 2018 and 2019, the data for 2020 shows there are no significant changes regarding the place of birth of animals.

Legislative Requirement

Data for 2020, 2019 and 2018:

Legislative Requirement	**2020**		**2019**		**2018**	
	number	**%**	**number**	**%**	**number**	**%**
Legislation satisfying EU requirements	2,515	6,61	4,244	14.80	2,461	9.53
Legislation satisfying national requirements only (within EU)	0	0	0	0	0	0
Legislation satisfying Non-EU requirements only	270	0,71	0	0	0	0

Compared to the data for 2018 and 2019, the data for 2020 shows that there is a significant decrease of number of animals used for scientific purposes regarding the legislation satisfying EU requirements and slightly increase of number of animals used for scientific purposes regarding the legislation satisfying Non-EU requirements only.

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 2020, 2019 and 2018:

Purpose Category	**2020**		**2019**		**2018**	
	number	**%**	**number**	**%**	**number**	**%**
Basic Research	11,086	29.15	10,195	35.54	18,865	73.07
Translational and applied research	22,456	59.04	12,664	44.15	3,169	12.28
Regulatory use and Routine production	2819	7.41	4,244	14.80	2,461	9.53

Higher education or training for the acquisition, maintenance or improvement of vocational skills	489	1.29	849	2.96	1,321	5.12
Maintenance of colonies of established genetically altered animals, not used in other procedures	1,186	3.12	732	2.55	0	0
Summary	38,036	100	28,684	100	25,816	100

Compared to the data from 2018 and 2019, the data for 2020 shows:

- significant decrease in number of animals used for basic research
- significant and continuous increase in number of animals used for translational and applied research
- continuous decrease in number of animals used for regulatory use and routine production
- significant and continuous decrease in number of animals used for higher education
- 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 2020, 2019 and 2018:

Severity of procedures	**2020**		**2019**		**2018**	
	number	**%**	**number**	**%**	**number**	**%**
Non-recovery	414	1.09	1,321	4.61	1,250	4.84
Mild (up to and including)	11,319	29.76	6,844	23.86	7,693	29.80
Moderate	17,043	44.81	18,266	63.68	16,170	62.64
Severe	9,260	24.35	2,253	7.85	703	2.72
Total number	38,036	100	28,684	100	25,816	100

Compared to the data from 2018 and 2019, the data for 2020 shows the decrease of number of animals used in non-recovery procedures, a significant increase 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 2020, intensive communication have been held among the National Committee for the Protection of Animals Used for Scientific Purposes, the Competent Authority, the Croatian Society for Laboratory Animal Sciences (CroLASA) and users on possibilities to improve animal welfare used in projects by better planning experiments and giving more attention to using humane endpoints.

In this way, the awareness of users about the application of the principles of replacement, reduction and improvement has increased.

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 2020, 2019 and 2018:

Purpose Category	**2020**		**2019**		**2018**	
	number	**%**	**number**	**%**	**number**	**%**
Regulatory use and routine production – Quality control (incl batch safety and potency testing) - Other quality controls	720	25.54	720	100	900	76.60

For regulatory use and routine production - Quality control (incl batch safety and potency testing) - Other quality controls in 2018, 2019 and 2020 tests performed have been required by EU Pharmacopeia and animals used in tests in 2020 were mice.

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

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

Croatia: Statistical Data 2020

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	28,507	78.3%
Rats	5,282	14.51%
Guinea-Pigs	121	0.33%
Rabbits	148	0.41%
Pigs	2	0.01%
Sheep	13	0.04%
Domestic fowl	2,335	6.41%
Total	36,408	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	36,344	99.82%
Animals born in the EU but not at a registered breeder	64	0.18%
Total	36,408	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	28,507		28,507
Rats	5,282		5,282
Guinea-Pigs	121	1	122
Rabbits	148		148
Horses, donkeys and cross-breeds		16	16
Pigs	2		2
Sheep	13	17	30
Domestic fowl	2,335		2,335
Total	36,408	34	36,442

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	10,751	29.5%
Translational and applied research	22,383	61.42%
Regulatory use and Routine production	2,819	7.74%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	489	1.34%
Total	36,442	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	233	2.17%
Cardiovascular Blood and Lymphatic System	378	3.52%
Nervous System	2,201	20.47%
Gastrointestinal System including Liver	65	0.6%
Musculoskeletal System	447	4.16%
Immune System	4,149	38.59%
Urogenital/Reproductive System	12	0.11%
Sensory Organs (skin, eyes and ears)	98	0.91%
Endocrine System/Metabolism	121	1.13%
Multisystemic	2,973	27.65%
Other basic research	74	0.69%
Total	10,751	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	798	3.57%
Human Infectious Disorders	6,641	29.67%
Human Respiratory Disorders	2,365	10.57%
Human Gastrointestinal Disorders including Liver	4,253	19%
Human Musculoskeletal Disorders	1,960	8.76%
Human Immune Disorders	5,331	23.82%
Human Sensory Organ Disorders (skin, eyes and ears)	559	2.5%
Diagnosis of diseases	41	0.18%
Non-regulatory toxicology and ecotoxicology	435	1.94%
Total	22,383	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	25.54%
Toxicity and other safety testing including pharmacology	2,065	73.25%
Routine production	34	1.21%
Total	2,819	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	270	37.5%
Other quality controls	450	62.5%
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
Target animal safety	359	17.38%
Other toxicity/safety testing	1,706	82.62%
Total	2,065	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	450	16.16%
Legislation on medicinal products for veterinary use and their residues	2,335	83.84%
Total	2,785	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2,515	90.31%
Legislation satisfying Non-EU requirements only	270	9.69%
Total	2,785	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	34	100.00%
Total	34	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	36,408	99.91%
Yes	34	0.09%

Total	36,442	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	300	0.82%
Mild [up to and including]	10,133	27.81%
Moderate	16,749	45.96%
Severe	9,260	25.41%
Total	36,442	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	32,645	89.58%
Genetically altered without a harmful phenotype	3,109	8.53%
Genetically altered with a harmful phenotype	688	1.89%
Total	36,442	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	367		367
Zebra fish	41		41
Total	408		408

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

Severity	Number of uses	Percentage
Non-recovery	114	27.94%
Moderate	294	72.06%
Total	408	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	41	10.05%
Genetically altered without a harmful phenotype	367	89.95%
Total	408	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	222	66.27%
Musculoskeletal System	37	11.04%
Immune System	16	4.78%
Endocrine System/Metabolism	60	17.91%
Total	335	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 Immune Disorders	32	43.84%
Non-regulatory toxicology and ecotoxicology	41	56.16%
Total	73	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	1,186		1,186
Total	1,186		1,186

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

Severity	Number of uses	Percentage
Mild [up to and including]	1,186	100.00%
Total	1,186	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	1,186	100.00%
Total	1,186	100.00%

Cyprus

Cyprus: Narrative 2020

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

The greater proportion of animals used in 2020 concerns mice. Also, a small number of zebra fish and rabbits were used. Severe and non-recovery severity were slightly increased.

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

In general, the use of animals is steadily increasing due to the increasing number of projects conducted in Cyprus. In 2019 the number of projects where animals were used was 25 whilst in 2020 was 30, which led to an increase of 71.36% of animals used in 2020.

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

There was a slight increase in the number of animals used in severe severity procedures. These animals were used in one project that was authorised for severe severity procedures.

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

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

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

A proportion of animals used in basic research (12.85%) was reported under the category “other” of basic research (Developmental biology, biomaterials toxicology and cardiovascular implants).

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 2020.

Cyprus: Statistical Data 2020

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	3,651	97.46%
Rabbits	90	2.4%
Zebra fish	5	0.13%
Total	3,746	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	3,746	100%
Total	3,746	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	3,651		3,651
Rabbits	90		90
Zebra fish	5		5
Total	3,746		3,746

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	3,307	88.28%
Translational and applied research	439	11.72%
Total	3,746	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	1,508	45.6%
Nervous System	1,000	30.24%
Urogenital/Reproductive System	120	3.63%
Endocrine System/Metabolism	254	7.68%
Other basic research	425	12.85%
Total	3,307	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	71	16.17%
Human Infectious Disorders	100	22.78%
Human Cardiovascular Disorders	60	13.67%
Human Urogenital/Reproductive Disorders	68	15.49%
Human Sensory Organ Disorders (skin, eyes and ears)	140	31.89%
Total	439	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	3,746	100.00%
Total	3,746	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	308	8.22%
Mild [up to and including]	3,182	84.94%
Moderate	156	4.16%
Severe	100	2.67%
Total	3,746	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	2,004	53.5%
Genetically altered without a harmful phenotype	1,639	43.75%
Genetically altered with a harmful phenotype	103	2.75%
Total	3,746	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

Czechia

Czechia: Narrative 2020

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. Overall numbers decreased by above 5% between 2019 and 2020. Opposite to this numbers of animals used in category *"Preservation of species"* started increase and number of animals is similar to number in 2019. There were used 36 non-human primates (NHP). All NHP were born at a registered breeder within EU. There is increase in numbers Re-Use animal. There is decrease in Creation on New Genetically Altered Animal Line.

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

Overall numbers decreased by above 5% between 2019 and 2020. Decrease is especially in category *"Basic Research", "Translational and applied research", "Regulatory use and Routine production"* and *"Higher education or training for the acquisition, maintenance or improvement of vocational skills"*. Perhaps due to COVID pandemic and lockdown in 2020. Opposite to this numbers of animals used in category *"Preservation of species"* started increase and number of animals is similar to number in 2019. There were mainly experiments of the university which deals with fish breeding.

In 2020, there is significant decrease in the use of animals in category "*Legislation satisfying EU requirements*", because there were less experiments in category "*Legislation on medicinal products for human use*", "*Legislation on medicinal products for veterinary use and their residues*" and "*Medical devices legislation*". Perhaps due to COVID pandemic and lockdown in 2020.

There is continual increase of rabbits because of increase in "*Regulatory use and Routine production*". Experiments were for production of antigen of Rabbit haemorrhagic disease.

There were less experiments with mice and rats because of decrease of experiments in "*Basic research*".

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

There is continual increase of severe uses in 2020 caused by an increasing number of fish experiments regarding waste legislation and toxicity of waste. There is also continual increasing of moderate uses. Opposite to this there is increase of mild uses between 2018 and 2019 and decrease between 2019 and 2020. There is continual decrease of non-recovery uses.

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

There is continuous decrease of warm-blooded vertebrates (mammals) and opposite to this increase of cold-blooded vertebrates (fish). We are expecting more impacts in subsequent years.

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

In category "*Other Fish*", more than 74% are of specie *Poecilia reticulata*, and mainly used for the purpose "*Protection of the natural environment in the interests of the health or welfare of human beings or animals*" and *"Other ecotoxicity"*. There are also experiments of the university which deals with wild fish in category "*Preservation of species*".

In category "*Testing by Legislation*", "*Other Legislation*" included mainly experiments with Zebra fish and *Poecilia reticulata* for the purposes of waste legislation and toxicity of waste.

Category "Other Basic Research" mainly included experiments on parasitology with different species.

In "*Regulatory use and routine production - Routine production*" in "*Other product types*", 72% of experiments were for purposes of acquisition of live attenuated lines of selected species of chicken coccidian for vaccine production and 27% of experiments were for production of antigen of Rabbit haemorrhagic disease.

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 2020.

Czechia: Statistical Data 2020

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	50,213	22.59%
Rats	15,695	7.06%
Guinea-Pigs	1,325	0.6%
Hamsters (Chinese)	15	0.01%
Mongolian gerbil	13	0.01%
Other rodents	787	0.35%
Rabbits	6,613	2.97%
Cats	79	0.04%
Dogs	215	0.1%
Ferrets	56	0.03%
Horses, donkeys and cross-breeds	145	0.07%
Pigs	1,631	0.73%
Goats	31	0.01%
Sheep	394	0.18%
Cattle	585	0.26%
Cynomolgus monkey	32	0.01%
Rhesus monkey	4	0%
Other mammals	112	0.05%
Domestic fowl	20,100	9.04%
Other birds	1,999	0.9%
Reptiles	460	0.21%

Zebra fish	5,228	2.35%
Other fish	116,593	52.44%
Total	222,325	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	199,425	89.71%
Animals born in the EU but not at a registered breeder	21,643	9.74%
Animals born in rest of world	1,221	0.55%
Total	222,289	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	36	100.00%
Total	36	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	36	100.00%
Total	36	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	50,213	1,072	51,285
Rats	15,695	469	16,164
Guinea-Pigs	1,325	6	1,331
Hamsters (Chinese)	15		15
Mongolian gerbil	13		13
Other rodents	787		787
Rabbits	6,613	51	6,664
Cats	79	36	115
Dogs	215	248	463
Ferrets	56		56
Horses, donkeys and cross-breeds	145	8	153
Pigs	1,631	12	1,643
Goats	31	5	36
Sheep	394	306	700
Cattle	585	35	620
Cynomolgus monkey	32		32
Rhesus monkey	4		4
Other mammals	112	7	119
Domestic fowl	20,100	38	20,138
Other birds	1,999	26	2,025
Reptiles	460	80	540
Zebra fish	5,228		5,228
Other fish	116,593	857	117,450
Total	222,325	3,256	225,581

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	55,619	24.66%
Translational and applied research	29,487	13.07%
Regulatory use and Routine production	66,997	29.7%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	64,970	28.8%
Preservation of species	6,213	2.75%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	2,218	0.98%
Forensic enquiries	77	0.03%
Total	225,581	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	8,794	15.81%
Cardiovascular Blood and Lymphatic System	3,994	7.18%
Nervous System	6,719	12.08%
Respiratory System	46	0.08%
Gastrointestinal System including Liver	3,456	6.21%
Musculoskeletal System	98	0.18%
Immune System	6,976	12.54%

Urogenital/Reproductive System	9,706	17.45%
Sensory Organs (skin, eyes and ears)	87	0.16%
Endocrine System/Metabolism	1,257	2.26%
Multisystemic	2,937	5.28%
Ethology / Animal Behaviour /Animal Biology	4,000	7.19%
Other basic research	7,549	13.57%
Total	55,619	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	4,931	16.72%
Human Infectious Disorders	990	3.36%
Human Cardiovascular Disorders	974	3.3%
Human Nervous and Mental Disorders	1,112	3.77%
Human Gastrointestinal Disorders including Liver	113	0.38%
Human Musculoskeletal Disorders	134	0.45%
Human Immune Disorders	208	0.71%
Human Urogenital/Reproductive Disorders	561	1.9%
Human Sensory Organ Disorders (skin, eyes and ears)	101	0.34%
Human Endocrine/Metabolism Disorders	584	1.98%
Other Human Disorders	183	0.62%
Animal Diseases and Disorders	2,145	7.27%
Animal Welfare	13,212	44.81%
Diagnosis of diseases	3,004	10.19%
Non-regulatory toxicology and ecotoxicology	1,235	4.19%
Total	29,487	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	9,577	14.29%
Other efficacy and tolerance testing	483	0.72%
Toxicity and other safety testing including pharmacology	35,566	53.09%
Routine production	21,371	31.9%
Total	66,997	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	523	5.46%
Pyrogenicity testing	41	0.43%
Batch potency testing	8,929	93.23%
Other quality controls	84	0.88%
Total	9,577	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	59	0.17%
Skin sensitisation	758	2.13%
Repeated dose toxicity	550	1.55%
Reproductive toxicity	688	1.93%
Developmental toxicity	362	1.02%
Kinetics	254	0.71%
Pharmaco-dynamics (incl safety pharmacology)	24	0.07%
Ecotoxicity	32,191	90.51%
Safety testing in food and feed area	108	0.3%
Target animal safety	40	0.11%
Other toxicity/safety testing	532	1.5%
Total	35,566	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	59	100.00%
Total	59	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	98	17.82%
29 - 90 days	344	62.55%
> 90 days	108	19.64%
Total	550	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	30,611	95.09%
Other ecotoxicity	1,580	4.91%
Total	32,191	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	772	1.69%
Legislation on medicinal products for veterinary use and their residues	9,926	21.76%
Medical devices legislation	963	2.11%
Industrial chemicals legislation	1,654	3.63%
Feed legislation including legislation for the safety of target animals, workers and environment	36	0.08%
Other legislation	32,275	70.74%
Total	45,626	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	23,176	50.8%
Legislation satisfying national requirements only [within EU]	22,450	49.2%
Total	45,626	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	461	2.16%
Monoclonal antibody by mouse ascites method	125	0.58%
Other product types	20,785	97.26%
Total	21,371	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	222,325	98.56%
Yes	3,256	1.44%
Total	225,581	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	4,526	2.01%
Mild [up to and including]	81,058	35.93%

Moderate	105,626	46.82%
Severe	34,371	15.24%
Total	225,581	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	210,540	93.33%
Genetically altered without a harmful phenotype	12,754	5.65%
Genetically altered with a harmful phenotype	2,287	1.01%
Total	225,581	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	10,110	1,977	12,087
Rats	60		60
Hamsters (Syrian)	45		45
Pigs	33		33
Domestic fowl	70		70
Zebra fish	301		301
Other fish	398		398
Total	11,017	1,977	12,994

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

Severity	Number of uses	Percentage
Non-recovery	3,707	28.53%
Mild [up to and including]	198	1.52%
Moderate	9,075	69.84%
Severe	14	0.11%
Total	12,994	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	1,214	9.34%
Genetically altered without a harmful phenotype	11,635	89.54%
Genetically altered with a harmful phenotype	145	1.12%
Total	12,994	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	136	1.05%
Cardiovascular Blood and Lymphatic System	131	1.01%
Nervous System	1,867	14.37%
Immune System	430	3.31%
Urogenital/Reproductive System	1,693	13.03%
Sensory Organs (skin, eyes and ears)	142	1.09%
Endocrine System/Metabolism	285	2.19%
Multisystemic	8,014	61.67%
Other basic research	296	2.28%
Total	12,994	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

Denmark

Denmark: Narrative 2020

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

In 2020, the overall number of animals used for experimental procedures in Denmark was 259,411. The number is slightly higher than in 2019, where the total number of animals was 252,987 resulting in a 2.5% increase.

The majority of experimental procedures used mice (60%), fish (18%) and rats (13%). Together these species were used in approx. 91% of all experimental procedures in 2020. A high percentage of experimental procedures involving mice and rats are Immune system and Nervous system (basic research purposes) and Human Endocrine / Metabolism Disorders, Human cancer 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 31% Basic research, 58% Translational and applied research and 8% Regulatory testing for 2020.

The severity assessment for 2020 shows that 50% of experimental procedures in animals were mild and 46% were moderate. Only about 1.5% of the animals used for experimental procedures experienced severe suffering in 2020 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 high number of other carnivores (6,128 in 2020 and 3,843 in 2019) are due to the actions taken towards COVID-19 infections in mink. For fish, the figures are respectively 48,320 in 2020 and 29,399 in 2019. In Denmark, we have e.g. focus on research within the breeding of rainbow trout, sea bass, cod and salmon in particular. Among other things, research is carried out in infections, vaccines and issues related to production.

There are some variations in the numbers of guinea pigs, dogs, cattle, domestic fowls and xenopus. 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 2020 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.

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 concern "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 in mink farms.

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 2020.

Denmark: Statistical Data 2020

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	144,681	58.38%
Rats	33,028	13.33%
Guinea-Pigs	2,249	0.91%
Hamsters (Syrian)	108	0.04%
Rabbits	2,344	0.95%
Cats	6	0%
Dogs	527	0.21%
Other carnivores	5,948	2.4%
Horses, donkeys and cross-breeds	11	0%
Pigs	8,654	3.49%
Goats	27	0.01%
Sheep	62	0.03%
Cattle	451	0.18%
Other mammals	35	0.01%
Domestic fowl	621	0.25%
Other birds	390	0.16%
Reptiles	21	0.01%
Rana	792	0.32%
Xenopus	390	0.16%
Other amphibians	6	0%
Zebra fish	7,731	3.12%
Other fish	39,745	16.04%
Total	247,827	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	175,998	71.02%
Animals born in the EU but not at a registered breeder	66,026	26.64%
Animals born in rest of Europe	483	0.19%
Animals born in rest of world	5,320	2.15%
Total	247,827	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	144,681	1,209	145,890
Rats	33,028	321	33,349
Guinea-Pigs	2,249		2,249
Hamsters (Syrian)	108	3	111
Rabbits	2,344		2,344
Cats	6		6
Dogs	527	62	589
Other carnivores	5,948	180	6,128
Horses, donkeys and cross-breeds	11	5	16
Pigs	8,654	162	8,816
Goats	27		27
Sheep	62	5	67
Cattle	451	292	743
Other mammals	35	1	36
Domestic fowl	621		621
Other birds	390	11	401
Reptiles	21	3	24
Rana	792		792
Xenopus	390		390
Other amphibians	6	10	16
Zebra fish	7,731		7,731
Other fish	39,745	36	39,781
Total	247,827	2,300	250,127

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	77,596	31.02%
Translational and applied research	144,032	57.58%
Regulatory use and Routine production	20,426	8.17%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3,329	1.33%
Preservation of species	913	0.37%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	3,831	1.53%
Total	250,127	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	10,434	13.45%
Cardiovascular Blood and Lymphatic System	2,979	3.84%
Nervous System	17,525	22.58%
Respiratory System	859	1.11%
Gastrointestinal System including Liver	7,331	9.45%
Musculoskeletal System	1,334	1.72%
Immune System	16,942	21.83%
Urogenital/Reproductive System	2,396	3.09%
Sensory Organs (skin, eyes and ears)	522	0.67%

Endocrine System/Metabolism	14,231	18.34%
Multisystemic	1,995	2.57%
Ethology / Animal Behaviour /Animal Biology	659	0.85%
Other basic research	389	0.5%
Total	77,596	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	18,838	13.08%
Human Infectious Disorders	10,334	7.17%
Human Cardiovascular Disorders	5,010	3.48%
Human Nervous and Mental Disorders	20,324	14.11%
Human Respiratory Disorders	316	0.22%
Human Gastrointestinal Disorders including Liver	2,087	1.45%
Human Musculoskeletal Disorders	862	0.6%
Human Immune Disorders	4,509	3.13%
Human Urogenital/Reproductive Disorders	2,263	1.57%
Human Sensory Organ Disorders (skin, eyes and ears)	358	0.25%
Human Endocrine/Metabolism Disorders	31,167	21.64%
Other Human Disorders	58	0.04%
Animal Diseases and Disorders	35,931	24.95%
Animal Welfare	9,265	6.43%
Diagnosis of diseases	870	0.6%
Non-regulatory toxicology and ecotoxicology	1,840	1.28%
Total	144,032	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	15,544	76.1%
Other efficacy and tolerance testing	1,091	5.34%
Toxicity and other safety testing including pharmacology	2,685	13.15%
Routine production	1,106	5.41%
Total	20,426	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	2,366	15.22%
Batch potency testing	13,137	84.51%
Other quality controls	41	0.26%
Total	15,544	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	26	0.97%
Skin irritation/corrosion	3	0.11%
Skin sensitisation	32	1.19%
Repeated dose toxicity	1,662	61.9%
Developmental toxicity	6	0.22%
Kinetics	205	7.64%
Pharmaco-dynamics (incl safety pharmacology)	751	27.97%
Total	2,685	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	26	100.00%

Total	26	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	866	52.11%
29 - 90 days	502	30.2%
> 90 days	294	17.69%
Total	1,662	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	19,314	99.97%
Medical devices legislation	6	0.03%
Total	19,320	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	19,286	99.82%
Legislation satisfying Non-EU requirements only	34	0.18%
Total	19,320	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	996	90.05%
Other product types	110	9.95%
Total	1,106	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	247,827	99.08%
Yes	2,300	0.92%
Total	250,127	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	7,599	3.04%
Mild [up to and including]	120,714	48.26%
Moderate	118,035	47.19%
Severe	3,779	1.51%
Total	250,127	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	212,222	84.85%
Genetically altered without a harmful phenotype	31,959	12.78%
Genetically altered with a harmful phenotype	5,946	2.38%
Total	250,127	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	2,983	39	3,022
Zebra fish	808		808
Total	3,791	39	3,830

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

Severity	Number of uses	Percentage
Mild [up to and including]	3,640	95.04%
Moderate	190	4.96%
Total	3,830	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	2,746	71.7%
Genetically altered without a harmful phenotype	1,043	27.23%
Genetically altered with a harmful phenotype	41	1.07%
Total	3,830	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	35	0.92%
Cardiovascular Blood and Lymphatic System	571	15%
Nervous System	360	9.46%
Gastrointestinal System including Liver	150	3.94%
Endocrine System/Metabolism	148	3.89%
Multisystemic	2,542	66.79%
Total	3,806	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	50%
Human Urogenital/Reproductive Disorders	12	50%
Total	24	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	7,793		7,793
Total	7,793		7,793

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

Severity	Number of uses	Percentage
Non-recovery	395	5.07%
Mild [up to and including]	5,873	75.36%
Moderate	1,517	19.47%
Severe	8	0.1%
Total	7,793	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	7,753	99.49%
Genetically altered without a harmful phenotype	40	0.51%
Total	7,793	100.00%

Estonia

Estonia: Narrative 2020

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

In 2020, 4,089 animals were used for scientific purposes. Compared to 2019 (3,055 animals), there has been a significant increase of 33.85% in the use of animals. This is in part due to an increased number of project authorisations granted both in 2019 and 2020 compared to prior years. No animals were re-used in 2020.

All animals used in 2020 were born in the EU. Of them 63.22% at a registered breeder (59.19% in 2019), and 36.78% not at a registered breeder (40.81% in 2019). 82.78% of all animals used in 2020 were not genetically altered, the remaining 17.22% of animals were genetically altered, but without a harmful phenotype. This is similar to 2019 with 78.78% not genetically altered animals and 21.11% genetically altered animals without a harmful phenotype.

Most used species in 2020 was mice with a total number of 1,864 accounting for 45.59% of all uses (1,415 mice and 46.32% in 2019). There was an increase also in the use of domestic fowl (58 on 2019, 79 in 2020), rats (285 in 2019, 669 in 2020) and cattle (866 in 2019, 1425 in 2020), however, less rabbits (65 in 2019, 52 in 2020), pigs (4 in 2019, 0 in 2020), other birds (204 in 2019, 0 in 2020) and other fish (158 in 2019, 0 in 2020) were used.

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

In 2019, 28 animals (0.92% of all uses in 2019) were used for education or training purposes, in 2020, these courses did not take place due to the COVID-19 pandemic and therefore no animals were used for this purpose.

Use of animals increased in translational and applied research from 917 animals in 2019 (30.01% of all uses) to 1,521 animals in 2020 (37.2% of all uses). This can mainly be attributed to an epidemiological study researching animal diseases and disorders in cattle.

2,437 animals (59.6% of all uses in 2020; 1,987 accounting for 65.04% in 2019) were used in basic research with 70% of them being used for oncology (720 in 2020, 351 in 2019) and nervous system (996 in 2020, 572 in 2019) research. The reason for the increase in uses can in part be attributed to the higher number of authorisations granted in these research areas in 2020.

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

There are no significant changes compared to 2019.

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

The ethics committee evaluates each project application thoroughly to make sure that 3Rs have been considered and applied accordingly before authorisation.

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

No “other” animals were used in 2020.

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 2020

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	1,864	45.59%
Rats	669	16.36%
Rabbits	52	1.27%
Cattle	1,425	34.85%
Domestic fowl	79	1.93%
Total	4,089	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	2,585	63.22%
Animals born in the EU but not at a registered breeder	1,504	36.78%
Total	4,089	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	1,864		1,864
Rats	669		669
Rabbits	52		52
Cattle	1,425		1,425
Domestic fowl	79		79
Total	4,089		4,089

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	2,437	59.6%
Translational and applied research	1,521	37.2%
Regulatory use and Routine production	131	3.2%
Total	4,089	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	720	29.54%
Cardiovascular Blood and Lymphatic System	268	11%
Nervous System	996	40.87%
Musculoskeletal System	5	0.21%
Immune System	320	13.13%
Urogenital/Reproductive System	8	0.33%
Endocrine System/Metabolism	120	4.92%
Total	2,437	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Respiratory Disorders	99	6.51%
Animal Diseases and Disorders	1,417	93.16%
Diagnosis of diseases	5	0.33%
Total	1,521	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Routine production	131	100.00%
Total	131	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	131	100.00%
Total	131	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	4,089	100.00%
Total	4,089	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	278	6.8%
Mild [up to and including]	2,611	63.85%
Moderate	1,165	28.49%
Severe	35	0.86%
Total	4,089	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	3,385	82.78%
Genetically altered without a harmful phenotype	704	17.22%
Total	4,089	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 2020

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

The overall picture was similar as in previous years. The number of procedures increased to 119,986 (98,457 in 2019).

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

The increase of animal use was seen both in the basic (+23,992 procedures) and translational research (+8,255 procedures), these being the most important areas of research in Finland. No special reasons for the increase were noticed. The changes include in the normal variation in research activities.

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

The number of severe procedures was decreased, being 4,793, 4 % of total use (6,371, 6.5 % in 2019). The reduction was due mainly by the decrease of severe procedures with mice in the purpose Human Nervous and Mental Disorders (Translational research). According to the users in this category the reasons for the change were more careful assessment of the actual severity of procedures for each animal and effective use of 3Rs.

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 3Rs via 3R working group. The 2-days course How to Reduce the Number of Animals and Increase the Research Quality was organized in December. The 3R group prepared further the Finnish 3R Center.

FinLAS experts supported the digitalization of laboratory animal courses by University of Helsinki. All Finnish universities may utilize the courses freely in their education and training

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.

The severe classification was not exceeded in any procedures.

Finland: Statistical Data 2020

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	54,739	48.69%
Rats	10,458	9.3%
Guinea-Pigs	8	0.01%
Hamsters (Syrian)	64	0.06%
Other rodents	4,745	4.22%
Rabbits	92	0.08%
Cats	138	0.12%
Dogs	1,210	1.08%
Other carnivores	160	0.14%
Horses, donkeys and cross-breeds	56	0.05%
Pigs	766	0.68%
Sheep	422	0.38%
Cattle	147	0.13%
Other mammals	134	0.12%
Domestic fowl	5,033	4.48%
Other birds	1,082	0.96%
Other amphibians	5	0%
Zebra fish	6,062	5.39%
Other fish	27,094	24.1%
Total	112,415	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	68,473	60.91%
Animals born in the EU but not at a registered breeder	38,593	34.33%
Animals born in rest of Europe	26	0.02%
Animals born in rest of world	5,323	4.74%
Total	112,415	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	54,739	70	54,809
Rats	10,458		10,458
Guinea-Pigs	8		8
Hamsters (Syrian)	64		64
Other rodents	4,745		4,745
Rabbits	92		92
Cats	138		138
Dogs	1,210	73	1,283
Other carnivores	160		160
Horses, donkeys and cross-breeds	56	58	114
Pigs	766	6	772
Sheep	422	270	692
Cattle	147	72	219
Other mammals	134		134
Domestic fowl	5,033	6	5,039
Other birds	1,082		1,082
Other amphibians	5		5
Zebra fish	6,062		6,062
Other fish	27,094	6	27,100
Total	112,415	561	112,976

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	63,641	56.33%
Translational and applied research	44,065	39%
Regulatory use and Routine production	4,210	3.73%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1,060	0.94%
Total	112,976	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	6,369	10.01%
Cardiovascular Blood and Lymphatic System	7,794	12.25%
Nervous System	9,087	14.28%
Respiratory System	314	0.49%
Gastrointestinal System including Liver	1,219	1.92%
Musculoskeletal System	187	0.29%
Immune System	2,639	4.15%
Urogenital/Reproductive System	14,525	22.82%
Sensory Organs (skin, eyes and ears)	944	1.48%
Endocrine System/Metabolism	3,,887	6.11%
Multisystemic	4667	7.33%
Ethology / Animal Behaviour /Animal Biology	11,731	18.43%
Other basic research	278	0.44%
Total	63,641	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	3,564	8.09%
Human Infectious Disorders	854	1.94%
Human Cardiovascular Disorders	462	1.05%
Human Nervous and Mental Disorders	19,968	45.31%
Human Gastrointestinal Disorders including Liver	182	0.41%
Human Musculoskeletal Disorders	522	1.18%
Human Immune Disorders	275	0.62%
Human Urogenital/Reproductive Disorders	18	0.04%
Human Sensory Organ Disorders (skin, eyes and ears)	2,524	5.73%
Human Endocrine/Metabolism Disorders	697	1.58%
Other Human Disorders	1,648	3.74%
Animal Diseases and Disorders	10,473	23.77%
Animal Welfare	234	0.53%
Diagnosis of diseases	439	1%
Non-regulatory toxicology and ecotoxicology	2,205	5%
Total	44,065	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1,276	30.31%
Other efficacy and tolerance testing	12	0.29%
Toxicity and other safety testing including pharmacology	2,050	48.69%
Routine production	872	20.71%
Total	4,210	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	1,276	100.00%
Total	1,276	100.00%

Regulatory uses - Toxicity and other safety testing including pharmacology

Regulatory uses - Toxicity and other safety testing including pharmacology	Number of uses	Percentage
Repeated dose toxicity	220	10.73%
Kinetics	1,709	83.37%
Pharmaco-dynamics (incl safety pharmacology)	121	5.9%
Total	2,050	100.00%

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

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

No data reported

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	220	100.00%
Total	220	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	3,312	99.22%
Legislation on medicinal products for veterinary use and their residues	26	0.78%
Total	3,338	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	3,338	100.00%
Total	3,338	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	866	99.31%
Other product types	6	0.69%
Total	872	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	112,415	99.5%
Yes	561	0.5%
Total	112,976	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	5,107	4.52%
Mild [up to and including]	62,222	55.08%
Moderate	40,884	36.19%
Severe	4,763	4.22%
Total	112,976	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	87,015	77.02%
Genetically altered without a harmful phenotype	20,665	18.29%
Genetically altered with a harmful phenotype	5,296	4.69%
Total	112,976	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	6,366		6,366
Rats	29		29
Zebra fish	520		520
Total	6,915		6,915

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

Severity	Number of uses	Percentage
Non-recovery	532	7.69%
Mild [up to and including]	5,381	77.82%
Moderate	972	14.06%
Severe	30	0.43%
Total	6,915	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	3,090	44.69%
Genetically altered without a harmful phenotype	2,837	41.03%
Genetically altered with a harmful phenotype	988	14.29%
Total	6,915	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	30	0.54%
Cardiovascular Blood and Lymphatic System	652	11.72%
Nervous System	1,909	34.33%
Gastrointestinal System including Liver	1,359	24.44%
Musculoskeletal System	183	3.29%
Immune System	882	15.86%
Urogenital/Reproductive System	338	6.08%
Endocrine System/Metabolism	43	0.77%
Multisystemic	165	2.97%
Total	5,561	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	394	29.1%
Human Gastrointestinal Disorders including Liver	40	2.95%
Human Sensory Organ Disorders (skin, eyes and ears)	2	0.15%
Human Endocrine/Metabolism Disorders	375	27.7%
Other Human Disorders	543	40.1%
Total	1,354	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	95		95
Total	95		95

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

Severity	Number of uses	Percentage
Mild [up to and including]	32	33.68%
Moderate	63	66.32%
Total	95	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	24	25.26%
Genetically altered without a harmful phenotype	4	4.21%
Genetically altered with a harmful phenotype	67	70.53%
Total	95	100.00%

France

France: Narrative 2020

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

For the biological research sector, as for all sectors of society, 2020 was marked by the impact of the COVID-19 pandemic. In the course of the year, 30 projects were specifically authorised for research on the new virus while, on the other hand, the activity of animal facilities and research units was severely affected by the lockdowns.

The 2020 survey comprises responses from the 617 establishments approved for the use of laboratory animals (user establishments), as compared with 621 in 2019. Of these 617 establishments, 64 stated that they had not used any animals in experimental procedures requiring project authorisation in 2020.

The total number of animal uses declared in 2020 is 1,643,787. This number fell for the fifth year in a row, by 12%, following the 2.4% decrease recorded in 2019. This sharp decrease is largely due to total or partial suspension of establishments' activities during lockdowns. An increase in the number of animal uses can therefore be expected in 2021 as a result of the resumption of activities.

Species used

The 2020 figures confirm the dominance of the mouse model in experimental procedures (64% of uses, as compared to 61% in 2019). Rats (9.1%) and rabbits (8.8%) remain the two next most popular species. Fish account for 7.3% of uses, all species combined.

The number of cat uses, largely for regulatory tests of tolerance for veterinary medicines or studies regarding cat nutrition, continues to decrease, with 970 uses in 2020 compared to 1,007 in 2019 and 1,185 in 2018. More than three quarters of these uses (78%) are classified as 'mild'.

Uses of dogs fell, with 4,079 uses in 2020 compared to 4,898 in 2019, a decrease of 17%. The tests carried out mainly concern regulatory toxicology in human or veterinary medicine. 66% of these uses are classified as mild.

The use of primates increased from 3,339 to 3,996, an increase of 20% as compared to 2019. This increase concerns cynomolgus macaques and is due to project authorisations for the evaluation of COVID-19 vaccines and treatments, and to the establishment of a biological sample bank by a user establishment which will allow researchers to validate scientific hypotheses or test the efficacy or toxicity of candidate medicines *in vitro*. In 69% of cases, primates used for the first time were of generation F2, a very similar percentage to that of 2019 (66%). The proportion of re-uses of primates – 44% in 2020 – has increased compared to 2019 (38%).

The largest decreases were in fish other than zebra fish (-52%), birds other than hens (-43%) and reptiles, which are a small category (-72%). These figures can be explained by the fact that the main research fields for these species (ethology, studies of their diseases, conservation) are characterised

by field studies involving travel, sometimes outside France. These sectors have been particularly affected by the restrictions on travel.

Correspondingly, the species for which use has increased include golden hamster (+43%) and ferret (+12%), two models of COVID-19 infection which were the subject of 11 new authorisations in 2020 for this purpose. The same is true of guinea pigs, for which the 14% increase is linked to vaccine batch testing. Chinese hamsters were also used in one establishment as a model of viral respiratory diseases.

Re-uses

All species combined, the total number of re-uses was 34,307 in 2020 compared with 37,816 in 2019. The rate of re-use remains fairly stable in percentage terms.

Genetically modified animals

The number of uses of genetically modified animals was 27%, as compared to 22% in 2019 and 25% in 2018. As in 2019, the vast majority of these were mice (90%). The proportion of phenotypes identified as harmful increased but remained low (5.1% in 2020 compared to 3.3% in 2019). This could be linked to a stricter assessment of the criteria for characterising a harmful phenotype or to developments in research. The 2021 data may help to clarify this point.

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 of animal uses fall into three main areas: basic research, translational or applied research and regulatory uses or production of biological products for therapeutic use, which together account for 95% of uses.

The share of animal uses for basic research decreased from 41% in 2019 to 37% in 2020, close to the 2018 figure of 36%. This year again, the field of neuroscience used the most animals.

Toxicological and regulatory research for the development, production or testing of quality and safety of medicines or foodstuffs follows with 31% of uses, a share which continues to increase (29% in 2019 and 27% in 2018). This can be explained by an increase in the number of rabbit uses (+6%), which is directly linked to the production of a medication used to treat transplant rejection in humans. This medication, which is mainly produced in France, is distributed worldwide with demand growing.

Translational or applied research increased from 22% in 2019 to 27% in 2020, close to the 2018 figure of 28%, with research on cancer making up a large share of the human diseases studied. Uses in the areas of animal welfare or animal diseases concern productive animals and species for human consumption.

The following areas are much less represented and are generally decreasing: maintenance of colonies of genetically modified animals (2.6% of uses), teaching and professional training (1.7%) and species conservation (1.2%).

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%). Uses falling under the categories 'severe' and 'non-recovery' comprise 14% and 6.4% respectively, in line with the 2019 figures (14% and 6% respectively).

The decrease in 2019 in the proportion of uses classified as 'severe' (-26% as compared to 2018) is therefore confirmed in 2020.

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

France continues to actively promote the principles of replacement, reduction and refinement (the 'three Rs'). In the context of the research framework law of 24 December 2020, France confirmed its willingness to support the development and increase the visibility of alternatives to the use of animals for scientific and educational purposes. To this end, the law provided for the establishment of a national centre dedicated to the 'three Rs' principle, the FC3R, supported by public research, in particular the research institutes INSERM, CNRS and INRAE.

The aims of the centre are to develop training on this topic, to promote project engineering in line with the principle, to encourage the exchange of animal lines and the publication of negative research results in order to avoid unnecessary repetition of projects, to promote funding for research into the development of alternative methods and to ensure transparent communication on the use of animals for scientific purposes. The centre, in close coordination with the National Committee for the Protection of Animals used for Scientific Purposes (CNEA) and the National Committee for Ethics in Animal Research (CNREEA), should contribute to a constructive national dialogue on this societal concern.

Establishing a basis in law for a structure dedicated to the specific issues of the 'three Rs' that is able to finance projects for the development and validation of alternative methods responds to the high expectations of society and also reflects the strong engagement of the various academic and private research bodies in these subjects. The 2021 report will describe the operational measures initiated subsequently.

France's commitment to the promotion and development of the 'three Rs' is also continuing through the ongoing activity of the National Committee for the Protection of Animals used for Scientific Purposes and the National Committee for Ethics in Animal Research. By providing advice, information and recommendations, these two committees are a driving force for the development of practices around the use of animals for scientific purposes. Professional associations for animal research as well as national networks of ethics committees and animal welfare monitoring structures are also important players in the field.

One specific example demonstrating France's commitment is the work to reduce the number of animal uses in the production of monoclonal antibodies (2.4% of uses). The user establishments have been contacted individually and project authorisations are being reviewed. Restrictions on the duration of authorisations are planned, or otherwise repeals for establishments which do not demonstrate the need to continue production using animals owing to a lack of available alternatives.

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

For basic research, the category 'other' constitutes 0.45% of uses, with projects primarily concerning human and animal nutrition. Work has been carried out to reallocate these 'other' uses into existing categories wherever possible.

For regulatory uses / routine production, the category 'other' constitutes 5.2% of uses and is due in particular to the production of Toxoplasma suspension for toxoplasmosis screening kits, which accounts for 48,265 uses.

As in 2019, the 'other fish' category remains sizeable, accounting for 5.2% of uses (84,936). This category includes fish for human consumption, such as European sea bass (9,250), rainbow trout (17,719) and tilapia (14,407), the reproduction, physiology and diet of which are the subject of studies by public research bodies such as the National Research Institute for Agriculture, Food and Environment (INRAE) and the National Institute for Ocean Science (Ifremer).

The 'other birds' category accounts for 1.3% of uses (21,272). It includes a project to produce vaccines for turkeys which alone uses 11,862 turkeys. This category also includes other domestic species, such as ducks with 5,779 uses, and some wild species such as quail involved in ethology studies.

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

No authorisations were issued in 2020 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 were pending in 2019. Following a detailed analysis, the projects concerned could be modified and the two applications were finally authorised without exceeding the 'severe' classification.

France: Statistical Data 2020

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	913,109	61.81%
Rats	138,180	9.35%
Guinea-Pigs	42,813	2.9%
Hamsters (Syrian)	8,247	0.56%
Hamsters (Chinese)	110	0.01%
Mongolian gerbil	342	0.02%
Other rodents	411	0.03%
Rabbits	142,318	9.63%
Cats	413	0.03%
Dogs	2,385	0.16%

Ferrets	169	0.01%
Other carnivores	6	0%
Horses, donkeys and cross-breeds	164	0.01%
Pigs	11,378	0.77%
Goats	322	0.02%
Sheep	2,280	0.15%
Cattle	1,249	0.08%
Prosimians	51	0%
Marmoset and tamarins	44	0%
Cynomolgus monkey	2,037	0.14%
Rhesus monkey	37	0%
Vervets (Chlorocebus spp.)	34	0%
Baboons	47	0%
Other mammals	174	0.01%
Domestic fowl	74,379	5.03%
Other birds	21,151	1.43%
Reptiles	524	0.04%
Xenopus	1,673	0.11%
Other amphibians	322	0.02%
Zebra fish	28,245	1.91%
Other fish	84,431	5.72%
Cephalopods	299	0.02%
Total	1,477,344	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	1,224,901	83.04%
Animals born in the EU but not at a registered breeder	180,949	12.27%
Animals born in rest of Europe	45,215	3.07%
Animals born in rest of world	24,029	1.63%
Total	1,475,094	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	212	9.42%
Animals born in rest of Europe	1	0.04%
Animals born in Asia	400	17.78%
Animals born in America	34	1.51%
Animals born in Africa	1,376	61.16%
Animals born elsewhere	227	10.09%
Total	2,250	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	641	28.49%
F2 or greater	1,558	69.24%
Self-sustaining colony	51	2.27%
Total	2,250	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	913,109	20,062	933,171
Rats	138,180	1,647	139,827
Guinea-Pigs	42,813	28	42,841
Hamsters (Syrian)	8,247	75	8,322
Hamsters (Chinese)	110		110
Mongolian gerbil	342		342
Other rodents	411	626	1,037
Rabbits	142,318	1,652	143,970
Cats	413	557	970
Dogs	2,385	1,662	4,047
Ferrets	169		169
Other carnivores	6	6	12
Horses, donkeys and cross-breeds	164	309	473
Pigs	11,378	465	11,843
Goats	322	212	534
Sheep	2,280	284	2,564
Cattle	1,249	541	1,790
Prosimians	51		51
Marmoset and tamarins	44	115	159
Cynomolgus monkey	2,037	1,533	3,570
Rhesus monkey	37	40	77
Vervets (Chlorocebus spp.)	34	3	37
Baboons	47	37	84
Other species of Old World Monkeys (Cercopithecoidea)		18	18
Other mammals	174	7	181
Domestic fowl	74,379	729	75,108
Other birds	21,151	121	21,272
Reptiles	524	1114	1638
Xenopus	1,673	1,316	2,989
Other amphibians	322	110	432
Zebra fish	282,45	437	28,682
Other fish	84,431	505	84,936
Cephalopods	299		299
Total	1,477,344	34,211	1,511,555

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	554,172	36.66%
Translational and applied research	401,995	26.59%
Regulatory use and Routine production	507,414	33.57%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1,187	0.08%
Preservation of species	19,483	1.29%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	27,302	1.81%
Forensic enquiries	2	0%
Total	1,511,555	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	85,166	15.37%
Cardiovascular Blood and Lymphatic System	31,154	5.62%
Nervous System	124,348	22.44%
Respiratory System	10,934	1.97%
Gastrointestinal System including Liver	31,293	5.65%
Musculoskeletal System	17,016	3.07%
Immune System	102,291	18.46%
Urogenital/Reproductive System	16,799	3.03%
Sensory Organs (skin, eyes and ears)	15,255	2.75%
Endocrine System/Metabolism	24,006	4.33%
Multisystemic	8,207	1.48%
Ethology / Animal Behaviour /Animal Biology	80,851	14.59%
Other basic research	6,852	1.24%
Total	554,172	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	119,466	29.72%
Human Infectious Disorders	45,670	11.36%
Human Cardiovascular Disorders	10,494	2.61%
Human Nervous and Mental Disorders	40,759	10.14%
Human Respiratory Disorders	7,618	1.9%
Human Gastrointestinal Disorders including Liver	7,209	1.79%
Human Musculoskeletal Disorders	18,738	4.66%
Human Immune Disorders	17,837	4.44%
Human Urogenital/Reproductive Disorders	3,608	0.9%
Human Sensory Organ Disorders (skin, eyes and ears)	4,858	1.21%
Human Endocrine/Metabolism Disorders	14,890	3.7%
Other Human Disorders	8,688	2.16%
Animal Diseases and Disorders	49,870	12.41%
Animal Welfare	19,252	4.79%
Diagnosis of diseases	14,826	3.69%
Non-regulatory toxicology and ecotoxicology	18,212	4.53%
Total	40,1995	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	168,478	33.2%
Other efficacy and tolerance testing	9,086	1.79%
Toxicity and other safety testing including pharmacology	99,382	19.59%
Routine production	230,468	45.42%
Total	507,414	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	28,861	17.13%
Pyrogenicity testing	10,325	6.13%
Batch potency testing	122,218	72.54%
Other quality controls	7,074	4.2%
Total	168,478	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	8,160	8.21%
Skin irritation/corrosion	1,604	1.61%

Skin sensitisation	12,706	12.79%
Eye irritation/corrosion	152	0.15%
Repeated dose toxicity	18,423	18.54%
Carcinogenicity	1,395	1.4%
Genotoxicity	292	0.29%
Reproductive toxicity	9,245	9.3%
Developmental toxicity	14,591	14.68%
Kinetics	16,912	17.02%
Pharmaco-dynamics (incl safety pharmacology)	6,079	6.12%
Phototoxicity	54	0.05%
Ecotoxicity	7,823	7.87%
Safety testing in food and feed area	1,178	1.19%
Target animal safety	573	0.58%
Other toxicity/safety testing	195	0.2%
Total	99,382	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	1,518	18.6%
Other lethal methods	4,780	58.58%
Non lethal methods	1,862	22.82%
Total	8,160	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
up to 28 days	11,303	61.35%
29 - 90 days	4,849	26.32%
> 90 days	2,271	12.33%
Total	18,423	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	5,894	75.34%
Chronic toxicity	1,586	20.27%
Endocrine activity	80	1.02%
Bioaccumulation	253	3.23%
Other ecotoxicity	10	0.13%
Total	7,823	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	197,772	71.41%
Legislation on medicinal products for veterinary use and their residues	36,848	13.31%
Medical devices legislation	22,395	8.09%
Industrial chemicals legislation	12,591	4.55%
Plant protection product legislation	3,071	1.11%
Biocides legislation	1,615	0.58%
Food legislation including food contact material	2,055	0.74%
Feed legislation including legislation for the safety of target animals, workers and environment	44	0.02%
Other legislation	555	0.2%
Total	276,946	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	274,664	99.18%
Legislation satisfying national requirements only [within EU]	718	0.26%
Legislation satisfying Non-EU requirements only	1,564	0.56%
Total	276,946	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	104,482	45.33%
Monoclonal antibody by mouse ascites method	40,649	17.64%
Other product types	85,337	37.03%
Total	230,468	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	1,477,344	97.74%
Yes	34,211	2.26%
Total	1,511,555	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	79,304	5.25%
Mild [up to and including]	418,035	27.66%
Moderate	790,351	52.29%
Severe	223,865	14.81%
Total	1,511,555	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	1,165,593	77.11%
Genetically altered without a harmful phenotype	275,431	18.22%
Genetically altered with a harmful phenotype	70,531	4.67%
Total	1,511,555	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	78,859	1	78,860
Rats	3,880	40	3,920
Hamsters (Syrian)	145		145
Rabbits	220		220
Dogs	18		18
Other carnivores	6		6
Horses, donkeys and cross-breeds		10	10
Sheep	245	18	263
Cattle	20	7	27
Reptiles	42		42
Xenopus	60		60
Zebra fish	5,964	20	5,984
Total	89,459	96	89,555

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

Severity	Number of uses	Percentage
Non-recovery	25,431	28.4%
Mild [up to and including]	43,256	48.3%
Moderate	20,066	22.41%
Severe	802	0.9%
Total	89,555	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	10,441	11.66%
Genetically altered without a harmful phenotype	69,403	77.5%
Genetically altered with a harmful phenotype	9,711	10.84%
Total	89,555	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	2,962	6.15%
Cardiovascular Blood and Lymphatic System	1,981	4.11%
Nervous System	30,173	62.67%
Respiratory System	295	0.61%
Gastrointestinal System including Liver	935	1.94%
Musculoskeletal System	1,759	3.65%
Immune System	1,491	3.1%
Urogenital/Reproductive System	38	0.08%
Sensory Organs (skin, eyes and ears)	510	1.06%
Endocrine System/Metabolism	1,244	2.58%
Multisystemic	5,345	11.1%
Ethology / Animal Behaviour /Animal Biology	891	1.85%
Other basic research	521	1.08%
Total	48,145	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	632	1.53%
Human Infectious Disorders	1,591	3.84%
Human Cardiovascular Disorders	366	0.88%
Human Gastrointestinal Disorders including Liver	240	0.58%
Human Musculoskeletal Disorders	87	0.21%
Human Immune Disorders	94	0.23%
Human Urogenital/Reproductive Disorders	6	0.01%
Human Sensory Organ Disorders (skin, eyes and ears)	264	0.64%
Human Endocrine/Metabolism Disorders	718	1.73%
Other Human Disorders	37,375	90.26%
Animal Diseases and Disorders	37	0.09%
Total	41,410	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	36,833		36,833
Rats	5,321		5,321
Dogs	14		14
Zebra fish	509		509
Total	42,677		42,677

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

Severity	Number of uses	Percentage
Non-recovery	427	1%
Mild [up to and including]	33,067	77.48%
Moderate	8,963	21%
Severe	220	0.52%
Total	42,677	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	27,210	63.76%
Genetically altered without a harmful phenotype	11,747	27.53%
Genetically altered with a harmful phenotype	3,720	8.72%
Total	42,677	100.00%

Germany

Germany: Narrative 2020

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

In 2020, just under 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 fell by 14% compared to the previous year.

Approximately 80% of the animals used for testing were rodents, mainly mice and rats, with mice accounting for around 71% and rats 7%. Approximately 12% of the animals were fish, around 4% were rabbits and around 2% were birds. Compared to previous years, there were no substantial changes in the distribution of animals used. The proportion of mice increased again compared to the previous year (67% in 2019), but did not reach the level of 2018 (around 72%). The proportion of fish used (approximately 9% in 2018; approximately 16% in 2019) also stabilised at a value between the previous years' figures. At most, it is worth noting that the share of other animals used for testing was slightly higher than in the previous years (approximately 2% in 2019; approximately 1% in 2018).

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

Killing for scientific purposes

In addition to the requirements of the EU Laboratory Animals Directive, Germany also records animals killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals' organs or cell material for scientific purposes. Around 634,000 animals were used for this purpose in 2020, which is approximately 66,000 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, with genetically modified animals used in around 914,000 cases. These animals thus accounted for approximately 48% of uses (compared to approximately 45% in 2018). This concerned in particular mice (89%) and fish (10%).

Primates

The number of animal tests using primates fell sharply. A total of 2,031 tests using primates were reported in 2020, which is 1,245 fewer than in the previous year. This represents a decrease of around 38% compared to 2019.

Dogs and cats

The number of dogs and cats used, in particular for statutory testing and for applied research, has also fallen sharply, to 2,560 and 644, respectively. Compared to the previous year, the number of dog uses decreased by around 27%, while the number of cats decreased by around 32%.

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 54% 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 translational research, e.g. researching human and animal diseases. Around 19% of the animals were used for regulatory purposes, such as the production and quality control of medical products or for toxicological safety tests. Around 10% of the animals used were needed to maintain colonies of established genetically modified animals and could not be used in other procedures. 4% were needed for other purposes, such as training or further education, protecting the natural environment or species protection.

Compared to 2019, the proportion of tests in the area of basic research increased by around 7%. The proportion of animals used in researching human and animal diseases and maintaining colonies of genetically modified animals changed by less than one percent compared to the previous year, while the proportion of animals used for the production and quality control of medical products decreased by around 3%.

- **Basic research**
  In 2020, important areas of basic research included, in particular, research into the nervous system and the immune system (around 18% each), and the cardiovascular system (about 11%). These figures are virtually unchanged compared to the previous year.

- **Human and animal diseases**
  As in previous years, in the area of researching human and animal diseases, there was an emphasis on human cancers. Some 43% 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 40% in 2019).

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 67%). Around 24% of the tests were classified as ‘moderate’ and 4% were classified as ‘severe’. Compared to the previous year, there was an increase of 2% in tests 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 Federal Republic of Germany 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) through the German Federal Ministry of Food and Agriculture (*Bundesministerium für Ernährung und*

Landwirtschaft, BMEL); 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 der Erforschung 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 other fish, primarily local wild fish (e.g. salmonids, whitefish, carp, perch and European eel) 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 91%).

As regards the other birds used, these were mostly local wild bird species (e.g. zebra finches, tits and birds of prey) or species used in poultry farming (e.g. turkeys and geese). These species were mainly used in the context of basic ethological research and protecting the natural environment. This partially concerned animals caught in the wild that were re-released after the test was finished. The severity classification for the animals involved was generally 'mild' (around 80%).

Moreover, a small number of additional species were used, including 'other mammals' and 'other rodents'. As regards other mammals, primarily bats were used in basic ethological research. As regards other rodents, primarily field mice, bank voles and wood mice were used in basic ethological research, as well as for studies on climate change. Also worth highlighting is that it was reported that various hamster species were used in the context of research into the novel coronavirus. The severity classification was generally 'mild' (around 96%).

Category 'other uses'

The emphasis in this category is on 'basic research' and tests for 'regulatory purposes'.

In the context of **other basic research**, there was particular emphasis on the following areas:

- research into molecular pathomechanisms;
- research into molecular developmental genetics;
- testing various new methods for marker, blood and biopsy sampling with the aim of refining these methods;
- research in the field of gerontology.

The severity classification for the animals involved was generally 'mild' (around 85%).

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

- monitoring of wild animal populations in conjunction with authorisation procedures in the area of agriculture;
- 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;
- breeding and feeding of parasites or pathogens.

The severity classification for the animals involved was generally 'mild' (around 95%).

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*);

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.

In 2020, no tests were reported or authorised in Germany where the 'severe' classification was exceeded.

Germany: Statistical Data 2020

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	1,014,753	67.9%
Rats	130,480	8.73%
Guinea-Pigs	11,226	0.75%
Hamsters (Syrian)	1,984	0.13%
Hamsters (Chinese)	24	0%
Mongolian gerbil	2,346	0.16%
Other rodents	14,548	0.97%
Rabbits	69,718	4.66%
Cats	364	0.02%
Dogs	1,361	0.09%
Ferrets	155	0.01%
Other carnivores	231	0.02%
Horses, donkeys and cross-breeds	2,000	0.13%
Pigs	18,858	1.26%
Goats	255	0.02%
Sheep	7,567	0.51%
Cattle	7,355	0.49%
Prosimians	3	0%
Marmoset and tamarins	127	0.01%
Cynomolgus monkey	1,405	0.09%
Rhesus monkey	39	0%
Baboons	6	0%
Other mammals	1,826	0.12%
Domestic fowl	17,682	1.18%
Other birds	10,728	0.72%
Reptiles	392	0.03%

Xenopus	9,727	0.65%
Other amphibians	4,095	0.27%
Zebra fish	82,062	5.49%
Other fish	83,215	5.57%
Cephalopods	31	0%
Total	1,494,563	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	1,376,464	92.2%
Animals born in the EU but not at a registered breeder	103,459	6.93%
Animals born in rest of Europe	954	0.06%
Animals born in rest of world	12,106	0.81%
Total	1,492,983	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	192	12.15%
Animals born in Asia	790	50%
Animals born in Africa	598	37.85%
Total	1,580	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	169	10.7%
F2 or greater	1,351	85.51%
Self-sustaining colony	60	3.8%
Total	1,580	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	1,014,753	27,016	1,041,769
Rats	130,480	5,417	135,897
Guinea-Pigs	11,226	139	11,365
Hamsters (Syrian)	1,984		1,984
Hamsters (Chinese)	24		24
Mongolian gerbil	2,346	26	2,372
Other rodents	14,548		14,548
Rabbits	69,718	1,122	70,840
Cats	364	280	644
Dogs	1,361	1,199	2,560
Ferrets	155	2	157
Other carnivores	231		231
Horses, donkeys and cross-breeds	2,000	219	2,219
Pigs	18,858	563	1,9421
Goats	255	8	263
Sheep	7,567	59	7,626
Cattle	7,355	395	7,750
Prosimians	3	26	29
Marmoset and tamarins	127	49	176
Cynomolgus monkey	1,405	361	1,766
Rhesus monkey	39	15	54
Baboons	6		6
Other mammals	1,826	44	1,870
Domestic fowl	17,682	833	18,515
Other birds	10,728	88	10,816
Reptiles	392	3	395
Xenopus	9,727	1,294	11,021
Other amphibians	4,095		4,095
Zebra fish	82,062	34	82,096
Other fish	83,215	3,079	86,294
Cephalopods	31		31
Total	1,494,563	42,271	1,536,834

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	852,411	55.47%
Translational and applied research	240,533	15.65%
Regulatory use and Routine production	364,957	23.75%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	15,486	1.01%
Preservation of species	23,580	1.53%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	39,867	2.59%
Total	1,536,834	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	86,014	10.09%
Cardiovascular Blood and Lymphatic System	82,637	9.69%
Nervous System	147,800	17.34%
Respiratory System	16,256	1.91%
Gastrointestinal System including Liver	33,058	3.88%
Musculoskeletal System	12,820	1.5%
Immune System	176,692	20.73%
Urogenital/Reproductive System	19,382	2.27%
Sensory Organs (skin, eyes and ears)	16,925	1.99%
Endocrine System/Metabolism	39,609	4.65%
Multisystemic	116,942	13.72%
Ethology / Animal Behaviour /Animal Biology	54,759	6.42%
Other basic research	49,517	5.81%
Total	852,411	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	104,363	43.39%
Human Infectious Disorders	16,046	6.67%
Human Cardiovascular Disorders	11,269	4.69%
Human Nervous and Mental Disorders	28,558	11.87%
Human Respiratory Disorders	6,918	2.88%
Human Gastrointestinal Disorders including Liver	8,225	3.42%
Human Musculoskeletal Disorders	1,178	0.49%
Human Immune Disorders	15,937	6.63%
Human Urogenital/Reproductive Disorders	1,717	0.71%
Human Sensory Organ Disorders (skin, eyes and ears)	2,563	1.07%
Human Endocrine/Metabolism Disorders	12,462	5.18%
Other Human Disorders	1,652	0.69%
Animal Diseases and Disorders	15,930	6.62%
Animal Welfare	5,313	2.21%
Diagnosis of diseases	3,411	1.42%
Plant diseases	74	0.03%
Non-regulatory toxicology and ecotoxicology	4,917	2.04%
Total	240,533	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	103,327	28.31%
Other efficacy and tolerance testing	11,314	3.1%
Toxicity and other safety testing including pharmacology	184,716	50.61%
Routine production	65,600	17.97%
Total	364,957	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	25,590	24.77%
Pyrogenicity testing	3,223	3.12%
Batch potency testing	74,078	71.69%
Other quality controls	436	0.42%
Total	103,327	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	3,688	2%

Skin irritation/corrosion	303	0.16%
Skin sensitisation	4,431	2.4%
Eye irritation/corrosion	14	0.01%
Repeated dose toxicity	11,928	6.46%
Carcinogenicity	85	0.05%
Genotoxicity	2,067	1.12%
Reproductive toxicity	23,293	12.61%
Developmental toxicity	19,145	10.36%
Neurotoxicity	100	0.05%
Kinetics	13,425	7.27%
Pharmaco-dynamics (incl safety pharmacology)	44,944	24.33%
Ecotoxicity	42,337	22.92%
Safety testing in food and feed area	2,174	1.18%
Target animal safety	7,581	4.1%
Other toxicity/safety testing	9,201	4.98%
Total	184,716	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	695	18.84%
Non lethal methods	2,993	81.16%
Total	3,688	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	6,491	54.42%
29 - 90 days	3,681	30.86%
> 90 days	1,756	14.72%
Total	11,928	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	6,683	15.79%
Chronic toxicity	20,739	48.99%
Reproductive ecotoxicity	1,328	3.14%
Endocrine activity	11,514	27.2%
Bioaccumulation	1,657	3.91%
Other ecotoxicity	416	0.98%
Total	42,337	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	177,593	59.32%
Legislation on medicinal products for veterinary use and their residues	13,808	4.61%
Medical devices legislation	5,553	1.85%
Industrial chemicals legislation	43,509	14.53%
Plant protection product legislation	53,145	17.75%
Biocides legislation	512	0.17%
Food legislation including food contact material	417	0.14%
Feed legislation including legislation for the safety of target animals, workers and environment	2,176	0.73%
Other legislation	2,644	0.88%
Total	299,357	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	295,470	98.7%
Legislation satisfying national requirements only [within EU]	614	0.21%
Legislation satisfying Non-EU requirements only	3,273	1.09%
Total	299,357	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	58,700	89.48%
Monoclonal antibody by mouse ascites method	1,056	1.61%
Other product types	5,844	8.91%
Total	65,600	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	1,494,563	97.25%
Yes	42,271	2.75%
Total	1,536,834	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	96,317	6.27%
Mild [up to and including]	952,280	61.96%
Moderate	425,807	27.71%
Severe	62,430	4.06%
Total	1,536,834	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	935,792	60.89%
Genetically altered without a harmful phenotype	486,386	31.65%
Genetically altered with a harmful phenotype	114,656	7.46%
Total	1,536,834	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	111,373	856	112,229
Rats	911		911
Pigs	98		98
Domestic fowl	223		223
Other birds	183		183
Xenopus	759		759
Other amphibians	368		368
Zebra fish	58,139		58,139
Other fish	550		550
Total	172,604	856	173,460

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

Severity	Number of uses	Percentage
Non-recovery	8,593	4.95%
Mild [up to and including]	145,825	84.07%
Moderate	17,846	10.29%
Severe	1,196	0.69%
Total	173,460	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	43,423	25.03%
Genetically altered without a harmful phenotype	99,790	57.53%
Genetically altered with a harmful phenotype	30,247	17.44%
Total	173,460	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	14,038	8.29%
Cardiovascular Blood and Lymphatic System	31,851	18.8%
Nervous System	35,737	21.09%
Respiratory System	107	0.06%
Gastrointestinal System including Liver	4,947	2.92%
Musculoskeletal System	2,315	1.37%
Immune System	11,545	6.81%
Urogenital/Reproductive System	11,065	6.53%
Sensory Organs (skin, eyes and ears)	608	0.36%
Endocrine System/Metabolism	8,359	4.93%
Multisystemic	41,303	24.38%
Ethology / Animal Behaviour /Animal Biology	472	0.28%
Other basic research	7,075	4.18%
Total	169,422	100.00%

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

Translational and applied research	Number of uses	Percentage
Human Cancer	1,341	33.21%
Human Infectious Disorders	179	4.43%

Human Cardiovascular Disorders	858	21.25%
Human Nervous and Mental Disorders	719	17.81%
Human Gastrointestinal Disorders including Liver	163	4.04%
Human Musculoskeletal Disorders	64	1.58%
Human Immune Disorders	220	5.45%
Human Sensory Organ Disorders (skin, eyes and ears)	115	2.85%
Human Endocrine/Metabolism Disorders	288	7.13%
Other Human Disorders	27	0.67%
Diagnosis of diseases	64	1.58%
Total	4,038	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	178,586	6,310	184,896
Rats	1,441		1,441
Pigs	92		92
Zebra fish	523		523
Other fish	394		394
Total	181,036	6,310	187,346

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

Severity	Number of uses	Percentage
Non-recovery	1,330	0.71%
Mild [up to and including]	169,442	90.44%
Moderate	8,091	4.32%
Severe	8,483	4.53%
Total	187,346	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	6,953	3.71%
Genetically altered without a harmful phenotype	137,011	73.13%
Genetically altered with a harmful phenotype	43,382	23.16%
Total	187,346	100.00%

Greece

Greece: Narrative 2020

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

A slightly increased use of animals is reported in Greece for 2020 despite the COVID- 19 pandemic by 3.23 %.

A slightly increased use of animals born in the EU but not by a registered breeder by 5.56 % has been reported compared to 2019. This refers to the lower number of fish of domestic species (other fish) that have been used.

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

- Approximately the same use of genetically altered mice without a harmful phenotype is noted in Greek statistical data in 2020 compared to 2019 and 2018. Furthermore a significant increase by 25% is noted in human cardiovascular studies (Translational and applied research) using mice. This is attributed to the different type of protocols performed in Greek establishments for 2020.
- A significant use of fish is still depicted in Greek statistical data in 2020 again compared to other MS for 2020 but lowered by 11.25% compared to 2019. More specifically a forther decrease of 50% compared to 2019 is noted. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as “mild”.
- No cephalopods were used in 2020.
- 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.
- 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.
- 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.
- 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.
- 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. Their number remains stable between 2019 and 2020.

- A continuous decreased use of dogs is noted during the years, according to the relevant protocols authorised. Their number remains stable between 2019 and 2020.
- No animals were used for protocols aimed for animal welfare purposes in contrast to 2019.
- A significant decrease in the use of rabbits and pigs by 50% and 70% respectively is declared due to the type of the protocols authorised.
- An increase by 51% in maintenance of colonies of established genetically altered animals is also noted.

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

- Animals with “Non recovery” severity seem to diminished by 42.49% due to a declared decrease in higher education trainings programs that are performed with the use of live animals in Greece as a result of the COVID-19 pandemic.
- Animals with “moderate” severity seem to have decreased by 34.06%. 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.
- A significant decrease in the severity of procedures in mice is depicted, which can be attributed to the decreased number of basic research oncology protocols compared to 2019. Furthermore, there is a constant 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 under different physicochemical water parameters (i.e. different temperatures). These protocols were classified as severe because mortality is caused to 100% of fish. In 2020 all fish used for this protocol died, increasing thus the number of severely affected animals in total.

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.

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

A significant proportion of other fish is reported in Greece for 2020 although with a slightly decreasing trend compared to 2019. Greece remains 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 in general. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”. “Severe” use where applicable has already been presented above.

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 2020.

Greece: Statistical Data 2020

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	21,614	48.92%
Rats	3,345	7.57%
Guinea-Pigs	1	0%
Rabbits	192	0.43%
Pigs	70	0.16%
Domestic fowl	1,690	3.82%
Zebra fish	678	1.53%
Other fish	16,595	37.56%
Total	44,185	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	31,783	71.93%
Animals born in the EU but not at a registered breeder	12,307	27.85%
Animals born in rest of world	95	0.22%
Total	44,185	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	21,614		21,614
Rats	3,345	46	3,391
Guinea-Pigs	1		1
Rabbits	192		192
Cats		3	3
Dogs		10	10
Pigs	70	8	78
Rhesus monkey		1	1
Domestic fowl	1,690		1,690
Zebra fish	678		678
Other fish	16,595	96	16,691
Total	44,185	164	44,349

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	19,571	44.13%
Translational and applied research	11,746	26.49%
Regulatory use and Routine production	6,619	14.92%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	5,800	13.08%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	613	1.38%
Total	44,349	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	2,873	14.68%
Cardiovascular Blood and Lymphatic System	1,573	8.04%
Nervous System	2,856	14.59%
Respiratory System	502	2.57%
Gastrointestinal System including Liver	1,114	5.69%
Musculoskeletal System	113	0.58%
Immune System	1,948	9.95%
Urogenital/Reproductive System	140	0.72%
Sensory Organs (skin, eyes and ears)	865	4.42%
Endocrine System/Metabolism	191	0.98%
Multisystemic	190	0.97%
Ethology / Animal Behaviour /Animal Biology	5,516	28.18%
Other basic research	1,690	8.64%
Total	19,571	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	1,003	8.54%
Human Infectious Disorders	717	6.1%
Human Cardiovascular Disorders	52	0.44%
Human Nervous and Mental Disorders	1,004	8.55%

Human Respiratory Disorders	156	1.33%
Human Gastrointestinal Disorders including Liver	300	2.55%
Human Musculoskeletal Disorders	301	2.56%
Human Immune Disorders	1,955	16.64%
Human Urogenital/Reproductive Disorders	10	0.09%
Human Sensory Organ Disorders (skin, eyes and ears)	242	2.06%
Other Human Disorders	100	0.85%
Animal Diseases and Disorders	1,460	12.43%
Animal Welfare	4,443	37.83%
Diagnosis of diseases	1	0.01%
Non-regulatory toxicology and ecotoxicology	2	0.02%
Total	11,746	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	6,619	100.00%
Total	6,619	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	290	4.38%
Carcinogenicity	41	0.62%
Safety testing in food and feed area	6,288	95%
Total	6,619	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	331	5%
Food legislation including food contact material	6,288	95%
Total	6,619	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	6,619	100.00%
Total	6,619	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	44,185	99.63%
Yes	164	0.37%
Total	44,349	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	2,674	6.03%
Mild [up to and including]	24,243	54.66%
Moderate	7,927	17.87%
Severe	9,505	21.43%
Total	44,349	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	33,529	75.6%
Genetically altered without a harmful phenotype	9,165	20.67%
Genetically altered with a harmful phenotype	1,655	3.73%
Total	44,349	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	6,258		6258
Total	6,258		6258

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

Severity	Number of uses	Percentage
Mild [up to and including]	5,990	95.72%
Moderate	268	4.28%
Total	6,258	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	268	4.28%
Genetically altered without a harmful phenotype	5,990	95.72%
Total	6,258	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	9.65%
Cardiovascular Blood and Lymphatic System	499	11.09%
Nervous System	1,538	34.19%
Gastrointestinal System including Liver	325	7.23%
Immune System	1,422	31.61%
Sensory Organs (skin, eyes and ears)	12	0.27%
Multisystemic	268	5.96%
Total	4,498	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	560	31.82%
Human Nervous and Mental Disorders	1,200	68.18%
Total	1,760	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	2,384		2,384
Total	2,384		2,384

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

Severity	Number of uses	Percentage
Mild [up to and including]	1,537	64.47%
Moderate	847	35.53%
Total	2,384	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	660	27.68%
Genetically altered without a harmful phenotype	696	29.19%
Genetically altered with a harmful phenotype	1,028	43.12%
Total	2,384	100.00%

Hungary

Hungary: Narrative 2020

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 2020 was 139,186, which represents 1.86% increase compared to 2019 and 15.48 % increase compared to the same figure of 2018. The reason is for the increased use that there was more experiment in 2020, where the use of animal cannot be replaced. The number of re-used animals was 3,325 (2.39% from total uses) which increased almost 3-fold compared to 2019, and 3.54% decrease compared with the data of 2018.

The number of genetically altered animal used without a harmful phenotype in 2020 was 9,780, which represent about 23.03% increase compared with the previous year and 12.71% increase compared with 2018. In 2020, the percentage of use is 7.02% from total uses. This also shows increase compare with 2019.

The data of origin of animals do not show significant difference compare with the previous years. In 2020, the percentage of use of animals born in the EU at a registered breeder was 94.24% and the use of animals born in the EU but not at a registered breeder was 5.68 %. This shows 1.84% decrease compare with 2019.

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 (92.68%) of used animals were warm-blooded vertebrates. There was decrease in the proportion of mammals (from 74.06% to 68.63%), while the proportion of birds and fish increased (the birds from 18.55% to 24.05% and the fish from 2.79% to 5.74%). In 2020 decreased the use of amphibians compare with 2019 (from 4.60% to 1.58%).

The proportion of rodents among mammals decreased from 95.97% to 93.80%. There was 6.24% decrease in the number of mice and 9.26% in the number of rats. In case of guinea-pigs there was a 21.28% decrease. Differently from the previous years, hamsters were used for scientific purposes in 2020 (48 pieces). The number of rabbits used for scientific purposes increased by 50.76% in 2020.

The number of cats used in experiments decreased slightly (24 compared to 11). The number of dogs increased to 32.15% compare with the previous year. 2 non-human primates was used in 2020.

The number of horses, donkeys and cross-breeds used for scientific purpose represents small decrease in 2020 compared with the previous year (from 19 to 17).

There was 50.71% increase on the number of pigs. The use of cattle for scientific purposes shows significant decrease (82.5%) compared with the previous year. The number of sheep represents significant decrease in 2020 compare with the previous year (from 47 to 4).

The number of domestic fowl increased to 32.44%, and the number of other birds shows a slight increase (from 739 to 872).

The use of zebra fish increased to 65 % compare with the previous year, and other fish also increased by 43.7%.

When analysed by the purposes of the use of animals, the “regulatory use and routine production” is 50.95 % of the total uses. The proportion of basic research shows a slight increase, the translational and applied research shows slight decrease than in 2019. 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 86 to 1,360) compare with 2019.

The use of the category of “Preservation of species” represents significant decrease in 2020 compare with the previous year (from 6,280 to 2,200).

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

The proportion of mild uses was increased from 46.18% to 51.20% and moderate uses decreased from 30.62% to 29.55%. The severe use also shows a slight decrease from 14.51% to 13.16%. On the other hand non-recoveries decreased from 8.68% to 6.09%

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. In 2020 the number of other amphibians dramatically decreased due to the current phase of the experiment.

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

The number of cases where the 'severe' classification exceeded is not show significant difference compared with 2019.

Hungary: Statistical Data 2020

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	57,669	42.86%
Rats	28,728	21.35%
Guinea-Pigs	2,634	1.96%
Hamsters (Syrian)	48	0.04%
Rabbits	1,524	1.13%
Cats	9	0.01%
Dogs	427	0.32%
Horses, donkeys and cross-breeds	12	0.01%
Pigs	3,747	2.78%
Sheep	4	0%
Cattle	4	0%
Rhesus monkey	2	0%
Domestic fowl	32,597	24.22%
Other birds	872	0.65%
Other amphibians	2,200	1.63%
Zebra fish	1,861	1.38%
Other fish	2,222	1.65%
Total	134,560	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	126,765	94.21%
Animals born in the EU but not at a registered breeder	7,,683	5.71%
Animals born in rest of Europe	40	0.03%
Animals born in rest of world	70	0.05%
Total	134558	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born in Asia	2	100.00%
Total	2	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	2	100.00%
Total	2	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	57,669	113	57,782
Rats	28,728		2,8728
Guinea-Pigs	2,634	144	2,778
Hamsters (Syrian)	48		48
Rabbits	1,524	14	1,538
Cats	9	2	11
Dogs	427	58	485
Horses, donkeys and cross-breeds	12	5	17
Pigs	3,747	63	3,810
Sheep	4		4
Cattle	4	3	7
Rhesus monkey	2		2
Domestic fowl	32,597		32,597
Other birds	872		872
Other amphibians	2,200		2,200
Zebra fish	1,861	1,283	3,144
Other fish	2,222	300	2,522
Total	134,560	1,985	136,545

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	36,921	27.04%
Translational and applied research	24,136	17.68%
Regulatory use and Routine production	70,921	51.94%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1,360	1%
Preservation of species	2,200	1.61%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1,007	0.74%
Total	136,545	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	2,768	7.5%
Cardiovascular Blood and Lymphatic System	2,401	6.5%
Nervous System	18,393	49.82%
Respiratory System	518	1.4%
Gastrointestinal System including Liver	2,381	6.45%
Musculoskeletal System	502	1.36%
Immune System	3,582	9.7%
Urogenital/Reproductive System	1,217	3.3%
Sensory Organs (skin, eyes and ears)	604	1.64%
Endocrine System/Metabolism	277	0.75%
Multisystemic	2,004	5.43%
Ethology / Animal Behaviour /Animal Biology	428	1.16%
Other basic research	1,846	5%
Total	36,921	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	5,163	21.39%
Human Infectious Disorders	749	3.1%
Human Cardiovascular Disorders	43	0.18%
Human Nervous and Mental Disorders	13,356	55.34%
Human Gastrointestinal Disorders including Liver	247	1.02%
Human Musculoskeletal Disorders	4	0.02%
Human Immune Disorders	2,416	10.01%
Human Sensory Organ Disorders (skin, eyes and ears)	213	0.88%
Human Endocrine/Metabolism Disorders	166	0.69%
Animal Diseases and Disorders	299	1.24%
Diagnosis of diseases	174	0.72%
Non-regulatory toxicology and ecotoxicology	1,306	5.41%
Total	24,136	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	33,623	47.41%
Other efficacy and tolerance testing	118	0.17%
Toxicity and other safety testing including pharmacology	26,119	36.83%
Routine production	11,061	15.6%
Total	70,921	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	10,511	31.26%
Pyrogenicity testing	14	0.04%
Batch potency testing	22,087	65.69%
Other quality controls	1,011	3.01%
Total	33,623	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	10,673	40.86%
Skin irritation/corrosion	111	0.42%
Skin sensitisation	2,293	8.78%
Eye irritation/corrosion	70	0.27%
Repeated dose toxicity	4,783	18.31%
Genotoxicity	730	2.79%
Reproductive toxicity	3,464	13.26%
Developmental toxicity	549	2.1%
Kinetics	481	1.84%
Pharmaco-dynamics (incl safety pharmacology)	1,803	6.9%
Phototoxicity	40	0.15%
Ecotoxicity	380	1.45%
Other toxicity/safety testing	742	2.84%
Total	26,119	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	9,185	86.06%
Other lethal methods	373	3.49%
Non lethal methods	1,115	10.45%
Total	10,673	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	1,960	40.98%
29 - 90 days	2,110	44.11%
> 90 days	713	14.91%
Total	4,783	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	380	100.00%
Total	380	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	17,710	29.59%
Legislation on medicinal products for veterinary use and their residues	37,437	62.54%
Industrial chemicals legislation	765	1.28%
Plant protection product legislation	3,039	5.08%
Biocides legislation	84	0.14%
Food legislation including food contact material	182	0.3%
Feed legislation including legislation for the safety of target animals, workers and environment	70	0.12%
Other legislation	573	0.96%
Total	59,860	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	59,825	99.94%
Legislation satisfying Non-EU requirements only	35	0.06%
Total	59,860	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	141	1.27%
Monoclonal antibody by mouse ascites method	66	0.6%
Other product types	10,854	98.13%
Total	11,061	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	134,560	98.55%
Yes	1,985	1.45%
Total	136,545	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	7,388	5.41%
Mild [up to and including]	70,555	51.67%
Moderate	40,288	29.51%
Severe	18,314	13.41%
Total	136,545	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	127,753	93.56%
Genetically altered without a harmful phenotype	8,061	5.9%
Genetically altered with a harmful phenotype	731	0.54%
Total	136,545	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	263	5	268
Rabbits	48		48
Zebra fish	990	1,335	2,325
Total	1,301	1,340	2,641

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

Severity	Number of uses	Percentage
Non-recovery	1,085	41.08%
Mild [up to and including]	715	27.07%
Moderate	841	31.84%
Total	2,641	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	265	10.03%
Genetically altered without a harmful phenotype	1,719	65.09%
Genetically altered with a harmful phenotype	657	24.88%
Total	2,641	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	130	5.22%
Immune System	990	39.78%
Urogenital/Reproductive System	34	1.37%
Multisystemic	1,335	53.64%
Total	2,489	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 Respiratory Disorders	152	100.00%
Total	152	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

Ireland

Ireland: Narrative 2020

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

- The total number of uses of animals reported for 2020 remains more or less unchanged from 2019.
- There was a significant reduction in the number of animals reused in 2020 versus 2019 (71% decrease).
- The numbers of animals reported as not genetically altered or genetically altered without a harmful phenotype remains more or less unchanged from 2019. There was a 48% decrease in the number of animals used reported as being genetically altered with a harmful phenotype.
- Mice remain the most commonly used species at 82% of all animal uses. There was a significant decrease in the numbers of rats used, with 46% fewer rats used in 2020 than in 2019. There was also a large reduction in the numbers of guinea pigs used, with 62% fewer guinea pigs used in 2020 than in 2019. The number of animals reported under the species category 'other rodents' has increased from 0 in 2019 to 59 in 2020. The use of rabbits has increased by 89% since 2019. The use of ferrets has decreased by 54% since 2019. There has been an eight-fold increase from 2019 in the numbers of horses used. In relation to agricultural species, the use of pigs has decreased by 60% from 2019, and uses of cattle have decreased by 51% from 2019. However, uses of sheep have increased by 32%. The number of uses of animals reported in the species category 'other mammals' has decreased by 97%. The number of uses of domestic fowl has increased by 79%, whereas the use of birds reported in the species category 'other birds' has seen an 87% decrease. There has been a 33% reduction in the numbers of uses of zebrafish reported, and a 47% reduction in the numbers of uses of fish reported under the species category 'other fish'.
- The number of animals reported as being used for the purpose of 'Basic research' decreased by 26%. The number of animals reported as being used for the purpose 'Protection of the natural environment in the interests of the health or welfare of human beings or animals' was 43% lower in 2020 versus 2019, whereas the number of uses reported under the project purpose 'Preservation of the species' increased by 278%. There was a 96% reduction in the numbers of animals used for the purpose of 'Regulatory use and routine production – blood based products'. 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.

- The significant reduction in the number of animals being reused in 2020 versus 2019 is largely due to the fact that cattle are one of the species that are most commonly reused, and there was a notable decrease in the total number of uses of cattle in procedures in 2020. This is due to the conclusion of several projects using large numbers of cattle in 2019. The COVID-19 pandemic, and government restrictions on movement prohibiting travel to commercial farms for the purpose of performing agricultural research may also have been a contributing factor.

- The reasons underpinning the decrease in the numbers of animals reported as being genetically altered with a harmful phenotype are not known.

- Significantly fewer rats, guinea pigs and ferrets were used in 2020 versus 2019. This is due to a reduction in the use of these species for the regulatory testing of certain types of human medicinal products (e.g. influenza vaccine products).

- The increase in the number of animals used reported under the category 'other rodents' is as a result of a wildlife conservation study investigating the habitats and behaviour of wild squirrels.

- The number of uses of rabbits increased from 2019 to 2020 due to the relocation of regulatory testing using this species from a Contract Research Organisation in another Member State to Ireland.

- The notable increase in the use of horses is a result of a large equine disease surveillance study being performed in 2020.

- The reduction in the numbers of cattle and pigs used in 2020 is primarily due to the conclusion of several projects using these species in 2019. The COVID-19 pandemic, and government restrictions on movement prohibiting travel to commercial farms for the purpose of performing agricultural research may also have been a factor in this reduction. The increase in the number of uses of sheep is because of several studies being performed in 2020 for the purpose of investigating methane emissions from sheep.

- The decrease in the number of animals used reported under the species category 'other mammals' is a result of the conclusion of several studies using species captured within this category in 2019.

- The increase in the number of uses of domestic fowl in 2020 is as a result of a large project performed for the purpose of avian disease surveillance and the protection of the health of the national poultry flock. The increase in the uses of birds reported under the species category 'other birds' is as a result of a conservation project studying wild birds.

- The reasons underlying the reduction in the number of uses of zebrafish in 2020 are not known. The reduction in the number of uses of fish reported under the species category 'other fish' may be due to the COVID-19 pandemic and logistical difficulties in travelling to

locations (rivers/sea) where wildlife studies are performed, due to restrictions on movement in place at various periods throughout 2020.

- The reasons underlying the decrease in the percentage of uses of animals for the project purpose 'Basic research' are not known, however the COVID-19 pandemic may have contributed to this decrease as a number of research studies were delayed or postponed due to logistical challenges arising as a result of lockdown restrictions.

- The significant reduction in the numbers of animals being used for the 'Regulatory use and routine production - blood based products' is due to a reduction in the numbers of animals being used for antisera production.

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

The distribution of animal numbers across the four severity categories in 2020 is broadly similar to that of 2019, with no significant changes noted.

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

We have focussed significant efforts over the past number of years to ensure 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 tests in 2020. For example, we have noted a reduction of 28% in the numbers of animals used for quality control (including batch safety and potency) testing from 2018 to 2020, and the percentage reduction in 2020 versus 2017 is 47% fewer animals used for testing of this nature (in absolute terms this represents a decrease of 91,466 animals used). 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.

Furthermore, throughout 2020 we shared regular communications with end-users in relation to the EURL ECVAM Recommendation on Non-Animal-Derived Antibodies, in addition to EURL ECVAM reviews of advanced non-animal models in biomedical research. The HPRA also regularly communicates information on 3Rs developments with end-users in a quarterly newsletter.

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 2% of animal use. These relate to studies of wild and farmed fish species, such as wildlife conservation and aquaculture research projects.

6. Information on the uses of animals in categories where a method or testing strategy for obtaining the results sought, not entailing the use of live animals, is recognised under the legislation of the Union.

In 2020, 943 rabbits were used for pyrogenicity testing. Alternative testing methods to determine the pyrogenicity of medicinal products are recognised under the legislation of the Union. However,

these methods are not suitable for certain classes of medicinal products, for example some blood/protein based medicines. Therefore, in order to meet the necessary regulatory safety requirements for release of certain medicinal products onto the market there is currently no alternative to the use of the rabbit pyrogen test.

Other types of regulatory testing using animals (such as batch potency determination e.g. of botulinum toxin medicinal products) are only authorised in circumstances where there is no non-animal alternative test validated and accepted by medicines regulators to be used for the specific product(s) in question.

7. 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 2020.

Ireland: Statistical Data 2020

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	113,209	82.44%
Rats	12,330	8.98%
Guinea-Pigs	228	0.17%
Hamsters (Syrian)	8	0.01%
Other rodents	59	0.04%
Rabbits	1,043	0.76%
Dogs	24	0.02%
Ferrets	186	0.14%
Horses, donkeys and cross-breeds	238	0.17%
Pigs	129	0.09%
Goats	16	0.01%
Sheep	1,239	0.9%
Cattle	2,104	1.53%
Other mammals	1	0%
Domestic fowl	129	0.09%
Other birds	87	0.06%
Xenopus	3	0%
Zebra fish	3,357	2.44%
Other fish	2,928	2.13%
Total	137,318	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	133,572	97.27%
Animals born in the EU but not at a registered breeder	3,553	2.59%
Animals born in rest of Europe	144	0.1%
Animals born in rest of world	49	0.04%
Total	137,318	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	113,209		113,209
Rats	12,330		12,330
Guinea-Pigs	228		228
Hamsters (Syrian)	8		8
Other rodents	59		59
Rabbits	1,043		1,043
Cats		20	20
Dogs	24	40	64
Ferrets	186		186
Horses, donkeys and cross-breeds	238	10	248
Pigs	129		129
Goats	16		16
Sheep	1,239	29	1,268
Cattle	2,104	557	2,661
Other mammals	1		1
Domestic fowl	129	14	143
Other birds	87		87
Xenopus	3		3
Zebra fish	3,357		3,357
Other fish	2,928		2,928
Total	137,318	670	137,988

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	10,455	7.58%
Translational and applied research	21,467	15.56%
Regulatory use and Routine production	102,861	74.54%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	2,891	2.1%
Preservation of species	68	0.05%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	246	0.18%
Total	137,988	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	31	0.3%
Cardiovascular Blood and Lymphatic System	61	0.58%
Nervous System	2,300	22%
Respiratory System	397	3.8%
Gastrointestinal System including Liver	64	0.61%
Immune System	3,220	30.8%
Sensory Organs (skin, eyes and ears)	590	5.64%
Endocrine System/Metabolism	332	3.18%
Multisystemic	824	7.88%
Ethology / Animal Behaviour /Animal Biology	2,636	25.21%
Total	10,455	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	625	2.91%
Human Infectious Disorders	1,163	5.42%
Human Cardiovascular Disorders	844	3.93%
Human Nervous and Mental Disorders	7,073	32.95%
Human Respiratory Disorders	239	1.11%
Human Gastrointestinal Disorders including Liver	1,115	5.19%
Human Musculoskeletal Disorders	3,926	18.29%
Human Immune Disorders	923	4.3%
Human Sensory Organ Disorders (skin, eyes and ears)	3,708	17.27%
Human Endocrine/Metabolism Disorders	285	1.33%
Other Human Disorders	70	0.33%
Animal Diseases and Disorders	1,213	5.65%
Animal Welfare	271	1.26%
Plant diseases	12	0.06%
Total	21,467	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	102,781	99.92%
Other efficacy and tolerance testing	62	0.06%
Routine production	18	0.02%
Total	102,861	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	1,304	1.27%
Pyrogenicity testing	943	0.92%
Batch potency testing	100,484	97.77%
Other quality controls	50	0.05%
Total	102,781	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	102,731	99.89%

Legislation on medicinal products for veterinary use and their residues	50	0.05%
Medical devices legislation	2	0%
Feed legislation including legislation for the safety of target animals, workers and environment	60	0.06%
Total	102,843	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	102,843	100.00%
Total	102,843	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	18	100.00%
Total	18	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	137,318	99.51%
Yes	670	0.49%
Total	137,988	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	1,110	0.8%
Mild [up to and including]	79,380	57.53%
Moderate	36,289	26.3%
Severe	21,209	15.37%
Total	137,988	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	128,424	93.07%
Genetically altered without a harmful phenotype	7,227	5.24%
Genetically altered with a harmful phenotype	2,337	1.69%
Total	137,988	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	104		104
Total	104		104

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

Severity	Number of uses	Percentage
Non-recovery	3	2.88%
Mild [up to and including]	89	85.58%
Severe	12	11.54%
Total	104	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	45	43.27%
Genetically altered with a harmful phenotype	59	56.73%
Total	104	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
Musculoskeletal System	3	100.00%
Total	3	100.00%

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

Translational and applied research	Number of uses	Percentage
Human Musculoskeletal Disorders	45	44.55%
Human Immune Disorders	56	55.45%
Total	101	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	491		491
Zebra fish	107		107
Total	598		598

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

Severity	Number of uses	Percentage
Mild [up to and including]	424	70.9%
Moderate	162	27.09%
Severe	12	2.01%
Total	598	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	270	45.15%
Genetically altered without a harmful phenotype	107	17.89%
Genetically altered with a harmful phenotype	221	36.96%

Total	598	100.00%

Italy

Italy: Narrative 2020

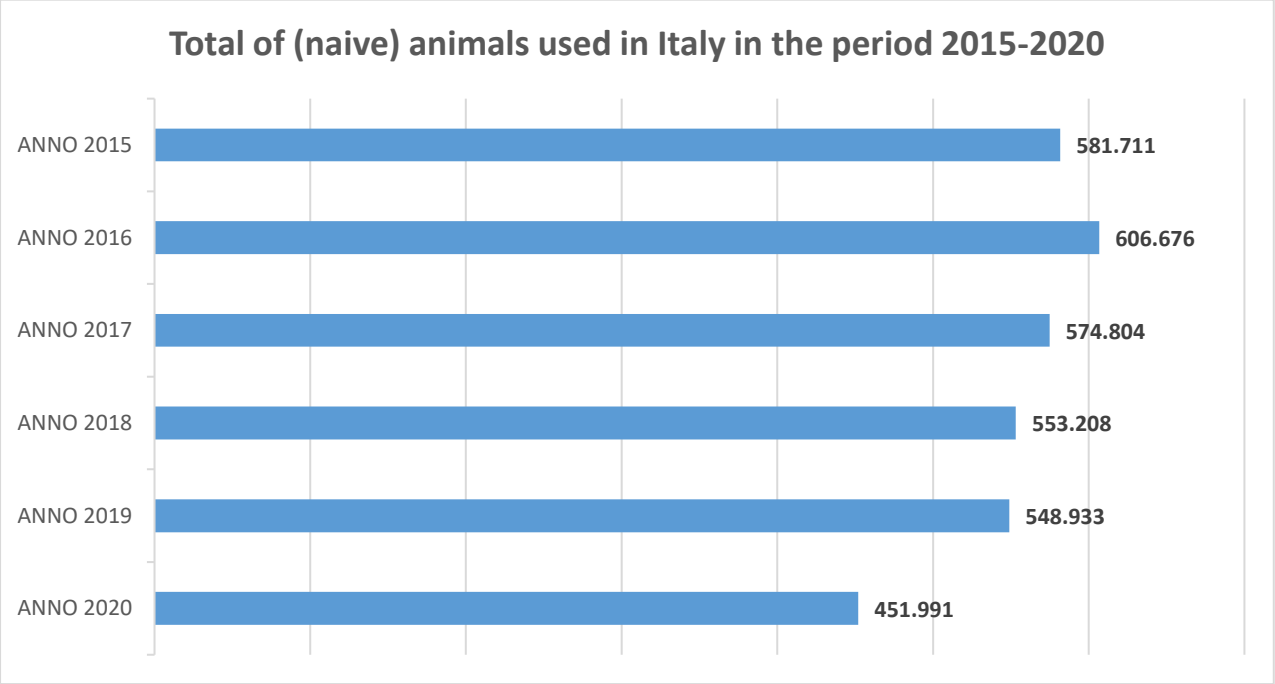
Preamble

The data for Italy for 2020 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 2020. In total, 451,991 animals were used in scientific procedures in 2020, a 17% drop compared to the previous year (see Figure 1). The scale of this drop can be attributed to difficulties in carrying out experiments as a result of the COVID-19 pandemic.

Figure 1



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

In terms of species, rodents and rabbits accounted for 85.66% of the animals, including reused animals, used in testing in 2015-2020 (see Table 1). Within these species, there was a slight percentage increase in the number of rodents compared to the previous year.

As regards non-human primates, although there was an increase in the number of animals compared to 2019, it remained below the number of animals used in 2018. Regulatory tests (toxicity and other safety tests) required under European and international law were again the main scientific purpose for which non-human primates were used in 2020 (accounting for 99% in 2018 and 2019 and 98% in 2020, up from 86.75% in 2015).

The most frequently used species was *Macaca fascicularis*. In 2020 the use of generation F1 animals dropped to 10.53%, with F2 or higher animals accounting for 89.47%.

Table 1

Animal species	% of total, 2015	% of total, 2016	% of total, 2017	% of total, 2018	% of total, 2019	% of total, 2020	Mean (%) Period 2015-2020
Rodents	89.02%	87.43%	84.73%	83.49 %	81.04%	83.26%	**84.82%**
Rabbits	1.66%	2.49%	3.33%	2.19%	2.01%	2.40%	**2.34%**
Total rodents + rabbits	**90.68%**	**89.82%**	**88.06%**	**85.68%**	**83.05%**	**85.66%**	**87.16%**
Total other animal species	**9.32%**	**10.18%**	**11.94%**	**14.32%**	**16.95%**	**14.34%**	**12.84%**
Total (all species)	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**

The breakdown for all animal species was as follows in 2020 (see Table 2):

29.64% of the animals were used in basic biological studies.

28.42% were used in translational or applied research.

40.05% were used for regulatory testing and routine production.

1.89% were used for other purposes.

No animals were used for forensic enquiries.

Table 2

Animal use by purpose of study

Purpose of study	YEAR 2015	YEAR 2016	YEAR 2017	YEAR 2018	YEAR 2019	YEAR 2020
Basic research	37.26%	35.42%	33.55%	29.11%	28.42%	29.64%
Translational research	24.92%	26.54%	26.48%	32.74%	33.75%	28.42%
Regulatory testing	36.07%	37.11%	38.96%	37.36%	36.77%	40.05%
Other	1.75%	0.93%	1.01%	0.79%	1.06%	1.89%

For 2020, there was a slight decrease in the number of animals used for translational or applied research in favour of regulatory research (40%) (experimental tests that are mandatory under national, European and international standards) (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 2020.

Table 3

Level of suffering / 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%
2020	3.49%	45.09%	29.46%	21.96%

Comparing the data for 2019 and 2020 shows that:

- there were slight variations in the ‘non-recovery’, ‘moderate’ and ‘severe’ levels of suffering;
- there was no variation in the ‘mild’ level of suffering.

Mice are the most affected species in terms of the ‘severe’ suffering level, accounting for 79%. Within that species, genetically modified animals with a ‘harmful’ phenotype are used.

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 2020 the National Committee for the Protection of Animals Used for Scientific Purposes collaborated with the Ministry of Health’s Directorate-General for Animal Health and Veterinary Medicines on addressing the problems that affected experimentation on animals during the COVID-19 pandemic and the associated bans on the displacement of personnel. It also gathered requests from animal welfare bodies.

The Committee also completed the animal welfare body coordination work that had been launched in previous years and collected the technical reports drawn up by the ad hoc working groups.

As far as staff skills are concerned, webinars, workshops and training courses were organised by various public or private bodies, with experts from the Ministry of Health participating as lecturers/speakers in some 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 (vaccine immunogenicity tests).

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 2020

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	265,357	59.79%
Rats	91,619	20.64%
Guinea-Pigs	14,017	3.16%
Hamsters (Syrian)	271	0.06%
Other rodents	376	0.08%
Rabbits	10,060	2.27%
Dogs	454	0.1%
Ferrets	20	0%
Pigs	1,027	0.23%
Goats	5	0%
Sheep	80	0.02%
Cattle	156	0.04%
Cynomolgus monkey	454	0.1%
Rhesus monkey	2	0%
Other mammals	18	0%
Domestic fowl	40,225	9.06%
Other birds	813	0.18%
Xenopus	144	0.03%
Zebra fish	11,592	2.61%
Other fish	6,788	1.53%
Cephalopods	333	0.08%
Total	443,811	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	393,071	88.66%
Animals born in the EU but not at a registered breeder	48,222	10.88%
Animals born in rest of Europe	33	0.01%
Animals born in rest of world	2,029	0.46%
Total	443,355	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	1	0.22%
Animals born in Asia	189	41.45%
Animals born in Africa	264	57.89%
Animals born elsewhere	2	0.44%
Total	456	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	48	10.53%
F2 or greater	408	89.47%
Total	456	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	265,357	238	265,595
Rats	91,619	159	91,778
Guinea-Pigs	14,017	114	14,131
Hamsters (Syrian)	271		271
Other rodents	376		376
Rabbits	10,060	855	10,915
Dogs	454	98	552
Ferrets	20		20
Horses, donkeys and cross-breeds		15	15
Pigs	1,027	74	1,101
Goats	5	20	25
Sheep	80	316	396
Cattle	156	3	159
Marmoset and tamarins		4	4
Cynomolgus monkey	454	44	498
Rhesus monkey	2		2
Other mammals	18	5	23
Domestic fowl	40,225	452	40,677
Other birds	813	104	917
Xenopus	144	19	163
Zebra fish	11,592	369	11,961
Other fish	6,788	174	6,962
Cephalopods	333		333
Total	443,811	3,063	446,874

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	131,359	29.4%
Translational and applied research	127,013	28.42%
Regulatory use and Routine production	182,265	40.79%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	5,476	1.23%
Preservation of species	52	0.01%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	709	0.16%
Total	446,874	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	25,793	19.64%
Cardiovascular Blood and Lymphatic System	8,447	6.43%
Nervous System	62,465	47.55%
Respiratory System	403	0.31%
Gastrointestinal System including Liver	4,268	3.25%
Musculoskeletal System	6,930	5.28%
Immune System	9,164	6.98%
Urogenital/Reproductive System	2,754	2.1%

Sensory Organs (skin, eyes and ears)	1,039	0.79%
Endocrine System/Metabolism	4,384	3.34%
Multisystemic	1,595	1.21%
Ethology / Animal Behaviour /Animal Biology	992	0.76%
Other basic research	3,125	2.38%
Total	131,359	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	43,485	34.24%
Human Infectious Disorders	16,816	13.24%
Human Cardiovascular Disorders	1,089	0.86%
Human Nervous and Mental Disorders	15,626	12.3%
Human Respiratory Disorders	14,045	11.06%
Human Gastrointestinal Disorders including Liver	1,739	1.37%
Human Musculoskeletal Disorders	4,379	3.45%
Human Immune Disorders	3,249	2.56%
Human Urogenital/Reproductive Disorders	1,683	1.33%
Human Sensory Organ Disorders (skin, eyes and ears)	1,997	1.57%
Human Endocrine/Metabolism Disorders	5,952	4.69%
Other Human Disorders	3,738	2.94%
Animal Diseases and Disorders	6,737	5.3%
Animal Welfare	1,339	1.05%
Diagnosis of diseases	4,983	3.92%
Non-regulatory toxicology and ecotoxicology	156	0.12%
Total	127,013	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	81,031	44.46%
Other efficacy and tolerance testing	38,342	21.04%
Toxicity and other safety testing including pharmacology	61,492	33.74%
Routine production	1,400	0.77%
Total	182,265	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	15,869	19.58%
Pyrogenicity testing	2,025	2.5%
Batch potency testing	58,377	72.04%
Other quality controls	4,760	5.87%
Total	81,031	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	7,164	11.65%
Skin irritation/corrosion	1,360	2.21%
Skin sensitisation	11,851	19.27%
Eye irritation/corrosion	117	0.19%
Repeated dose toxicity	10,456	17%
Genotoxicity	323	0.53%
Reproductive toxicity	3,740	6.08%
Developmental toxicity	2,418	3.93%
Neurotoxicity	209	0.34%
Kinetics	7,925	12.89%
Pharmaco-dynamics (incl safety pharmacology)	1,037	1.69%
Phototoxicity	20	0.03%

Ecotoxicity	6,370	10.36%
Safety testing in food and feed area	6,690	10.88%
Target animal safety	15	0.02%
Other toxicity/safety testing	1,797	2.92%
Total	61,492	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	1,677	23.41%
Other lethal methods	47	0.66%
Non lethal methods	5,440	75.94%
Total	7,164	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	6,325	60.49%
29 - 90 days	3,230	30.89%
> 90 days	901	8.62%
Total	10,456	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	6,342	99.56%
Other ecotoxicity	28	0.44%
Total	6,370	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	106,050	58.63%
Legislation on medicinal products for veterinary use and their residues	31,888	17.63%
Medical devices legislation	18,240	10.08%
Industrial chemicals legislation	7,322	4.05%
Plant protection product legislation	328	0.18%
Food legislation including food contact material	6,760	3.74%
Feed legislation including legislation for the safety of target animals, workers and environment	5,429	3%
Other legislation	4,848	2.68%
Total	180,865	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	168,197	93%
Legislation satisfying national requirements only [within EU]	1,166	0.64%
Legislation satisfying Non-EU requirements only	11,502	6.36%
Total	180,865	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	1,029	73.5%
Other product types	371	26.5%
Total	1,400	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	443,811	99.31%
Yes	3,063	0.69%
Total	446,874	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	15,783	3.53%
Mild [up to and including]	200,445	44.85%
Moderate	131,919	29.52%
Severe	98,727	22.09%
Total	446,874	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	347,956	77.86%
Genetically altered without a harmful phenotype	80,904	18.1%
Genetically altered with a harmful phenotype	18,014	4.03%
Total	446,874	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	4,378	6	4,384
Rats	38		38
Cattle	1		1
Zebra fish	1,377	80	1,457
Total	5,794	86	5,880

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

Severity	Number of uses	Percentage
Non-recovery	113	1.92%
Mild [up to and including]	2,768	47.07%
Moderate	2,002	34.05%
Severe	997	16.96%
Total	5,880	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	1,406	23.91%
Genetically altered without a harmful phenotype	3,542	60.24%
Genetically altered with a harmful phenotype	932	15.85%
Total	5,880	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	758	21.29%
Cardiovascular Blood and Lymphatic System	534	15%
Nervous System	492	13.82%
Gastrointestinal System including Liver	12	0.34%
Musculoskeletal System	160	4.49%
Immune System	40	1.12%
Sensory Organs (skin, eyes and ears)	54	1.52%
Endocrine System/Metabolism	363	10.2%
Multisystemic	16	0.45%
Other basic research	1,131	31.77%
Total	3,560	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	671	28.92%
Human Nervous and Mental Disorders	407	17.54%
Human Musculoskeletal Disorders	234	10.09%
Other Human Disorders	1,008	43.45%
Total	2,320	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	2,386		2,386
Total	2,386		2,386

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

Severity	Number of uses	Percentage
Mild [up to and including]	1,999	83.78%
Moderate	177	7.42%
Severe	210	8.8%
Total	2,386	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	706	29.59%
Genetically altered with a harmful phenotype	1,680	70.41%
Total	2,386	100.00%

Latvia

Latvia: Narrative 2020

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

In 2018 competent authority has approved 8 projects, in 2019 – 7, but in 2020 - 12. The total number of animals used for scientific purposes has been decreased in recent years – 4,417 in 2018, 4,245 in 2019 and 4,002 –in 2020. During the 2018 and 2019 active licence had 29 projects, but in 2020 –34 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 2019 increased the use of genetically altered animals with (n=10) and without (n=271) harmful phenotype. In 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%) and in 2020 the using of genetically altered animals started to grow again – 271 (7.0%) as well as the first time the animals with altered harmful genotype were started to use (n=10, 0.3%) and new studies were creation of new genetic line was performed begun including 3.6% (n=145) of all animals. 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 a result animal 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 continued to re-use rodents (n=45), that were previous used in mild procedures as animals from control groups. However, this number easily decreased compering to previous year (n=100). Using repeatedly, 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 (99.0%), and the biggest part 71.34% from the registered breeder. During 2020 significantly raised animal number used in procedures but born not at a registered breeder – from 8.6% in 2019 to 28.7% in 2020, that was due to large number of wildlife studies. More detailed information concerning animals that are coming not from a registered breeder, is provided in Table 1 (see below).

Table 1

Animals born not at a registered breeder			
Region	**Species**	**Number**	**Explanation of the need**
USA	mice	40	specific altered genotype, that is not available at the breeders in EU and Europe
European Union	mice	38	animals bred at the user establishment for their specific procedure
	rabbits	2	animals could not be delivered during short time of procedure from closest countries and long journey was contraindicated and significantly affected survey and its results; animals were taken from registered farm.
	wild birds	232	field survey (basic research/ethology/animal biology)
	red deer	4	field survey (basic research/ethology/animal biology)
	bats	610	field survey - basic research/ethology/animal biology, Trans./Appl. Research- Animal Diseases and Disorders
	pigs	10	Non recovery procedure (higher education or training for the acquisition, maintenance or improvement of vocational skills)

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 4,601 in 2016 to 2,368 in 2020 as well as total amount of rats also decreases from 632 in 2016 to 578 in 2020 (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.

In this year continued to decrease number of used pigs – respectively from 24 in 2018 and 2019 to 10 in 2020. As these animals are used only in one procedure (for higher education or training for the acquisition, maintenance or improvement of vocational skills), the decreasing is mainly related to peculiarities of the project process.

Also, this year significantly increased using of other mammals and birds which can be explained by performing several projects (n=5) related to wildlife research – 232 wild birds and 4 red deer were used in field survey (basic research/ethology/animal biology), 610 bats in field survey - basic research/ethology/animal biology and Trans./Appl. Research - Animal Diseases and Disorders purposes.

Figure 1

	Mice	Rats	Rabbits	Cats	Pigs	Other birds	Red deer	Bats	Other Fish
2016	4601	632	14		40	171			
2017	3332	1795			22			140	
2018	2975	1093	36		24	49			240
2019	3178	717	6		24	80			240
2020	2368	578	2	198	10	0	4	610	0

During the Covid-19 pandemic period a new study was performed with purpose to find out if there are positive Covid-19 cases in cats and if there is possibility to transmit the infection between people and cats. In this study from 198 cats' faeces, nasal discharge and blood samples were taken for further testing.

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

The biggest part of all animals was used in **mild procedures** (see Fig. 2 and Fig. 3) – 25.4.% (n=1,926) from which 1,605 were used in planned mild procedures, but other animals that were supposed to undergo moderate or severe procedures for the following reasons underwent mild procedure.

1. For 10 mice (purpose – Trans/Appl Research) Human Cancer)) the severity of the procedure was mild instead of moderate due to the smaller tumour size at the endpoint for animals and no metastasis as planned was observed during euthanasia.

2. 11 mice (purpose – Trans/Appl Research) Human Nervous and Mental Disorders)) were supposed to be used in severe procedure as a control group without surgical intervention.

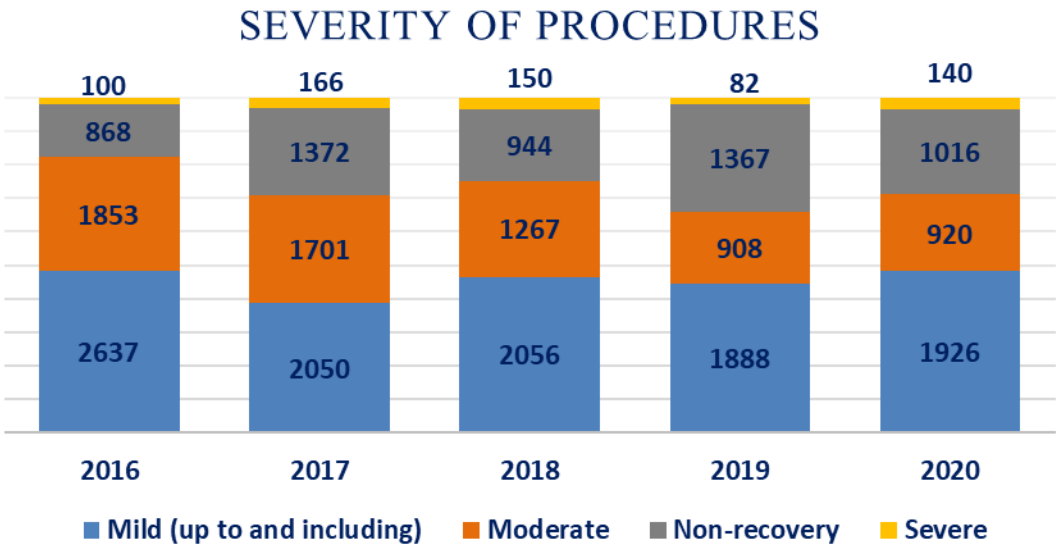
3. 40 mice (purpose - Trans/Appl Research) Human Infectious Disorders)) were supposed to be used in severe procedure as a control group without exposing to all harmful manipulations.

4. 36 mice (purpose -Basic Research) Immune System)) were supposed to be used in moderate procedure as a control group without exposing to all harmful manipulations.

5. 94 mice (purpose -Basic Research) Cardiovascular Blood and Lymphatic System)) were supposed to be used in moderate procedure as a control group without exposing to all harmful manipulations.

6. 30 rats (purpose -Trans/Appl Research) Human Cardiovascular Disorders)) were supposed to be used in severe procedure as a control group without exposing to all harmful manipulations.

Figure 2



In total 140 (3.5%) animals in 2020 were used in **severe procedures** from which 10 mice for purpose Trans/Appl Research (Human Infectious Disorders) and 61 rats for purpose Trans/Appl Research (Human Cardiovascular Disorders and Human Nervous and Mental Disorders).

1. During planned moderate procedure (purpose - Basic Research) Nervous System)) one rat died during surgical intervention.

2. During planned moderate procedure (purpose - Basic Research) Immune System)) two mice underwent severe sufferings due to an individual unpredictable body reaction.

3. During planned moderate procedure (purpose – Basic Research) Nervous System)) death of two mice - an unplanned skull fracture during surgical intervention. Therefore, animals were excluded from the experiment and were euthanized.

4. During planned moderate procedure (purpose – Basic Research) Nervous System)) death of 21 mice– unexpected break of *dura mater* during surgical intervention 12 mice (were euthanised and excluded from procedure) and 9 mice died immediately after induced planned trauma (surgical intervention).

5. During planned mild procedure (purpose – Trans/Appl Research) Animal Diseases and Disorder)) 12 mice died without previously detectable signs of suffering.

6. During planned moderate procedure (purpose - Trans/Appl Research) Human Nervous and Mental Disorders)) 1) 19 mice underwent severe sufferings - animal health condition after stroke or colostomy operation was not satisfactory resulted with severe weight lost why decision for euthanasia was performed; 2) 12 mice were supposed in pilot studies to approbate surgical technology.

In **moderate procedures** in 2020 were used 920 (23.0%) animals from which 865 mice and 35 rats were exposed to previous planned moderate procedures. 20 mice from planned severe procedure (purpose - Trans/Appl Research) Human Infectious Disorders)) underwent moderate sufferings – harm was less than planned previous.

In 2020 in **non-recovery procedures** were used 1016 (25.4%) animals from which all animals were used for planned non-recovery procedures with following purposes:

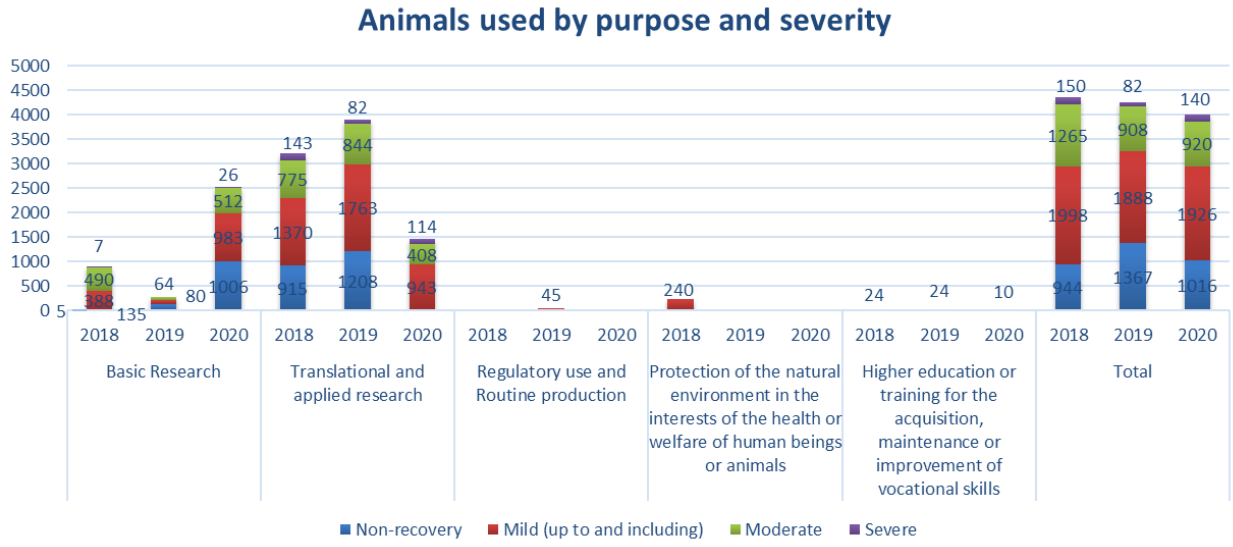
a) Higher education or training for the acquisition, maintenance or improvement of vocational skills – 10 pigs,

b) Basic Research (Nervous System) – 338 mice and 54 rats,

c) Basic Research (Cardiovascular Blood and Lymphatic System) – 310 mice and 200 rats,

d) Basic Research (Urogenital/Reproductive System) – 12 mice

Figure 3



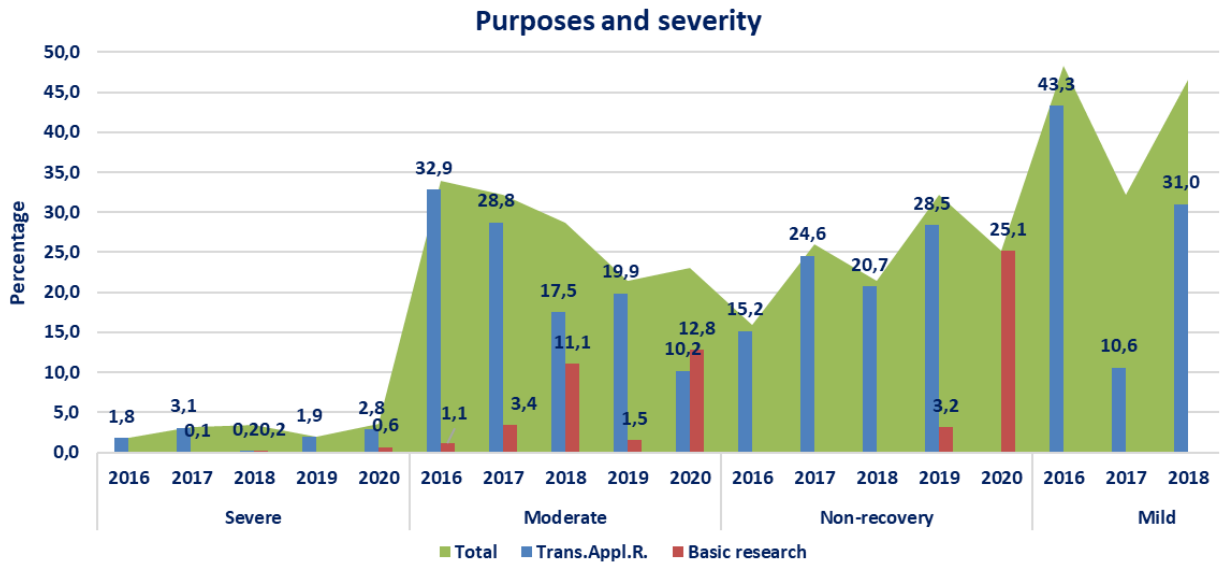
In general observation there are evident changes in severity of procedures. Comparing previous year in 2020 increased animal using in severe procedures (from 1.9% in 2018 to 3.5% in 2020), in moderate procedures (from 21.4% in 2019 to 23.0% in 2020), in mild procedures (from 44.5% in 2019 to 48.1% in 2020), but decreased animal using in non-recovery procedures (from 32.2% in 2019 to 25.4% in 2020). This is explained by starting several new projects where surgical intervention is performed (mostly basic research) and infectious agents used (for example SARSCoV-2 infection) for investigation of new drugs and vaccine.

The main research purpose is basic and 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 as well as to better understand some infection and performing of some pathological state (stroke, trauma, cancer, metabolic disorders), including its genetical level.

In these research branches (basic and translation and applied research) for the last year increased animal using (see Fig. 3 and Fig.4). However, last year in translation and applied research field decreased total amount of used animals. The biggest part of animals was used in basic research purposes such as Nervous System (n=903), Cardiovascular Blood and Lymphatic system (n=834), Ethology/Animal Behaviour/Animal Biology (646) and Immune system (130). Comparing to previous

years animal using in directions of science mentioned above were increased as well as increased animal using for and Translation and Applied Research purposes – Human Urogenital/Reproductive Disorders and Animal Diseases and Disorders.

Figure 4



Reason for animal amount changes mentioned previous (tendency to decrease animal using procedures from 2019 to 2020) is a result of scientist more carefully planned work and choosing new alternative methods and/or more thorough work before *in vivo* research that results with less and less animal need and several previously used steps – safety and efficiency tests are done without presence of animals. 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 animal 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 verify whether 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 2020, as the project was continued from 2019, 10 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 2020 several other mammals and birds were used for Basic and Trans/Appl Research purposes (see Tab.2)

Table 2

Other species used in research			
Purpose	**Species**		**Number**
	Latin	**English**	
Basic Research) Ethology / Animal Behaviour /Animal Biology	*Carduelis spinus*	Eurasian siskin	10
	Poecile palustris	Marsh tit	5
	Poecile montanus	Willow tit	3
	Lophophanes cristatus	European crested tit	3
	Periparus ater	Coal tit	1
	Parus major	Great tit	26
	Fringilla coelebs	Common chaffinch	1
	Carduelis chloris	European greenfinch	63
	Cervus elaphus	Red Deer	4
	Sturnus vulgaris	European starling	100
	Sturnus vulgaris	European starling	20
Trans/Appl Research Animal Diseases and Disorders	*Pipistrellus nathusii*	Nathusius' pipistrelle bat	200
Basic Research) Ethology / Animal Behaviour /Animal Biology	*Pipistrellus nathusii, Eptesicus nilssonii*	Nathusius' pipistrelle bat, Northern bat	410

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 2020 there have not been any cases or detected information from users that the 'severe' classification was exceeded in any of procedures.

In 2020 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

Latvia: Statistical Data 2020

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	2,178	57.14%
Rats	578	15.16%
Rabbits	2	0.05%
Cats	198	5.19%
Pigs	10	0.26%
Other mammals	614	16.11%
Other birds	232	6.09%
Total	3,812	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	2,678	70.25%
Animals born in the EU but not at a registered breeder	1,094	28.7%
Animals born in rest of world	40	1.05%
Total	3,812	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	2,178	45	2,223
Rats	578		578
Rabbits	2		2
Cats	198		198
Pigs	10		10
Other mammals	614		614
Other birds	232		232
Total	3,812	45	3,857

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	2,382	61.76%
Translational and applied research	1,465	37.98%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	10	0.26%
Total	3,857	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	2	0.08%
Cardiovascular Blood and Lymphatic System	689	28.93%
Nervous System	903	37.91%
Immune System	130	5.46%
Urogenital/Reproductive System	12	0.5%
Ethology / Animal Behaviour /Animal Biology	646	27.12%
Total	2,382	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	99	6.76%
Human Infectious Disorders	349	23.82%
Human Cardiovascular Disorders	181	12.35%
Human Nervous and Mental Disorders	196	13.38%
Human Urogenital/Reproductive Disorders	145	9.9%
Animal Diseases and Disorders	495	33.79%
Total	1,465	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	3,812	98.83%
Yes	45	1.17%
Total	3,857	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	1,016	26.34%
Mild [up to and including]	1,781	46.18%
Moderate	920	23.85%
Severe	140	3.63%
Total	3,857	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	3,576	92.71%
Genetically altered without a harmful phenotype	271	7.03%
Genetically altered with a harmful phenotype	10	0.26%
Total	3,857	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	145		145
Total	145		145

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

Severity	Number of uses	Percentage
Mild [up to and including]	145	100.00%
Total	145	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	145	100.00%
Total	145	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	145	100.00%
Total	145	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

Lithuania

Lithuania: Narrative 2020

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

In 2020, there were 3,788 laboratory animals used for scientific or educational purposes in Lithuania. In comparison to the previous year, 1,278 (were 5,066) **less** animals were used in the projects.

The number of users increased from 8 in 2013 to 12 in 2015 to 14 in 2017 and to 15 to 2020.

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” (~ 6 % decrease/ 2,524 animals was 2,684), then Trans/Appl Research (~ 0.3 % increase, 972 animals was 969), for the purpose Higher education or training for the acquisition, maintenance or improvement of vocational skills (~ 76 % decrease / 292 animals was 1,200).

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 2020 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 (~68,2 %) were used for the procedures classified as mild [up to and including] severity, non-recovery (~ 22,5 %), moderate (~ 9,2 %).

Decrease in use of animals for the procedures classified as and non-recovery during year 2019-2020. 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 2020 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 publicly available on the webpage of the European Commission.

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 (fish 168), Other birds (45) Serinus canaria, Spinus spinus (7) were used during the reporting in 2020.

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.

Additional information:

- *the misunderstandings:*

In Lithuania, was misunderstood what a “*procedure*” is. When evaluating projects, each step of the procedure was classified as a separate procedure. As a result, the number of animals used in the data presented in the non-technical project summaries was two to three times higher than was used indeed. The same animals were reported in each severity category. “*Non recovery*” was also misunderstood, because in this case indicated all the animals that were killed after all procedures.

- *the impracticality of retroactively correcting already collected figures:*

It is practically impossible to retroactively correct the statistical reports, projects, non-technical project summaries and other data, which was already collected, since all the projects are already approved and some of them have already used the animals. This action would create difficulties in the legal system as well. We understand that statistical information has affected both Lithuania and the European Union, but these actions do not determine animal welfare requirements, and the animal’s health did not have any negative actions. Compared to other European Union countries Lithuania is using small percentage of animal, so in this case correcting these data would not show positive results.

- *steps taken to ensure that 2021 will see a clear improvement in the use of correct actual severity categories:*

Lithuania faced with problems to change the 2021 period, as the projects have already been approved and some of them may have already used animals. The possibility to change the information cannot be excluded.

The period of 2022 will be replaced. Discussions are currently underway with the *users* as well as with the Lithuanian Laboratory Animal Ethics Commission. Newly submitted projects are already being assessed against these issues. The data submitted through ALURES/DECLARE will be replaced when all the necessary information will be received from the users. Users will give more attention for monitoring to separate the information that is indicated in "*Prospective*" and "*Actual*".

Lithuania: Statistical Data 2020

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	2,395	63.23%
Rats	842	22.23%
Guinea-Pigs	36	0.95%
Rabbits	114	3.01%
Pigs	169	4.46%
Sheep	12	0.32%
Other birds	52	1.37%
Other fish	168	4.44%
Total	3,788	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	3,788	100.00%
Total	3,788	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	2,395		2,395
Rats	842		842
Guinea-Pigs	36		36
Rabbits	114		114
Pigs	169		169
Sheep	12		12
Other birds	52		52
Other fish	168		168
Total	3,788		3,788

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	2,524	66.63%
Translational and applied research	972	25.66%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	292	7.71%
Total	3,788	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	203	8.04%
Cardiovascular Blood and Lymphatic System	10	0.4%
Nervous System	86	3.41%
Immune System	288	11.41%
Urogenital/Reproductive System	20	0.79%
Sensory Organs (skin, eyes and ears)	1,788	70.84%
Other basic research	129	5.11%
Total	2,524	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	49	5.04%
Human Infectious Disorders	18	1.85%
Human Cardiovascular Disorders	87	8.95%
Human Nervous and Mental Disorders	425	43.72%
Human Gastrointestinal Disorders including Liver	15	1.54%
Human Musculoskeletal Disorders	17	1.75%
Human Urogenital/Reproductive Disorders	138	14.2%
Human Endocrine/Metabolism Disorders	60	6.17%
Animal Diseases and Disorders	18	1.85%
Non-regulatory toxicology and ecotoxicology	145	14.92%
Total	972	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	3,788	100.00%
Total	3,788	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	853	22.52%
Mild [up to and including]	2,583	68.19%
Moderate	352	9.29%
Total	3,788	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	3,669	96.86%
Genetically altered without a harmful phenotype	119	3.14%
Total	3,788	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 2020

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

In Luxembourg we could observe a significant decrease in the total number of uses from 25,841 total uses in 2017, 14,656 total uses in 2018, 11,375 total uses in 2019 to 5,457 total uses in 2020. This important decrease of 52,03 % of the total uses between the year 2019 to 2020 may be a consequence of the reduction of the research activity during the lockdown and the sanitary measures caused by the Covid-19 pandemic.

Concerning the distribution in the species, the main reduction results by the decrease in use of mice in procedures, notably in 2020 a total of 4,775 mice were used compared to 10,821 mice used in 2019.

Between 2019 and 2020, the use of zebrafish and rats in procedures was rather stable.

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, a significant decrease in the total number of uses and in the total number of uses in mice could be observed between 2019 and 2020. This decrease of uses is caused by the Covid-19 pandemic, which involved in 2020 a reduction in the activities of the animal facilities.

Furthermore, in Luxembourg two main institutions are involved in animal testing. Both modernised. 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.

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

Comparing the actual severities from 2019 to 2020, no trend had been 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 encouraged the users and the members of the animal welfare bodies to participate in 3R webinar focusing on the replacement, reduction and refinement during the lockdown caused by the Covid-19 pandemic.

- 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 2020 there was no case where the severe-classification has been exceeded.

Luxembourg: Statistical Data 2020

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	4,775	89.4%
Rats	10	0.19%
Zebra fish	556	10.41%
Total	5,341	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	5,291	99.06%
Animals born in rest of Europe	50	0.94%
Total	5,341	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	4,775		4,775
Rats	10		10
Zebra fish	556		556
Total	5,341		5,341

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	3,847	72.03%
Translational and applied research	1,337	25.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	157	2.94%
Total	5,341	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	1,316	34.21%
Nervous System	772	20.07%
Immune System	1,759	45.72%
Total	3,847	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	1,125	84.14%
Human Immune Disorders	212	15.86%
Total	1,337	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	Number of	Percentage

dose toxicity	uses	

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	5,341	100.00%
Total	5,341	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	202	3.78%
Mild [up to and including]	2,156	40.37%
Moderate	2,730	51.11%
Severe	253	4.74%
Total	5,341	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	2,491	46.64%
Genetically altered without a harmful phenotype	2,396	44.86%
Genetically altered with a harmful phenotype	454	8.5%
Total	5,341	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	116		116
Total	116		116

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

Severity	Number of uses	Percentage
Mild [up to and including]	116	100%
Total	116	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	116	100.00%
Total	116	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
Endocrine System/Metabolism	116	100.00%
Total	116	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 2020

Not provided

Malta: Statistical Data 2020

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	47,490	100.00%
Total	47,490	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	41,490	87.37%
Animals born in rest of world	6,000	12.63%
Total	47,490	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	47,490		47,490
Total	47,490		47,490

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	15,215	32.04%
Translational and applied research	15,145	31.89%
Regulatory use and Routine production	17,130	36.07%
Total	47,490	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Other basic research	15,215	100.00%
Total	15,215	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Animal Diseases and Disorders	15,145	100.00%
Total	15,145	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	4,269	24.92%
Toxicity and other safety testing including pharmacology	12,861	75.08%
Total	17,130	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	2,622	61.42%
Batch potency testing	1,647	38.58%
Total	4,269	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	12,861	100.00%
Total	12,861	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 veterinary use and their residues	17,130	100.00%
Total	17,130	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	17,130	100.00%
Total	17,130	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	47,490	100.00%
Total	47,490	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]	27,683	58.29%
Severe	19,807	41.71%
Total	47,490	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	47,490	100.00%
Total	47,490	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 2020

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

In 2020, the Dutch establishments reported 406,799 animals used in procedures. This is 6,838 (+1.7%) more than in 2019.

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 2020 is within the normal range of fluctuation of previous years. Several specific categories to be highlighted:

- The increase in cats and dogs used can largely be attributed to research on Covid-19 amongst pet animals.

- The increased use of Macaques can be attributed to Covid-19 research.

- The increased use of hamsters is attributed to Covid-19 research.

- The increase in the use of zebrafish is largely attributed to the rise in use by specific research organisations who used the zebra fish for research into tox research, endocrinological research, cancer research and breeding exceeding the severity threshold.

- The increased use of sheep is attributed to a certain company's rise in demand in products.

- The increased use of Xenopus is attributed to a specific company's rise in research for tox research.

- The decrease of other rodents is attributed to a single organisation finishing a project with other rodents.

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

The actual severities reported in 2020 (mild 60.1%, moderate 30.4%, severe 0.9%, and non-recovery: 8.5%) are generally in line with the actual severities reported in 2019.

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.

The Dutch establishments use the category "other" in significant proportions, even were "other" might not be the best option. This issue has our priority for future data collection rounds. For 2020 this has led to the rise in 'multisystemic' uses under Basic research, since i.e. a single research

organization previously registered the uses under ‘other’. Also the Netherlands registers a significant amount of ‘other fish’ and ‘ other birds’ which can be attributed to field research. The use of ‘other product types’ under routine production refers to the production of human medicines.

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 2020 exceedance of the severity classification ‘severe’ has not been reported and no exemption was authorised.

Netherlands: Statistical Data 2020

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	136,611	34.93%
Rats	86,375	22.08%
Guinea-Pigs	8,509	2.18%
Hamsters (Syrian)	2,856	0.73%
Mongolian gerbil	109	0.03%
Other rodents	495	0.13%
Rabbits	15,337	3.92%
Cats	560	0.14%
Dogs	551	0.14%
Ferrets	537	0.14%
Other carnivores	25	0.01%
Horses, donkeys and cross-breeds	241	0.06%
Pigs	8,861	2.27%
Goats	99	0.03%
Sheep	2,076	0.53%
Cattle	2,604	0.67%
Marmoset and tamarins	25	0.01%
Cynomolgus monkey	28	0.01%
Rhesus monkey	137	0.04%
Other mammals	244	0.06%
Domestic fowl	44,992	11.5%
Other birds	17,906	4.58%
Reptiles	360	0.09%
Xenopus	2,641	0.68%
Other amphibians	74	0.02%
Zebra fish	14,225	3.64%
Other fish	44,673	11.42%
Total	391,151	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	262,455	67.13%
Animals born in the EU but not at a registered breeder	114,240	29.22%
Animals born in rest of Europe	2,505	0.64%
Animals born in rest of world	11,761	3.01%
Total	390,961	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	186	97.89%
Animals born in Asia	4	2.11%
Total	190	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F2 or greater	4	2.11%
Self-sustaining colony	186	97.89%
Total	190	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	136,611	1,126	137,737
Rats	86,375	686	87,061
Guinea-Pigs	8,509	28	8,537
Hamsters (Syrian)	2,856		2,856
Mongolian gerbil	109		109
Other rodents	495		495
Rabbits	15,337	36	15,373
Cats	560	44	604
Dogs	551	252	803
Ferrets	537	33	570
Other carnivores	25		25
Horses, donkeys and cross-breeds	241	69	310
Pigs	8,861	331	9,192
Goats	99	149	248
Sheep	2,076	202	2,278
Cattle	2,604	1,486	4,090
Marmoset and tamarins	25		25
Cynomolgus monkey	28		28
Rhesus monkey	137	22	159
Other mammals	244		244
Domestic fowl	44,992	276	45,268
Other birds	17,906	140	18,046
Reptiles	360		360
Xenopus	2,641		2,641
Other amphibians	74		74
Zebra fish	14,225		14,225
Other fish	44,673	10	44,683
Total	391,151	4,890	396,041

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	139,215	35.15%
Translational and applied research	102,642	25.92%
Regulatory use and Routine production	119,859	30.26%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	602	0.15%
Preservation of species	23,008	5.81%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	10,689	2.7%
Forensic enquiries	26	0.01%
Total	396,041	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	27,523	19.77%
Cardiovascular Blood and Lymphatic System	2,552	1.83%
Nervous System	19,831	14.24%

Respiratory System	624	0.45%
Gastrointestinal System including Liver	1,815	1.3%
Musculoskeletal System	901	0.65%
Immune System	10,546	7.58%
Urogenital/Reproductive System	496	0.36%
Sensory Organs (skin, eyes and ears)	744	0.53%
Endocrine System/Metabolism	11,525	8.28%
Multisystemic	33,950	24.39%
Ethology / Animal Behaviour /Animal Biology	28,708	20.62%
Total	139,215	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	12,963	12.63%
Human Infectious Disorders	18,740	18.26%
Human Cardiovascular Disorders	5,302	5.17%
Human Nervous and Mental Disorders	5,663	5.52%
Human Respiratory Disorders	568	0.55%
Human Gastrointestinal Disorders including Liver	1,112	1.08%
Human Musculoskeletal Disorders	882	0.86%
Human Immune Disorders	2,703	2.63%
Human Urogenital/Reproductive Disorders	632	0.62%
Human Sensory Organ Disorders (skin, eyes and ears)	1,257	1.22%
Human Endocrine/Metabolism Disorders	775	0.76%
Other Human Disorders	94	0.09%
Animal Diseases and Disorders	19,063	18.57%
Animal Welfare	28,958	28.21%
Diagnosis of diseases	1,030	1%
Non-regulatory toxicology and ecotoxicology	2,900	2.83%
Total	102,642	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	35,431	29.56%
Other efficacy and tolerance testing	3,559	2.97%
Toxicity and other safety testing including pharmacology	80,547	67.2%
Routine production	322	0.27%
Total	119,859	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	831	2.35%
Batch potency testing	34,314	96.85%
Other quality controls	286	0.81%
Total	35,431	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	974	1.21%
Skin irritation/corrosion	83	0.1%
Skin sensitisation	3,239	4.02%
Eye irritation/corrosion	60	0.07%
Repeated dose toxicity	11,848	14.71%
Genotoxicity	1,038	1.29%
Reproductive toxicity	21,451	26.63%
Developmental toxicity	28,690	35.62%
Neurotoxicity	1,773	2.2%

Kinetics	531	0.66%
Ecotoxicity	6,341	7.87%
Safety testing in food and feed area	1,834	2.28%
Target animal safety	2,596	3.22%
Other toxicity/safety testing	89	0.11%
Total	80,547	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	974	100.00%
Total	974	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	5,385	45.45%
29 - 90 days	5,653	47.71%
> 90 days	810	6.84%
Total	11,848	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	312	4.92%
Chronic toxicity	2,552	40.25%
Reproductive ecotoxicity	1,325	20.9%
Endocrine activity	2,085	32.88%
Bioaccumulation	67	1.06%
Total	6,341	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	29,343	24.55%
Legislation on medicinal products for veterinary use and their residues	24,738	20.69%
Medical devices legislation	3	0%
Industrial chemicals legislation	54,187	45.33%
Plant protection product legislation	7,089	5.93%
Biocides legislation	2,231	1.87%
Food legislation including food contact material	86	0.07%
Feed legislation including legislation for the safety of target animals, workers and environment	1,843	1.54%
Other legislation	17	0.01%
Total	119,537	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	118,068	98.77%
Legislation satisfying Non-EU requirements only	1,469	1.23%
Total	119,537	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	7	2.17%
Other product types	315	97.83%
Total	322	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	391,151	98.77%
Yes	4,890	1.23%
Total	396,041	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	34,776	8.78%
Mild [up to and including]	235,413	59.44%
Moderate	122,341	30.89%
Severe	3,511	0.89%
Total	396,041	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	323,786	81.76%
Genetically altered without a harmful phenotype	68,635	17.33%
Genetically altered with a harmful phenotype	3,620	0.91%
Total	396,041	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	5,343	2	5,345
Zebra fish	15		15
Total	5,358	2	5,360

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

Severity	Number of uses	Percentage
Mild [up to and including]	4,759	88.79%
Moderate	601	11.21%
Total	5,360	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	4,851	90.5%
Genetically altered without a harmful phenotype	494	9.22%
Genetically altered with a harmful phenotype	15	0.28%
Total	5,360	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	3,411	63.95%
Cardiovascular Blood and Lymphatic System	28	0.52%
Nervous System	101	1.89%
Respiratory System	47	0.88%
Gastrointestinal System including Liver	512	9.6%
Musculoskeletal System	28	0.52%
Immune System	541	10.14%
Urogenital/Reproductive System	201	3.77%
Multisystemic	465	8.72%
Total	5,334	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	26	100.00%
Total	26	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	5,145		5,145
Rats	108		108
Zebra fish	70		70
Total	5,323		5,323

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

Severity	Number of uses	Percentage
Mild [up to and including]	4,353	81.78%
Moderate	705	13.24%
Severe	265	4.98%

Total	5,323	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	5,323	100.00%
Total	5,323	100.00%

Poland

Poland: Narrative 2020

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

In 2020, the slight downward trend in the number of animals used in Poland continued. However, the main cause this time was seemingly the COVID-19 pandemic and the resulting suspension of research.

2. Information on significant increase or decrease in animal use 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, orders from external parties.

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

As animal experimentation was suspended in 2020 on account of the pandemic, it is difficult to mention any trends compared to previous years. It is likely that users reported the severity indicated by the competent authorities (local ethics committees on animal experiments). The severity may have been exaggerated in the authorisations. Animal welfare groups are well represented within the Polish competent authorities. Representatives of such groups often propose higher levels of severity. We therefore believe that severity levels are possibly being overestimated.

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.

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 and its activities in Poland account for 98.22% of tests under the category 'legally required/routine production'.

In 2020, none of the animal species included in the 'other' category accounted for over 10% of a given group.

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 2020

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	62,679	55.76%
Rats	17,917	15.94%
Guinea-Pigs	6,325	5.63%
Hamsters (Syrian)	9	0.01%
Mongolian gerbil	38	0.03%
Other rodents	5,443	4.84%
Rabbits	698	0.62%
Cats	1	0%
Dogs	18	0.02%
Other carnivores	268	0.24%
Horses, donkeys and cross-breeds	40	0.04%
Pigs	550	0.49%
Goats	1	0%
Sheep	119	0.11%
Cattle	233	0.21%
Other mammals	505	0.45%
Domestic fowl	2,004	1.78%
Other birds	4,063	3.61%
Other amphibians	15	0.01%
Zebra fish	6,605	5.88%

Other fish	4,881	4.34%
Total	112,412	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	103,234	91.84%
Animals born in the EU but not at a registered breeder	8,694	7.73%
Animals born in rest of world	484	0.43%
Total	112,412	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	62,679		62,679
Rats	17,917		17,917
Guinea-Pigs	6,325		6,325
Hamsters (Syrian)	9		9
Mongolian gerbil	38		38
Other rodents	5,443		5,443
Rabbits	698	199	897
Cats	1		1
Dogs	18	5	23
Other carnivores	268		268
Horses, donkeys and cross-breeds	40		40
Pigs	550		550
Goats	1		1
Sheep	119	22	141
Cattle	233	3	236
Other mammals	505	12	517
Domestic fowl	2,004		2,004
Other birds	4,063	62	4,125
Other amphibians	15		15
Zebra fish	6,605		6,605
Other fish	4,881		4,881
Total	112,412	303	112,715

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	76,744	68.09%
Translational and applied research	12,390	10.99%
Regulatory use and Routine production	22,862	20.28%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	380	0.34%
Preservation of species	74	0.07%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	265	0.24%
Total	112,715	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	7,328	9.55%
Cardiovascular Blood and Lymphatic System	3,417	4.45%
Nervous System	38,554	50.24%
Respiratory System	84	0.11%
Gastrointestinal System including Liver	3,096	4.03%
Musculoskeletal System	837	1.09%
Immune System	3,859	5.03%
Urogenital/Reproductive System	1,267	1.65%
Sensory Organs (skin, eyes and ears)	865	1.13%
Endocrine System/Metabolism	1,768	2.3%

Multisystemic	3,181	4.14%
Ethology / Animal Behaviour /Animal Biology	9,229	12.03%
Other basic research	3,259	4.25%
Total	76,744	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	3,466	27.97%
Human Infectious Disorders	156	1.26%
Human Cardiovascular Disorders	561	4.53%
Human Nervous and Mental Disorders	572	4.62%
Human Respiratory Disorders	578	4.67%
Human Gastrointestinal Disorders including Liver	118	0.95%
Human Musculoskeletal Disorders	87	0.7%
Human Immune Disorders	192	1.55%
Human Urogenital/Reproductive Disorders	41	0.33%
Human Endocrine/Metabolism Disorders	318	2.57%
Other Human Disorders	28	0.23%
Animal Diseases and Disorders	2,948	23.79%
Animal Welfare	1,895	15.29%
Diagnosis of diseases	1,290	10.41%
Plant diseases	10	0.08%
Non-regulatory toxicology and ecotoxicology	130	1.05%
Total	12,390	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	18,136	79.33%
Other efficacy and tolerance testing	39	0.17%
Toxicity and other safety testing including pharmacology	4,133	18.08%
Routine production	554	2.42%
Total	22,862	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	2,876	15.86%
Pyrogenicity testing	186	1.03%
Batch potency testing	14,908	82.2%
Other quality controls	166	0.92%
Total	18,136	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	519	12.56%
Skin irritation/corrosion	152	3.68%
Skin sensitisation	1,282	31.02%
Eye irritation/corrosion	35	0.85%
Repeated dose toxicity	761	18.41%
Carcinogenicity	48	1.16%
Reproductive toxicity	89	2.15%
Developmental toxicity	347	8.4%
Kinetics	54	1.31%
Ecotoxicity	836	20.23%
Other toxicity/safety testing	10	0.24%
Total	4,133	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	154	29.67%
Non lethal methods	365	70.33%
Total	519	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	344	45.2%
29 - 90 days	356	46.78%
> 90 days	61	8.02%
Total	761	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	803	96.05%
Chronic toxicity	33	3.95%
Total	836	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	16,904	75.78%
Legislation on medicinal products for veterinary use and their residues	1,681	7.54%
Medical devices legislation	2,485	11.14%
Industrial chemicals legislation	602	2.7%
Plant protection product legislation	460	2.06%
Food legislation including food contact material	176	0.79%
Total	22,308	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	22,032	98.76%
Legislation satisfying national requirements only [within EU]	200	0.9%
Legislation satisfying Non-EU requirements only	76	0.34%
Total	22,308	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	49	8.84%
Other product types	505	91.16%
Total	554	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	112,412	99.73%
Yes	303	0.27%
Total	112,715	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	3,913	3.47%
Mild [up to and including]	17,743	15.74%

Moderate	48,561	43.08%
Severe	42,498	37.7%
Total	112,715	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	105,089	93.23%
Genetically altered without a harmful phenotype	6,432	5.71%
Genetically altered with a harmful phenotype	1,194	1.06%
Total	112,715	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	137		137
Other mammals	10		10
Total	147		147

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

Severity	Number of uses	Percentage
Non-recovery	4	2.72%
Moderate	143	97.28%
Total	147	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	92	62.59%
Genetically altered without a harmful phenotype	55	37.41%
Total	147	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	27.21%
Nervous System	21	14.29%
Urogenital/Reproductive System	18	12.24%
Multisystemic	68	46.26%
Total	147	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	443		443
Rats	36		36
Total	479		479

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

Severity	Number of uses	Percentage
Mild [up to and including]	443	92.48%
Moderate	36	7.52%
Total	479	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	443	92.48%
Genetically altered with a harmful phenotype	36	7.52%
Total	479	100.00%

Poland, corrected statistical data 2019

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

Numbers of animals used for the first time by species

Animal species	Number of animals	Percentage
Mice	74,107	52.61%
Rats	23,334	16.56%
Guinea-Pigs	5,901	4.19%
Hamsters (Syrian)	121	0.09%
Mongolian gerbil	160	0.11%
Other rodents	5,486	3.89%
Rabbits	1,054	0.75%
Cats	12	0.01%
Dogs	9	0.01%
Other carnivores	58	0.04%
Pigs	1,044	0.74%
Sheep	387	0.27%
Cattle	140	0.1%
Other mammals	510	0.36%
Domestic fowl	6,275	4.45%
Other birds	6,735	4.78%
Reptiles	40	0.03%
Other amphibians	368	0.26%
Zebra fish	1,1433	8.12%
Other fish	3,697	2.62%
Total	140,871	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	124,649	88.48%
Animals born in the EU but not at a registered breeder	15,346	10.89%
Animals born in rest of world	876	0.62%
Total	140,871	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 (corrected)

First use versus reuses

Animal species	First uses	Reuses	Total
Mice	74,107	21	74,128
Rats	23,334	144	23,478
Guinea-Pigs	5,901		5,901
Hamsters (Syrian)	121		121
Mongolian gerbil	160		160
Other rodents	5,486		5,486
Rabbits	1,054	168	1,222
Cats	12		12
Dogs	9	2	11
Other carnivores	58		58
Horses, donkeys and cross-breeds		21	21
Pigs	,1044	2	1,046
Goats		13	13
Sheep	387	66	453
Cattle	140	5	145
Other mammals	510	60	570
Domestic fowl	6,275		6,275
Other birds	6,735	55	6,790
Reptiles	40		40
Other amphibians	368		368
Zebra fish	11,433		11,433
Other fish	3,697		3,697
Total	140,871	557	141,428

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	103,595	73.25%
Translational and applied research	13,937	9.85%
Regulatory use and Routine production	22,364	15.81%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	30	0.02%
Preservation of species	248	0.18%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1,254	0.89%
Total	141,428	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	10,126	9.77%
Cardiovascular Blood and Lymphatic System	4,270	4.12%
Nervous System	53,652	51.79%
Respiratory System	239	0.23%
Gastrointestinal System including Liver	3,729	3.6%
Musculoskeletal System	635	0.61%
Immune System	7,592	7.33%
Urogenital/Reproductive System	1,628	1.57%
Sensory Organs (skin, eyes and ears)	450	0.43%

Endocrine System/Metabolism	1,515	1.46%
Multisystemic	4,331	4.18%
Ethology / Animal Behaviour /Animal Biology	11,428	11.03%
Other basic research	4,000	3.86%
Total	103,595	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	5,440	39.03%
Human Infectious Disorders	15	0.11%
Human Cardiovascular Disorders	433	3.11%
Human Nervous and Mental Disorders	244	1.75%
Human Respiratory Disorders	474	3.4%
Human Gastrointestinal Disorders including Liver	454	3.26%
Human Musculoskeletal Disorders	188	1.35%
Human Immune Disorders	235	1.69%
Human Urogenital/Reproductive Disorders	99	0.71%
Human Sensory Organ Disorders (skin, eyes and ears)	13	0.09%
Human Endocrine/Metabolism Disorders	287	2.06%
Other Human Disorders	40	0.29%
Animal Diseases and Disorders	189	1.36%
Animal Welfare	4,181	30%
Diagnosis of diseases	1,477	10.6%
Non-regulatory toxicology and ecotoxicology	168	1.21%
Total	13,937	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	16,824	75.23%
Other efficacy and tolerance testing	65	0.29%
Toxicity and other safety testing including pharmacology	4,536	20.28%
Routine production	939	4.2%
Total	22,364	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	3,761	22.35%
Pyrogenicity testing	225	1.34%
Batch potency testing	12,734	75.69%
Other quality controls	104	0.62%
Total	16,824	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	596	13.14%
Skin irritation/corrosion	235	5.18%
Skin sensitisation	1,484	32.72%
Eye irritation/corrosion	6	0.13%
Repeated dose toxicity	280	6.17%
Carcinogenicity	60	1.32%
Kinetics	354	7.8%
Pharmaco-dynamics (incl safety pharmacology)	40	0.88%
Ecotoxicity	1,128	24.87%
Safety testing in food and feed area	263	5.8%
Other toxicity/safety testing	90	1.98%
Total	4,536	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	52	8.72%
Other lethal methods	62	10.4%
Non lethal methods	482	80.87%
Total	596	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	100	35.71%
> 90 days	180	64.29%
Total	280	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	1,065	94.41%
Chronic toxicity	63	5.59%
Total	1,128	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	16,120	75.24%
Legislation on medicinal products for veterinary use and their residues	1,540	7.19%
Medical devices legislation	2,432	11.35%
Industrial chemicals legislation	190	0.89%
Plant protection product legislation	809	3.78%
Food legislation including food contact material	142	0.66%
Feed legislation including legislation for the safety of target animals, workers and environment	192	0.9%
Total	21,425	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	20,798	97.07%
Legislation satisfying national requirements only [within EU]	550	2.57%
Legislation satisfying Non-EU requirements only	77	0.36%
Total	21,425	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	60	6.39%
Monoclonal antibody by mouse ascites method	4	0.43%
Other product types	875	93.18%
Total	939	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	140,871	99.61%
Yes	557	0.39%
Total	141,428	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	6,677	4.72%
Mild [up to and including]	29,903	21.14%
Moderate	63,035	44.57%
Severe	41,813	29.56%
Total	141,428	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	132,995	94.04%
Genetically altered without a harmful phenotype	6,465	4.57%
Genetically altered with a harmful phenotype	1,968	1.39%
Total	141,428	100.00%

Section 3: Creation and maintenance of genetically altered animal lines (corrected)

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	202		202
Other mammals	6		6
Zebra fish	36		36
Total	244		244

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

Severity	Number of uses	Percentage
Non-recovery	4	1.64%
Mild [up to and including]	38	15.57%
Moderate	202	82.79%
Total	244	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	79	32.38%
Genetically altered without a harmful phenotype	165	67.62%
Total	244	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	20	8.2%
Nervous System	206	84.43%
Urogenital/Reproductive System	12	4.92%
Multisystemic	6	2.46%
Total	244	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	405		405
Total	405		405

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

Severity	Number of uses	Percentage
Mild [up to and including]	258	63.7%
Moderate	147	36.3%
Total	405	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	45	11.11%
Genetically altered with a harmful phenotype	360	88.89%

Total	405	100.00%

Portugal

Portugal: Narrative 2020

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

In 2020 there was a decrease in animal use compared to the previous year (2019). The total number of animals used in 2020 is 65,966, which constitutes a 20.43% decrease in animal use, compared to 2019 (total uses: 79,447).

Mice continue to be the most used animal species (73.28%), followed by the entry Other fish (13.57%), Zebra fish (5.04%) and Rats (7.45%).

There is a slight decrease in the use of all Fish (18.61%) compared to 2019 (22.32%) and the use of Mammals increased 4.32%.

With the exception of Other rodents, Other mammals and Domestic fowl, which showed an increase, all the use of other animal species have increased.

There was also a decrease on reuse of animals (total reuses: 1,705) compared to the previous year (total reuses: 2,026).

Compared to the previous year, there was a decrease in the number of use of animals in all the categories of purposes, i.e, in Basic and Translational and applied research, Higher education, Maintenance of colonies of established genetically altered animals not used in other procedures and Protection of the natural environment in the interests of the health or welfare of human beings or animals.

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 2020 is a reflection of the generalized reduction in the use of animals for scientific purposes, due to the reduction in the performance of procedures in animals due to the COVID pandemic.

Basic Research continues to represent the majority of all uses (61.78%), followed by Translational and applied research (33.56%), Maintenance of colonies of established genetically altered animals, not used in other procedures (2.04%), Protection of the natural environment in the interests of the health or welfare of human beings or animals (2.00%), Regulatory use and Routine production (0.35%) and Higher education or training for the acquisition, maintenance or improvement of vocational skills (2.00%).

Despite the decrease in numbers observed in Basic Research, the majority use of animals continues to be in studies on the Immune System, Nervous System, Oncology, Endocrine System/Metabolism and Cardiovascular Blood and Lymphatic System.

The same happening with Translational and applied research, the use decreased, but was mainly due to studies in Human Cancer, Human Infectious Disorders, Human Nervous and Mental Disorders, Human Cardiovascular Disorders, Human Immune Disorders and Human Musculoskeletal Disorders.

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

In 2020, the percentages reported for each of the categories of actual severities experienced by the animals were as follows:

- Non-recovery: 4.00%
- Mild: 46.80%
- Moderate: 33.60%
- Severe: 15.60%

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

Compared to the previous year, is of note a slight decrease in and Mild (2.7%) procedures and a slight increase in Non-recovery (0.44%), Moderate (1.81%) and Severe (1.45%) procedures.

The increase in Moderate and Severe procedures was due to the performance of procedures in the areas of Human Cancer, Immune Disorders and Nervous and Mental Disorders.

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

Not particular or specific efforts, only the promotion always made by the competent authority when evaluating requests for authorisation of projects, establishments and of persons that are going to perform functions, when carrying out inspections to establishments and in every opportunity it has to talk about the theme.

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

In 2020, the further breakdown on the use of "other" categories is as follows:

On **Animal species**:

- **Other fish** include:
    - *Ameirus melas*
    - *Argyrosomus regius*
    - *Australoheros facetus*
    - *Danionella translucida*
    - *Devario aequipinnatus*
    - *Dicentrarchus labrax*
    - *Diplodus cervinus*
    - *Diplodus sargus*
    - *Lepomis gibbosus*
    - *Onchorynchus mykiss*
    - *Oreochromis mossambicus*
    - *Oreochromis niloticus*

- *Sarpa salpa*
- *Silurus glanis*
- *Solea senegalensis*
- *Sparus aurata*
- *Zebrasoma scopas*

- **Other mammals** include:

  - *Globicephala macrorhynchus*
  - *Physeter macrocephalus*
  - *Pseudorca crassidens*
  - *Tursiops truncatus*

- **Other rodents** include *Acomys cahirinus*

On **Purpose**:

- **Other Basic Research** include:

  - Bacterial metabolite profile *in vivo*
  - Blood/brain/barrier translocation
  - Cryopreservation
  - Embryonic development
  - Intestinal microbiota composition
  - Intestinal microbiota composition and colonization resistance
  - Morphogenesis
  - Stem cell 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.

These cases have not occurred.

Portugal: Statistical Data 2020

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	46,715	75.88%
Rats	4,964	8.06%
Other rodents	114	0.19%
Rabbits	14	0.02%
Pigs	119	0.19%
Other mammals	24	0.04%
Domestic fowl	120	0.19%
Xenopus	38	0.06%
Zebra fish	1,423	2.31%
Other fish	8,032	13.05%

Total	61,563	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	55,590	90.3%
Animals born in the EU but not at a registered breeder	5,911	9.6%
Animals born in rest of world	62	0.1%
Total	61,563	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	46,715	4	46,719
Rats	4,964	1	4,965
Other rodents	114	2	116
Rabbits	14		14
Pigs	119		119
Goats		66	66
Other mammals	24		24
Domestic fowl	120		120
Xenopus	38		38
Zebra fish	1,423	470	1,893
Other fish	8,032	888	8,920
Total	61,563	1,431	62,994

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	39,062	62.01%
Translational and applied research	22,142	35.15%
Regulatory use and Routine production	298	0.47%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	1,320	2.1%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	172	0.27%
Total	62,994	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	4,652	11.91%
Cardiovascular Blood and Lymphatic System	1,350	3.46%
Nervous System	7,782	19.92%
Respiratory System	120	0.31%
Gastrointestinal System including Liver	125	0.32%
Musculoskeletal System	129	0.33%
Immune System	18,457	47.25%
Urogenital/Reproductive System	191	0.49%
Sensory Organs (skin, eyes and ears)	76	0.19%
Endocrine System/Metabolism	1,186	3.04%
Multisystemic	873	2.23%
Ethology / Animal Behaviour /Animal Biology	3,662	9.37%
Other basic research	459	1.18%
Total	39,062	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	3,531	15.95%
Human Infectious Disorders	10,484	47.35%
Human Cardiovascular Disorders	1,102	4.98%
Human Nervous and Mental Disorders	4,704	21.24%

Human Respiratory Disorders	9	0.04%
Human Gastrointestinal Disorders including Liver	62	0.28%
Human Musculoskeletal Disorders	914	4.13%
Human Immune Disorders	549	2.48%
Human Sensory Organ Disorders (skin, eyes and ears)	76	0.34%
Human Endocrine/Metabolism Disorders	301	1.36%
Animal Welfare	192	0.87%
Diagnosis of diseases	59	0.27%
Non-regulatory toxicology and ecotoxicology	159	0.72%
Total	22,142	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Toxicity and other safety testing including pharmacology	232	77.85%
Routine production	66	22.15%
Total	298	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	106	45.69%
Safety testing in food and feed area	126	54.31%
Total	232	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	106	45.69%
Food legislation including food contact material	126	54.31%
Total	232	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	232	100.00%
Total	232	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Other product types	66	100.00%

Total	66	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	61,563	97.73%
Yes	1,431	2.27%
Total	62,994	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	2,641	4.19%
Mild [up to and including]	28,138	44.67%
Moderate	21,936	34.82%
Severe	10,279	16.32%
Total	62,994	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	37,886	60.14%
Genetically altered without a harmful phenotype	19,568	31.06%
Genetically altered with a harmful phenotype	5,540	8.79%
Total	62,994	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	296		296
Zebra fish	1,090	345	1,435
Other fish	29		29
Total	1,415	345	1,760

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

Severity	Number of uses	Percentage
Mild [up to and including]	,	95.17%
Moderate	81	4.6%
Severe	4	0.23%
Total	1,760	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	161	9.15%
Genetically altered without a harmful phenotype	1587	90.17%
Genetically altered with a harmful phenotype	12	0.68%
Total	1,760	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	55	3.13%
Cardiovascular Blood and Lymphatic System	42	2.39%
Nervous System	483	27.44%
Immune System	154	8.75%
Endocrine System/Metabolism	1,026	58.3%
Total	1,760	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	1,345		1,345
Total	1,345		1,345

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

Severity	Number of uses	Percentage
Mild [up to and including]	1,150	85.5%
Moderate	188	13.98%
Severe	7	0.52%
Total	1,345	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	918	68.25%
Genetically altered with a harmful phenotype	427	31.75%
Total	1,345	100.00%

Romania

Romania: Narrative 2020

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

Since the previous reporting year, there was a significant decrease in the number of animals used for scientific purposes, from 13,635 in 2019 to 7,874 in 2020 due to the COVID-19 pandemic.

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

The proportion of animals used for basic research purposes and in higher education or training for the acquisition, maintenance or improvement of vocational skills decreased due to a drop in projects within these categories, as a result of the pandemic. On the other hand, there was a significant increase in batch potency testing.

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

The proportion of non-recovery uses increased by 4.87% although the number of animals experiencing non-recovery severity was lower compared to 2019. A part of the studies from 2019 continued in 2020 and in the vast majority, the severity experienced by the animals was similar as in 2019. That led to an increased share of non-recovery severity in relation to the total number of animals used (dropped by 42% in comparison with 2019).

Moreover, the high percentage of non-recovery uses is due to the studies performed for translational and applied research purposes.

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. Data published by research groups were used. The animals were provided with housing that allowed the expression of species-specific behaviours, and appropriate anaesthesia and analgesia were used to minimise pain.

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 2020

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	4,999	65.9%
Rats	1,890	24.91%
Guinea-Pigs	198	2.61%
Hamsters (Syrian)	64	0.84%
Rabbits	295	3.89%
Dogs	6	0.08%
Pigs	3	0.04%
Sheep	20	0.26%
Domestic fowl	111	1.46%
Total	7,586	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	7,565	99.72%
Animals born in the EU but not at a registered breeder	1	0.01%
Animals born in rest of world	20	0.26%
Total	7,586	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	4,999		4,999
Rats	1,890		1,890
Guinea-Pigs	198		198
Hamsters (Syrian)	64		64
Rabbits	295		295
Dogs	6		6
Horses, donkeys and cross-breeds		2	2
Pigs	3		3
Sheep	20	226	246
Cattle		3	3
Domestic fowl	111	49	160
Other birds		8	8
Total	7,586	288	7,874

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	2,189	27.8%
Translational and applied research	3,951	50.18%
Regulatory use and Routine production	1,584	20.12%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	150	1.91%
Total	7,874	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	865	39.52%
Cardiovascular Blood and Lymphatic System	199	9.09%
Nervous System	191	8.73%
Musculoskeletal System	300	13.7%
Immune System	53	2.42%
Urogenital/Reproductive System	9	0.41%
Endocrine System/Metabolism	140	6.4%
Multisystemic	432	19.74%
Total	2,189	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	230	5.82%
Human Infectious Disorders	78	1.97%
Human Cardiovascular Disorders	857	21.69%
Human Nervous and Mental Disorders	34	0.86%
Human Musculoskeletal Disorders	50	1.27%
Human Immune Disorders	560	14.17%
Human Sensory Organ Disorders (skin, eyes and ears)	46	1.16%
Human Endocrine/Metabolism Disorders	401	10.15%
Animal Diseases and Disorders	10	0.25%
Diagnosis of diseases	1,685	42.65%

Total	3,951	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1,266	79.92%
Routine production	318	20.08%
Total	1,584	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	416	32.86%
Batch potency testing	850	67.14%
Total	1,266	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	250	19.75%
Legislation on medicinal products for veterinary use and their residues	1,016	80.25%
Total	1,266	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1,016	80.25%
Legislation satisfying Non-EU requirements only	250	19.75%
Total	1,266	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	318	100.00%
Total	318	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	7,586	96.34%
Yes	288	3.66%

Total	7,874	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	1,706	21.67%
Mild [up to and including]	2,491	31.64%
Moderate	2,704	34.34%
Severe	973	12.36%
Total	7,874	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	7,509	95.36%
Genetically altered without a harmful phenotype	365	4.64%
Total	7,874	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

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

Animal species	First uses	Reuses	Total

No data reported

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

Severity	Number of uses	Percentage

No data reported

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

Genetic status	Number of uses	Percentage

No data reported

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

Basic research	Number of uses	Percentage

No data reported

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

Translational and applied research	Number of uses	Percentage

No data reported

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

Animal species	First uses	Reuses	Total uses

No data reported

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

Severity	Number of uses	Percentage

No data reported

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

Genetic status	Number of uses	Percentage

No data reported

Slovakia

Slovakia: Narrative 2020

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

In 2020, the number of animals used in projects dropped more significantly to 15,211, in comparison with year 2019, when 18,385 animals were used throughout the whole year. The reduction in the number of animals used in projects was caused by measures adopted by the government of the Slovak Republic during the COVID-19 pandemic, when a state of emergency was declared for several months. In this area, this was reflected in the fact that several users, breeders, and suppliers of animals - with a few exceptions - could not be present at the workplace and worked from home. Because of this, only those projects for which animals have already been physically accepted at the user's facilities were carried out or completed. New projects did not start during the state of emergency.

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

There was no significant increase in the use of individual species of animals during 2020 compared to 2019. We can only point to a slight decrease in the number of guinea pigs used in projects in 2020 to 291, which represents 1.91% of the total number of animals used compared to 2019, when 607 guinea pigs were used, which was 3.30% of the total number of animals used. At the same time, the number of "other" birds used increased from 0.17%, which represented 31 animals in 2019 compared to 200 individuals of "other" birds, which represents 1.31% of the total number of animals used in the given year. The number of animals used in the applied research increased from 2.77% (2019) to 6.09% (2020), what represents 927 animals. The most significant increase was recorded in implementation of the applied research - human infectious diseases (COVID 19), in which 465 animals (50.16%) were used. This caused the fact that several facilities have been involved in the scientific research of COVID 19 from the point of view of vaccine production, namely the determination of the effectiveness of vaccines, etc. At the same time, the number of animals used in other basic research decreased significantly to 17 animals (0.16%) compared to 2019, when 724 animals (5.57%) were used in other basic research. We can see in the statistical report that in 2020, when the EU legislation was introduced for the first time, according to which projects were implemented as legislation regulating food, including food packaging material. The purposes and numbers of projects implemented in 2020 are affected by the state of emergency, the presence of workers at the workplace and the possibility of obtaining animals from foreign breeders/suppliers.

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

The changes in trends were related to the global COVID 19 pandemic situation, in which several user facilities were involved in international cooperation in the fight against the pandemic. There was no significant change in the classification of current cruelty for 2020 compared to 2019. In Slovakia, projects classified as “moderately severity” prevail. For their implementation, 9,521 animals were used, which represents 62.59% of the total number of animals used in 2020. The severity

classification of the procedures is closely related to the purpose of the project, i.e., procedures causing moderate severity were performed in the applied research to address COVID 19.

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

In the Slovak Republic, the law stipulates requirements for compliance with the 3R principles. In each application for project approval, the applicant must describe their compliance in detail. Several users have introduced a system of using one control group for several experimental groups of animals in the implementation of the project. At the same time, the results obtained from the project are evaluated continuously. Based on this, the implementation of the project does or does not continue. Several users have built their own centres for non-invasive MRI imaging methods for their user equipment, what significantly reduces the number of animals used.

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

In 2020, the number of “other” birds used increased. These are mainly songbirds used in the approved projects, namely Zebra finch (*Taeniopygia guttata*) and Society finch (*Lonchura striata domestica*), and their offspring. In the **Quality control of registered inactive vaccines**, domestic turkeys are also used in the number of 15-35 per batch, depending on the manufacturer’s instructions. At the same time, projects involving the use of Japanese quail were approved for 2019-2024.

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 2020, there was no case of violation of the approved severity classification of the procedures in the project. The law of the Slovak Republic has established a system of using project retrospective assessment, which is not only conditioned by the classification of project severity as severe, but also by the high number of animals used, use of several complex techniques and methodologies within one project, and testing and use of substances in the project, results of which from in vitro tests were not available in full at the time of project approval. In these cases, the applicant for project approval must submit the partial results for retrospective assessment after the partial study has been performed. The outcome of the assessment will decide whether the project will continue in order to avoid unnecessary suffering of the animals by exceeding the classified cruelty. At the same time, the implementation of the project is approved by a decision. This means that the applicant for project approval is obliged to duly comply with the provisions set out in the project approval decision. If he proceeds differently, he risks an imposition of veterinary measures or penalty according to the seriousness of the ascertained violation.

Slovakia: Statistical Data 2020

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	6,287	42.66%
Rats	7,347	49.85%
Guinea-Pigs	291	1.97%
Mongolian gerbil	17	0.12%
Rabbits	180	1.22%
Cats	13	0.09%
Domestic fowl	402	2.73%
Other birds	200	1.36%
Total	14,737	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	14,737	100.00%
Total	14,737	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	6,287		6,287
Rats	7,347		7,347
Guinea-Pigs	291		291
Mongolian gerbil	17		17
Rabbits	180	7	187
Cats	13		13
Cattle		4	4
Domestic fowl	402	9	411
Other birds	200		200
Total	14,737	20	14,757

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	10,865	73.63%
Translational and applied research	927	6.28%
Regulatory use and Routine production	2,947	19.97%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	4	0.03%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	14	0.09%
Total	14,757	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	858	7.9%
Cardiovascular Blood and Lymphatic System	805	7.41%
Nervous System	4,150	38.2%
Respiratory System	356	3.28%
Gastrointestinal System including Liver	450	4.14%
Musculoskeletal System	105	0.97%
Immune System	740	6.81%
Urogenital/Reproductive System	1,528	14.06%
Sensory Organs (skin, eyes and ears)	12	0.11%
Endocrine System/Metabolism	365	3.36%
Multisystemic	80	0.74%
Ethology / Animal Behaviour /Animal Biology	1,399	12.88%
Other basic research	17	0.16%
Total	10,865	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	80	8.63%
Human Infectious Disorders	465	50.16%
Human Immune Disorders	45	4.85%
Human Sensory Organ Disorders (skin, eyes and ears)	55	5.93%
Other Human Disorders	42	4.53%
Animal Diseases and Disorders	240	25.89%

Total	927	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	450	15.27%
Toxicity and other safety testing including pharmacology	2,487	84.39%
Routine production	10	0.34%
Total	2,947	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	91	20.22%
Batch potency testing	359	79.78%
Total	450	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	177	7.12%
Skin sensitisation	280	11.26%
Repeated dose toxicity	140	5.63%
Developmental toxicity	1,890	76%
Total	2,487	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	177	100.00%
Total	177	100.00%

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

Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose toxicity	Number of uses	Percentage
29 - 90 days	140	100.00%
Total	140	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	371	12.63%
Legislation on medicinal products for veterinary use and their residues	359	12.22%
Industrial chemicals legislation	2,067	70.38%
Food legislation including food contact material	140	4.77%
Total	2,937	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	2,937	100.00%
Total	2,937	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	10	100.00%
Total	10	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	14,737	99.86%
Yes	20	0.14%
Total	14,757	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	571	3.87%
Mild [up to and including]	3,369	22.83%
Moderate	9,521	64.52%
Severe	1,296	8.78%
Total	14,757	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	13,658	92.55%
Genetically altered without a harmful phenotype	414	2.81%
Genetically altered with a harmful phenotype	685	4.64%
Total	14,757	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	318		318
Rats	136		136
Total	454		454

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

Severity	Number of uses	Percentage
Mild [up to and including]	454	100.00%
Total	454	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	275	60.57%
Genetically altered with a harmful phenotype	179	39.43%
Total	454	100.00%

Slovenia

Slovenia: Narrative 2020

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

In 2020, 5,796 animals were used for scientific purposes. Almost 93% of all used animals were rodents (mice and rats) and rabbits. Beside that, the following species were used in low %: pigs, sheep, horses and poultry. No cats, dogs and non-human primates were used for scientific purposes in 2020.

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

4.109 animals, which present 81% of all used animals, were used in basic and translational and applied research, for the purpose of oncology, research on endocrine, immune and gastrointestinal system including liver and diagnostic of diseases, welfare and animal behaviour. Laboratory rodents (mice and rats), sheep and poultry were used.

In the field of regulatory use and routine production, 1.677 animals were used, mainly mice and 68 rabbits. Animals were used for the purpose of quality control, including batch safety and potency testing. Although alternatives exist, pyrogenicity test was still used, as regulatory organs still require to perform this test when there is LER (low endotoxins recovery) effect in BET method suspected or confirmed, to show absence of pyrogenic substances. Test is also required in pre-registration process to show absence of pyrogenic substances with non-endotoxin origin (not possible to detected with alternative BET/MAT method). BET test is used a s a main assay for detection of pyrogenic substances in sterile medicinal products for release purposes. Only a minor part of sterile medicinal products (mainly biological drugs) are tested in a limited amount (e.g. three batches) with rabbit pyrogen test for above mentioned purposes. This represents approximately 1-2 % of all endotoxin/pyrogenicity testing.

615 GA animals (approx. 11%) were used in the field of basic research, for oncology, endocrinology, gastrointestinal system, immunology, etc. Only mice were used.

For higher education 10 animals (2 horses and 8 pigs) were used, which represent 0.17% of all animals used in 2020.

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

Majority of procedures was classified as mild (approx. 76%), almost 24% were moderate and less than 1% severe or non-recovery. Animals used in “severe” procedures were used in translational and applied research in the field of oncology and diagnostic of diseases.

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. At Biotechnical faculty at the University of Ljubljana, scientists

presented a poster on different techniques of handling laboratory animals, especially mice. The technique with a tunnel proved to be very successful.

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

Category “other” was used under translational and applied research for other human disorders (research on iron efficiency).

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 not exceeded.

Slovenia: Statistical Data 2020

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	4,498	91.2%
Rats	19	0.39%
Pigs	8	0.16%
Domestic fowl	407	8.25%
Total	4,932	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	4,932	100.00%
Total	4,932	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	4,498	792	5,290
Rats	19		19
Rabbits		68	68
Horses, donkeys and cross-breeds		2	2
Pigs	8		8
Sheep		2	2
Domestic fowl	407		407
Total	4,932	864	5,796

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	1,461	25.21%
Translational and applied research	2,648	45.69%
Regulatory use and Routine production	1,677	28.93%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	10	0.17%
Total	5,796	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	733	50.17%
Nervous System	56	3.83%
Gastrointestinal System including Liver	10	0.68%
Musculoskeletal System	22	1.51%
Immune System	470	32.17%
Urogenital/Reproductive System	38	2.6%
Endocrine System/Metabolism	14	0.96%
Multisystemic	96	6.57%
Ethology / Animal Behaviour /Animal Biology	22	1.51%
Total	1,461	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	2,023	76.4%
Human Respiratory Disorders	15	0.57%
Human Gastrointestinal Disorders including Liver	160	6.04%
Other Human Disorders	155	5.85%
Animal Welfare	240	9.06%
Diagnosis of diseases	55	2.08%
Total	2,648	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	1,677	100.00%
Total	1,677	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	25	1.49%
Pyrogenicity testing	68	4.05%
Batch potency testing	1,584	94.45%
Total	1,677	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	1,677	100.00%
Total	1,677	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1,677	100.00%
Total	1,677	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	4,932	85.09%
Yes	864	14.91%
Total	5,796	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	24	0.41%
Mild [up to and including]	4,387	75.69%
Moderate	1,371	23.65%
Severe	14	0.24%
Total	5,796	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	5,181	89.39%
Genetically altered without a harmful phenotype	615	10.61%
Total	5,796	100.00%

Section 3: Creation and maintenance of genetically altered animal lines

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

Animal species	First uses	Reuses	Total

No data reported

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

Severity	Number of uses	Percentage

No data reported

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

Genetic status	Number of uses	Percentage

No data reported

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

Basic research	Number of uses	Percentage

No data reported

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

Translational and applied research	Number of uses	Percentage

No data reported

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

Animal species	First uses	Reuses	Total uses

No data reported

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

Severity	Number of uses	Percentage

No data reported

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

Genetic status	Number of uses	Percentage

No data reported

Spain

Spain: Narrative 2020

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

In 2020, the number of projects authorised fell by about 8% compared with 2019.

The number of uses also decreased significantly, having decreased by around 10% compared with 2019 and more than 12% compared with 2018.

On a general point, the use of animals decreased significantly over the course of 2020, due mainly to the inactivity caused by lockdown, as a result of which many procedures were not started at the planned time or even not carried out at all.

Another factor contributing to this decrease is the replacement of the technique of distal tail docking for the purpose of genetic characterisation by the use of tissue removed during tagging. There are tools available on the market, thanks to which the quality of the surplus tissue from identification allows use for genetic sampling. This trend was already noticeable in 2019. In addition, the pandemic slowed down or even halted some projects and reduced the financial resources in certain branches of research.

The use of mammals has decreased markedly, falling almost 18% since 2018. The most notable decreases are seen in the number of uses of pigs (which have fallen by over 30% since 2018 and by 12% compared with 2019). Notable decreases have also occurred in the use of rodents and, to a lesser extent, rabbits.

With regard to uses of pigs, the decrease is due to the significant fall in uses of pigs in regulatory studies (this has led to a reduction of 70% in uses), aimed at checking the quality of batches produced, in particular their safety and potency, and to the reduction in activities to improve surgical skills and other forms of staff training linked to health resources having been channelled into fighting the COVID pandemic.

In relation to rodents, the decrease stands out for mice, due in part to several centres having modified their protocol for determining the genotype of animals, and to the suspension of many educational activities at universities.

The number of uses of primates is on the increase, as a result of the authorisation, in 2020, of three new projects on toxicity and one on nervous system disorders.

The number of uses of birds has increased by 30% since 2019, above all in trials to assess the potency and safety of batches of veterinary medicinal products and in nutritional studies in a commercial setting.

With regard to amphibians, frogs have not been used for scientific purposes in the last three years. The proportion of uses falling under the heading of ‘other amphibians’ has increased greatly. This is discussed further in point 5 of this report. Virtually all uses of amphibians have been for the purpose of studies relating to the biology of animals and their ethology and behaviour.

Fish and cephalopod uses have fallen notably, due to the large numerical variability in counts of very early-stage animals. A single investigation into early-stage animals, which may go up to the stage of autonomous larvae for feeding, makes a difference of thousands of uses in the statistics.

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

As in the previous year, the changes observed in the proportions of animals of different **origins** towards a reduction in the use of animals from centres registered in the EU are linked to the change in the type of animal used (wild or farm animals, as opposed to animals of species conventionally used in research), rather than to the origin of a particular type of animal having changed.

Thus, when the number of mice and rats used falls, since these animals come mainly from registered centres, the proportion of animals originating from a registered centre also falls (although the rats and mice that are used continue to come from registered centres), while an increase in use of animals that typically come from non-registered centres leads to an increase in the proportion of animals not reared in registered centres.

As in previous years, most of the animals used were born at centres registered as breeding centres for animals for scientific purposes[1] and a little over 7.5% were born at establishments which are not registered as breeding centres for animals used for scientific purposes. Proportionately, excluding wild animals, the species of animal which most frequently comes from centres that are not specifically registered as breeding centres for animals for scientific purposes is pigs.

With regard to the **genetic status** of the animals, the proportionate increase both in animals that have not been genetically altered and in those with a harmful phenotype continues. As stated previously in the report on uses in 2019, it is necessary to contextualise the proportionate increase in animals not exhibiting an alteration in genotype and to bear in mind that fewer uses for invasive tissue sampling are being reported due to a change in the system for obtaining the sample needed. Given that genotyping is carried out on animals in order to confirm their genetic alteration, the consequent decrease in uses of genetically altered animals has led to an increase in the proportion of animals that are not genetically altered.

With regard to **purposes**, it is notable that there has been a large increase in uses for regulatory reasons and routine production, particularly in tests to monitor the safety and potency of batches, as required under the legislation on veterinary medicinal products and their residues. In 2020 there were six centres, two of which accounted for a very high number of uses, which had not reported any activity in this area in 2019.

The proportion of animals used in basic and applied research remained similar to the percentages observed in previous years, with the one-off exception of 2019, when the proportion of uses for translational research, and in particular for research into animal diseases and animal welfare, accounted between them for almost 40% of uses in applied research. Of note in 2020 was the use of

[1] In Spain, all establishments which may at some time house animals must be registered, whatever use the animals are intended to be put to. For the purposes of this report, only animals born at a centre which is also registered as a breeding centre for animals for scientific purposes are counted under this heading. It should be noted that this national registration system does sometimes give rise to errors in reports.

animals in oncology and human cancer studies, which accounted for one quarter of uses, looking at basic research and applied research together. A progressive increase is also being observed in uses for the purposes of biology, ethology and the diagnosis of diseases.

The downward trend in the use of animals for the maintenance of colonies of genetically altered animals not used in other procedures has continued, due to the change in the system of tissue sampling for the genotyping of animals already referred to above. Looking globally at the use of animals for systems which are the subject of study or their pathologies, the great majority of the animals are used for oncology and human cancer studies (about 80% of uses), which has been the situation in recent years. There has been a progressive decline in uses in research into situations affecting various systems, due, among other things, to improvements in the classification of uses.

In 2020, due largely to the coronavirus pandemic, which meant fewer courses and classes, less teaching and reduced financial resources, uses of animals for training to acquire, maintain or improve professional skills were much reduced.

The completion of the only project using reptiles, which was aimed at conserving the species concerned, resulted in such uses halving.

As is becoming the norm, animals were not used in forensic investigations.

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

In 2019, the downward trend in the proportion of non-recovery uses changed, due to a single project which used more than 15,000 larvae of the common octopus. With the completion of this project, the trend observed towards a reduction in non-recovery uses of animals is reappearing.

Mild-severity uses have been increasing over the last few years, largely due to nutritional studies on farmed animal species under commercial conditions.

Over the years, moderate-severity uses have been declining in a gradual but sustained way, due to increased awareness and cautiousness in the assessment of severity, such that situations that would previously have been classified as being of moderate severity are now considered to be severe.

Severe-grade severity for the purposes of basic research, applied research and legal requirements applicable to production. The proportion of animals subjected to severe procedures during basic research studies has been in decline in recent years (having decreased from approximately half of severe uses to less than one quarter of such uses), especially in oncology and nervous system studies. Conversely, severity for animals involved in applied research studies has increased over the same period (especially in studies of animal diseases, which account for 30% of all uses of this level of severity). In parallel, and due to controls on the quality of veterinary medicinal products, in this section [*sic*].

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

A variety of approaches have been taken to implement the 3Rs principle, with a range of contributing actions.

Work has continued along the same lines as in previous years, and other new measures have also been initiated.

a. General measures:

- preparation of harmonised working documents;
- appropriate training of staff, including ongoing training to maintain skills;
- during controls, stressing the importance of replacing, reducing and refining methods during the course of the project, and the obligation to do so, in order to ensure that any change in the alternatives available is given due consideration and employed as soon as possible;
- requiring detailed information to be included in the documentation associated with the project to enable checking that the 3Rs principle has been borne in mind and, in turn, to make it possible to require from and/or to suggest to interested parties improvements in this regard before the project is authorised;
- establishing specific supervision protocols according to the consequences of procedures and the results expected;
- actively promoting a culture of being careful at centres;
- establishing and reviewing standard working procedures in housing for laboratory animals.

b. Measures to promote replacement:

- assessing the techniques used to select 'candidates' before they use live animals,
- when evaluating projects, placing an emphasis on looking at the protocol followed to check for the existence of alternative strategies, in particular the sources or keywords used for searches, the date of references and the date searches were performed;
- improvement or replacement of certain techniques, such as the replacement of distal tail-docking to obtain tissue for tissue sampling for the genetic characterisation of animals by the use of tissue removed during tagging;
- promoting the use of dead bodies in teaching and research, coordinating euthanasia procedures where possible to optimise the use of dead bodies, or using organs and parts from slaughterhouses, dead bodies, butchers/fishmongers, and remains of specimens donated for teaching purposes. At universities, dead bodies are often used in a step prior to the use of live animals.

c. Measures to promote reduction:

- impress upon researchers the importance of prior statistical studies to determine the minimum number of animals essential for statistically significant results;
- monitoring by animal-welfare bodies;
- performing sequential studies;
- placing an emphasis on the correct selection of the sex of the animals in studies or their balanced inclusion.
- Measures to promote refinement:
- improving websites by adding information on refining the most common procedures;
- monitoring the anaesthetic and analgesic techniques involved in procedures;

- applying monitoring protocols (including corrective measures and end-point criteria) designed specifically for the procedure in question, with expected parameters according to the type of procedure and/or the animal species;
- facility improvements, e.g. providing thermal blankets for rodents, both for surgery and post-operatively;
- putting in place and maintaining adequate measures to enrich the environment;
- thorough justification of the various aspects of the procedure, with supporting evidence, where relevant. For example, fasting time, the use of animals of one sex only, the number of animals, the type of anaesthesia, the inability to use analgesics because they are incompatible, etc.
- stressing that end-point criteria be clearly defined for each procedure.

Inspections at centres are also considered to be an action to promote this principle, whereby corrective measures are to be indicated both in relation to the facilities (material, dimensions, flows, biosecurity measures, enrichment aspects, etc.) and in relation to the different control records (animals, staff, material, etc.).

These measures are developed at the project evaluation and authorisation 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.

a. The following can be reported with regard to '**other animal species**':

The use of other animal species – which accounted for over 11% of all uses in Spain in 2018 and increased to 13% in 2019 – decreased to 10.5% in 2020. Here again, one of the reasons for this was the variability in the number of individuals in samples of early stages of development of fish and other oviparous animals. Specifically:

- '**Other mammals**' were used mainly for basic and translational research in studies on the urogenital system (Pyrenean goat and mouflon), human infectious diseases (bat, badger) and animal diseases (llamas, dromedaries, wild boar).
    - Other rodents used in 2020 were mainly: the long-tailed chinchilla in research linked to the sense organs, in animal diseases, voles, and other wild rodents in order to gain a better understanding of their biology and behaviour (wood mouse, garden dormouse, etc.).
    - The carnivores not included in the list were: American mink for animal diseases and the European wildcat, mongoose, stone marten for studies in connection with the conservation of species.
- The '**other amphibians**' used were wild animals (different types of toad, salamanders, etc.), all in studies of animal biology, ethology and behaviour).
- In 2020, there was an increase compared with the previous year in uses reported as '**other birds**', due mainly to uses of turkeys in studies on the effectiveness of products for treating coccidia in this animal species, with the objective of health improvements in production systems for this species.
- Once again, most uses were of '**other fish**', although, due to lesser use being made of studies on immature stages, the number of uses reported was lower than in previous years, many instances relating to research linked to animal populations and using very early developmental stages. This, in addition to greatly increasing the number of uses with very

few projects, gives rise to large fluctuations in the use figures from year to year. Much of the research carried out on 'other fish' is aimed at improving understanding of their biology and the factors affecting their well-being, so as to improve their farming conditions and prevent or treat disease in aquaculture (gilthead bream, sea bass, turbot, seriola, sole).

Wild species also continue to be used. In these cases, the research is mainly conducted for the purposes of protecting the environment, preserving biodiversity or studying the biology and ethology of the species in question (wild terrestrial animals such as the red squirrel or lynx, birds including various species of eagle, marine mammals, etc.).

b. As regards animals '**used for other purposes**' the following is noted:

In the report for 2020, a number of basic research projects begun in 2019 concerning studies of palatability and nanoparticles for administration of substances continued, and others were conducted on diets, the establishment and maintenance of a mouse embryo bank, and biodiversity.

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

Various tests on the quality of artificial ventilators were also carried out in 2020.

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 are no records of this scenario having occurred.

Spain: Statistical Data 2020

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	362,610	53.65%
Rats	36,448	5.39%
Guinea-Pigs	8,720	1.29%
Hamsters (Syrian)	713	0.11%
Mongolian gerbil	36	0.01%
Other rodents	202	0.03%
Rabbits	17,336	2.57%
Cats	234	0.03%
Dogs	401	0.06%
Ferrets	109	0.02%
Other carnivores	48	0.01%
Horses, donkeys and cross-breeds	219	0.03%
Pigs	8,265	1.22%
Goats	109	0.02%
Sheep	1,511	0.22%
Cattle	1,092	0.16%
Cynomolgus monkey	264	0.04%
Other mammals	47	0.01%
Domestic fowl	129,061	19.1%
Other birds	6,140	0.91%
Reptiles	240	0.04%
Xenopus	596	0.09%
Other amphibians	5,067	0.75%
Zebra fish	33,330	4.93%
Other fish	62,054	9.18%
Cephalopods	970	0.14%
Total	675,822	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	620,338	91.83%
Animals born in the EU but not at a registered breeder	54,336	8.04%
Animals born in rest of Europe	66	0.01%
Animals born in rest of world	818	0.12%
Total	675,558	100.00%

Source of non-human primates

NHP Source (origin)	Number of animals	Percentage
Animals born at a registered breeder within EU	12	4.55%
Animals born in Asia	199	75.38%
Animals born in Africa	53	20.08%
Total	264	100.00%

Generation of non-human primates

NHP Generation	Number of animals	Percentage
F1	7	2.65%
F2 or greater	257	97.35%
Total	264	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	362,610	792	363,402
Rats	36,448	232	36,680
Guinea-Pigs	8,720	308	9,028
Hamsters (Syrian)	713		713
Mongolian gerbil	36		36
Other rodents	202		202
Rabbits	17,336	2,580	19,916
Cats	234	545	779
Dogs	401	388	789
Ferrets	109		109
Other carnivores	48		48
Horses, donkeys and cross-breeds	219	16	235
Pigs	8,265	8	8,273
Goats	109	113	222
Sheep	1,511	338	1,849
Cattle	1,092	1,075	2,167
Cynomolgus monkey	264	211	475
Other mammals	47	33	80
Domestic fowl	129,061	81	129,142
Other birds	6,140	119	6,259
Reptiles	240		240
Xenopus	596		596
Other amphibians	5,067		5,067
Zebra fish	33,330		33,330
Other fish	62,054	5,234	67,288
Cephalopods	970		970
Total	675,822	12,073	687,895

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	346,936	50.43%
Translational and applied research	197,752	28.75%
Regulatory use and Routine production	133,558	19.42%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	3,299	0.48%
Preservation of species	330	0.05%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	6,020	0.88%
Total	687,895	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	61,014	17.59%
Cardiovascular Blood and Lymphatic System	19,510	5.62%
Nervous System	69,092	19.91%
Respiratory System	3,107	0.9%
Gastrointestinal System including Liver	8,509	2.45%
Musculoskeletal System	4,819	1.39%
Immune System	19,914	5.74%

Urogenital/Reproductive System	5,776	1.66%
Sensory Organs (skin, eyes and ears)	6,363	1.83%
Endocrine System/Metabolism	20,448	5.89%
Multisystemic	26,077	7.52%
Ethology / Animal Behaviour /Animal Biology	95,775	27.61%
Other basic research	6,532	1.88%
Total	346,936	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	35,406	17.9%
Human Infectious Disorders	9,440	4.77%
Human Cardiovascular Disorders	7,686	3.89%
Human Nervous and Mental Disorders	17,426	8.81%
Human Respiratory Disorders	1,933	0.98%
Human Gastrointestinal Disorders including Liver	6,436	3.25%
Human Musculoskeletal Disorders	3,116	1.58%
Human Immune Disorders	7,515	3.8%
Human Urogenital/Reproductive Disorders	1,917	0.97%
Human Sensory Organ Disorders (skin, eyes and ears)	7,514	3.8%
Human Endocrine/Metabolism Disorders	14,681	7.42%
Other Human Disorders	548	0.28%
Animal Diseases and Disorders	55,755	28.19%
Animal Welfare	18,542	9.38%
Diagnosis of diseases	3,659	1.85%
Plant diseases	10	0.01%
Non-regulatory toxicology and ecotoxicology	6,168	3.12%
Total	197,752	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	98,098	73.45%
Other efficacy and tolerance testing	6,070	4.54%
Toxicity and other safety testing including pharmacology	26,572	19.9%
Routine production	2,818	2.11%
Total	133,558	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	23,056	23.5%
Pyrogenicity testing	7,005	7.14%
Batch potency testing	68,034	69.35%
Other quality controls	3	0%
Total	98,098	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	3,639	13.69%
Skin irritation/corrosion	454	1.71%
Skin sensitisation	862	3.24%
Eye irritation/corrosion	43	0.16%
Repeated dose toxicity	6,149	23.14%
Genotoxicity	277	1.04%
Developmental toxicity	24	0.09%
Kinetics	1,750	6.59%
Pharmaco-dynamics (incl safety pharmacology)	669	2.52%
Ecotoxicity	29	0.11%

Safety testing in food and feed area	12,370	46.55%
Target animal safety	291	1.1%
Other toxicity/safety testing	15	0.06%
Total	26,572	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	2,941	80.82%
Non lethal methods	698	19.18%
Total	3,639	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	4,271	69.46%
29 - 90 days	1,618	26.31%
> 90 days	260	4.23%
Total	6,149	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	29	100.00%
Total	29	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	23,587	18.04%
Legislation on medicinal products for veterinary use and their residues	93,844	71.78%
Medical devices legislation	503	0.38%
Industrial chemicals legislation	39	0.03%
Plant protection product legislation	42	0.03%
Food legislation including food contact material	12,036	9.21%
Feed legislation including legislation for the safety of target animals, workers and environment	678	0.52%
Other legislation	11	0.01%
Total	130,740	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	114,439	87.53%
Legislation satisfying national requirements only [within EU]	11,485	8.78%
Legislation satisfying Non-EU requirements only	4,816	3.68%
Total	130,740	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	1,786	63.38%
Monoclonal antibody by mouse ascites method	20	0.71%
Other product types	1,012	35.91%
Total	2,818	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	675,822	98.24%
Yes	12,073	1.76%
Total	687,895	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	32,218	4.68%
Mild [up to and including]	356,941	51.89%
Moderate	235,774	34.27%
Severe	62,962	9.15%
Total	687,895	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	492,492	71.59%
Genetically altered without a harmful phenotype	163,192	23.72%
Genetically altered with a harmful phenotype	32,211	4.68%
Total	687,895	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	15,892	82	15,974
Rats	61		61
Rabbits	9		9
Zebra fish	2,827	127	2,954
Other fish	876		876
Total	19,665	209	19,874

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

Severity	Number of uses	Percentage
Non-recovery	1,984	9.98%
Mild [up to and including]	11,782	59.28%
Moderate	6,047	30.43%
Severe	61	0.31%
Total	19,874	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	5,775	29.06%
Genetically altered without a harmful phenotype	11,252	56.62%
Genetically altered with a harmful phenotype	2,847	14.33%
Total	19,874	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	3,406	19.92%
Cardiovascular Blood and Lymphatic System	1,316	7.7%
Nervous System	3,082	18.02%
Respiratory System	24	0.14%
Gastrointestinal System including Liver	101	0.59%
Musculoskeletal System	409	2.39%
Immune System	604	3.53%
Urogenital/Reproductive System	1,541	9.01%
Sensory Organs (skin, eyes and ears)	2,309	13.5%
Endocrine System/Metabolism	532	3.11%
Multisystemic	3,776	22.08%
Total	17,100	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	403	14.53%
Human Infectious Disorders	111	4%
Human Nervous and Mental Disorders	1,479	53.32%
Human Urogenital/Reproductive Disorders	189	6.81%
Human Endocrine/Metabolism Disorders	345	12.44%
Animal Diseases and Disorders	120	4.33%
Animal Welfare	127	4.58%
Total	2,774	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	25,062		25,062
Total	25,062		25,062

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

Severity	Number of uses	Percentage
Mild [up to and including]	20,886	83.34%
Moderate	4,077	16.27%
Severe	99	0.4%
Total	25,062	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	578	2.31%
Genetically altered without a harmful phenotype	4,600	18.35%
Genetically altered with a harmful phenotype	19,884	79.34%
Total	25,062	100.00%

Sweden

Sweden: Narrative 2020

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

Total number of uses
There was an increase in the total number of uses reported for 2020 (274,076 uses) compared to 2019 (260,525 uses). However, the figure for 2018 was almost the same, 274,472 uses.

Re-use
In 2020, fewer animals were re-used compared to the previous years (2020: 3,094 1%, 2019: 8,234 3% and 2018: 7,598 uses 3%).

Creation of new genetically altered line
There was a continued decrease in the use of animals in the creation of new genetically altered lines in 2020 (14,406) compared to both 2019 (23,783) and 2018 (30,472). Mice dominate with 7,671 followed by zebrafish at 6,735 uses. The decrease from 2019 figures is due to a drastically lower use of zebrafish (16,739), the mice use is approximately the same (7,044). In 2018, both the use of zebrafish and mice was more than double compared to 2020, 14,629 mice and 15,211 zebrafish and in addition, 632 uses of rats were reported.

Genetic status
The use of genetically altered animals with a harmful phenotype decreased in 2020 (14,419 uses) compared to 2019 and 2018 (25,959 and 27,341 uses respectively). The use of genetically altered without a harmful phenotype was approximately the same as in 2018 (113,621 vs 114,594), but slightly higher than in 2019 (106,496).

Place of birth
Uses with animals born in the EU at a registered breeder was slightly lower in 2020 (214,381) than in both 2019 (218,018) and 2018 (219,137). However, uses with animals born in the EU but not at a registered breeder was higher in 2020 (55,003) than in both 2019 (32,759 uses) and 2018 (29,671 uses). Much fewer of the animal uses in 2020 and 2019 were with animals born in the rest of Europe (200 and 148 uses) compared to 2018 (15,975 uses). The 1,398 uses on animals born in the rest of the world is similar to 2019 (1,361) but lower than 2018 (2,077).

Non-human Primate Source
All of the 23 non-human primates in 2020 were re-used, thus no source was noted. In 2019, 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.

Species
Mice had 176,073 uses in 2020 which is similar to 2018 (173,815) but slightly higher than 2019 (168,194). The main purpose for 2020, as well as for 2019 and 2018, was *Basic research*, on *Immune System* (32,046). Similar figures are seen for *Nervous System* (28, 048), *Cardiovascular Blood and Lymphatic System* (22, 584) and *Oncology* (20,116). Those areas had high numbers in 2019 and 2018 as well, albeit in differing orders. *Basic Research* has a similar percentage of all uses of mice in 2020 (77%) and 2019 (76%) but lower compared to 2018 (83%). The use within *Translational and applied research* is also similar between 2020 (20%) and 2019 (22%) but higher than 2018 (15%).

Rats had an increase to 18,385 uses in 2020, compared to 15,502 uses in 2019 and 15,438 in 2018. For 2020, as well as for 2019 and 2018, *Basic Research*, especially about the *Nervous System*, was the

main purpose (4,997, 3,884 and 3,245 respectively). Another large use in *Basic research* was the purpose *Multisystemic* (3,003), higher than both 2019 (2,127) and 2018 (21). In total, most uses are in *Basic Research* (2020: 12,520, 2019: 11,106 and 2018: 9,723). Within *Translational and applied research* the uses were 4,975, 3,907 and 4,848 uses respectively, the highest uses being within *Human Respiratory Disorders* (1,713) and *Human Nervous and Mental Disorders* (1,327).

409 uses of guinea-pigs were reported in 2020, similar to 2019 (437) but lower than 2018 (623). The highest use was for *Basic research*, mainly within *Sensory organs* (192, 253 and 292) and in *Respiratory System* (103, 125 and 250). For *Translational and applied research*, total figures for 2020, 2019 and 2018 were 113, 59 and 71 respectively. 100 uses were reported under *Human Respiratory Disorders*, an increase compared to both 2019 (10) and 2018 (17).

No Syrian hamsters were used in 2020, as was the case in 2019. In 2018, all 39 uses were reported under *Translational and applied research, Human Endocrine/Metabolism Disorders.*

82 uses of other rodents were reported in 2020, which is less than a third of the use in 2019 (304) and about half of the use in 2018 (181). All uses in 2020 were within *Basic Research*, whereas the main areas of use for 2019 and 2018 were within *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (219) and *Preservation of species* (169). The main part for 2020 was used for research in *Immune System* (79).

The amount of uses on rabbits have increased to 3,181 in 2020 from 2,765 in 2019 and 1,738 uses in 2018. In 2020, they are mostly reported as *Basic Research*, the majority divided between *Other basic research* (2020: 2,057, 2019: 1,247 and 2018: 859), *Respiratory System* (2020: 579, 2019: 662 uses but none in 2018) and *Cardiovascular Blood and Lymphatic System* (2020: 318, 2019: 25 and 2018: 539). There was a decrease in the use within *Nervous System* (55) compared to 2019 (614 uses) but the figures were similar to 2018 (35). Within *Translational and applied research* the use was similar for *Human Respiratory Disorders,* 14 (2019: 0 and 2018: 42) *Diagnosis of Disease,* 13 (2019: 38 and 2018: 23) and *Human Musculoskeletal Disorders*, 12 (2019: 16 and 2018: 0). No animals were used for *Other Human disorders* in 2020 same as for 2018, whereas 42 uses were reported in 2019.

There were 147 uses of cats in 2020, which is a decrease compared to 2019 (288 uses) but an increase compared to 2018 (4 uses). Most uses of cats in 2020 were reported as *Translational and applied research* and *Animal diseases and disorders* (112 uses). In 2019, 262 uses were reported under the same category, whereas the 4 uses in 2018 were in *Basic research, Musculoskeletal System*.

There was an increase of the use of dogs in 2020 (494 uses) compared to 2019 (364 uses) but a decrease compared to 2018 (531 uses). 392 uses were in *Translational research*, mostly within *Animal Diseases and disorders* (282 uses), and 102 uses were in *Basic research*, all but two in *Musculoskeletal System*. The use in *Translational research* is higher compared with 2019 (299) and 2018 (198), and the use in *Basic research* is higher compared to 2019 (28), but lesser than 2018 (304), where 150 uses were registered within *Oncology* and *Ethology/Animal Behaviour/Animal Biology* respectively.

18 uses of ferrets were reported in 2020 compared to 25 uses in 2019 and 0 uses in 2018. All uses for 2020 were within *Translational and applied research, Human Infectious Disorders* whereas all 25 uses for 2019 were reported in *Basic Research, Nervous System.*

Other carnivores had 119 uses in 2020, which is similar to 2019 (115 uses) but lower than 2018 (237 uses). All uses were reported as *Basic Research* with subcategory *Ethology/ Animal Behaviour/Animal Biology*. In 2019 2 uses were recorded as *Preservation of Species* (2018: 201 uses),

48 uses were reported as *Basic Research* (2018: 0 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).

Horses, donkeys and cross-breeds had 570 uses in 2020, which is an increase compared to 2019 and 2018 (340 and 146, respectively). The increase is largest in *Basic Research* with 198 uses (2019: 21 and 2018: 33), although *Translational and applied research* also increased to 250 from 193 in 2019 and 13 in 2018. The use in *Higher Education or Training for the Acquisition, Maintenance or Improvement of Vocational Skills* is steady with 122 uses compared to 126 uses in 2019, but slightly higher than 2018 (100 uses).

In 2020, 1,325 uses of pigs were reported, a decrease from 2019 (1,730) and 2018 (1,579). Most uses were within *Higher education or training for the acquisition, maintenance or improvement of vocational skills* 689 (2019: 780 and 2018: 509), followed by *Basic Research* 373 (2019: 664 and 2018: 572) and *Translational and applied research* 263 (2019: 286 and 2018: 498).

The use of goats is similar (59) to 2019 (53), which is a decrease compared to 2018 (261 uses). The main use in 2020 was in *Regulatory use and Routine production, Blood based products*, 25 compared to 0 uses in 2019 and 2018), followed by *Higher education or training for the acquisition, maintenance or improvement of vocational skills*, 16 similar to both 2019 (16) and 2018 (14) and *Translational and applied research,* 13 similar to 25 in 2019 but a decrease from 228 in 2018.

The amount of uses on sheep decreased again to 167 in 2020 from a drastic increase in 2019 (442) compared to 2018 (46). The majority of uses in both 2020 and 2019 were reported in *Translational and applied research* (95 and 395 uses) and mainly in *Diagnosis of diseases* (85 and 85 uses). In 2019, 296 uses were reported under *Animal Welfare*. Smaller portions were categorized as *Basic Research* (2020: 52, 2019: 0 and 2018: 32) as well as in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (2020: 20, 2019: 47, 2018: 0 uses).

Cattle had 2,908 uses in 2020, which is an increase compared to 2019 (1,621 uses) but similar to 2018 (2,394 uses). The increase is mainly due to a higher use in *Translational and applied research*, 1,359 compared to 10 in 2019 and 932 in 2018. Most uses of cattle are recorded in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* with 1,397 in 2020, 1,489 in 2019 and 1,379 in 2018. The major part of the animals use in *Translational and Applied Research* is in *Animal Diseases and Disorders* for 2020 (1,116) and 2018 (930), whereas no uses were reported in this category for 2019. 10 uses in 2019 are reported in the subcategory *Diagnosis of diseases*. The number of uses reported in *Basic Research* have increased to 152 uses in 2020 from 122 and 83 in 2019 and 2018, respectively, with *Other Basic research* (2020: 84, 2019: 0 and 2018: 33) and *Ethology/Animal Behaviour /Animal Biology* (2020: 68, 2019: 122 and 2018: 48). In 2020, the use under *Other Basic Research* was within development of feeding or husbandry systems and tests of milking machines.

Cynomolgus monkey had 4 uses 2020, compared to 20 in 2019 and 10 in 2018. Similar to 2019 and 2018, all uses were reported in *Basic Research*. In 2020, all uses were in *Cardiovascular Blood and Lymphatic System*, whereas in 2019, 17 uses were for the purpose *Nervous System* (2018: 4) and 3 uses in *Cardiovascular Blood and Lymphatic System*. In 2018, 6 uses were reported for the purpose of *Endocrine System/Metabolism*.

Rhesus monkeys had 19 uses in 2020, 8 uses in 2019, and 10 uses in 2018. All uses in 2020 were reported as *Translational and Applied Research, Human Infectious Disorders*. 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 uses in 2019 were reported as *Translational and Applied Research, Human Infectious Disorders*.

Other mammals had 382 uses in 2020, which is an increase compared to both 2019 (200) and 2018 (260). The main uses have been in *Basic research* (377, 193 and 155 respectively) but in 2018, 92 uses were recorded for *Preservation of Species*. Most uses are within the category *Ethology/Animal Behaviour/Animal Biology* (301, 193 and 155 respectively) but 76 uses were recorded as virology studies in 2020 under *Other Basic Research,* and 5 uses were reported for *Routine production, blood based products* in 2020.

The use of domestic fowl is similar in 2020 (1,988) to 2019 (1,994), but higher than in 2018 (1,153). Most uses in 2020 are reported under *Basic research* (1,777) in *Ethology/Animal Behaviour/Animal Biology* (880), *Oncology* (600) and *Multisystemic* (266), although 190 uses were reported within *Translational and applied research*, mainly within *Animal Diseases and Disorders*, and 21 uses in *Regulatory use and Routine production, Routine production of blood based products*. In 2019, approximately half of the use was within *Basic Research* (1,022), mainly in *Ethology/Animal Behaviour/Animal Biology* and half within *Translational and applied research* (972), mainly in *Animal Diseases and Disorders*. In 2018, the ratio was different, with 778 uses in *Basic Research,* mainly *Ethology/Animal Behaviour/Animal Biology,* and 375 uses in *Translational and applied research,* mainly in *Animal Welfare.*

In 2020, 3,906 uses of *Other birds* were reported. This is a significant decrease compared to 2019 and 2018 (10,810 and 10,625 uses, respectively). For all years, the major part of the uses are reported under *Basic Research, Ethology/Animal Behaviour/Animal Biology*.

Reptiles have decreased to 34 uses in 2020 compared with 139 uses in 2019 and 529 uses in 2018. All uses were reported as *Basic Research, Ethology/Animal Behaviour/Animal Biology*, whereas the uses in 2019 are reported as *Basic Research (Endocrine System/Metabolism* 110 uses, *Ethology/Animal Behaviour/Animal Biology* 29 uses) and all 529 uses in 2018 were reported as *Preservation of species*.

The frogs *Rana temporaria* och *Rana pipiens* had 0 uses in both 2020 and 2019, which is a decrease compared to 2018 (2 uses). The 2018 uses were in *Translational and Applied Research, Animal Diseases and Disorders*, specifically testing for prevalence of *Batrachochytrium*.

Xenopus frogs have increased significantly compared to previous years (2020: 1,761, 2019: 171, and 2018: 298 uses). The majority are reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (2020: 1,679, 2019: 137, and 2018: 237 uses). A smaller portion is reported as *Basic Research, Nervous System* (58 uses) and *Ethology/Animal behaviour/Animal Biology* (24 uses). In 2019 and 2018, the use in *Basic Research* was for *Nervous System* only (34 and 61 uses, respectively).

The use of *Other amphibians* decreased in 2020 to 1,256 from 2,041 in 2019 and 2,538 in 2018. The difference is due to zero use in *Ethology/Animal Behaviour/Animal Biology* for 2020 compared to 846 for 2019 and 2,100 for 2018. The major use in 2020 was in *Nervous System,* 1,014, which is an increase compared to 2019 (897) and 2018 (250), but some uses were in *Cardiovascular Blood and Lymphatic System* (2020: 242, 2019: 298: and 2018: 46). The only use in *Translational and applied research* during the past three years is recorded for 2018 with 122 uses under *Animal Diseases and Disorders.*

Zebrafish has decreased significantly in 2020 compared to the previous years (2020: 18,285, 2019: 35,089 and 2018: 36,476), both in *Basic research* (16,733, 28,611 and 29,516 respectively) and *Translational and applied research* (1,552, 6,478 and 6,960 respectively). The main uses are within *Basic Research*, in subcategories *Cardiovascular Blood and Lymphatic System* (2020: 4,644, 2019: 16,103 and 2018: 16,799 uses), *Nervous System* (2020: 3,617, 2019: 4,066 and 2018: 3,914) and *Multisystemic* (2020: 2,663, 2019: 5,378 and 2018: 5,058). An increase is seen in the use under

Musculoskeletal System for 2020, 2,462 compared to 771 in 2019 and 240 in 2018. Under *Translational and applied research* most uses are reported as *Human Nervous and Mental Disorders* (2020: 1,432, 2019: 4,426 and 2018: 5,960). In 2019, 2,052 uses were in *Non-regulatory toxicology and ecotoxicology* and in 2018, 1000 uses were recorded under *Human Endocrine/Metabolism Disorders.* No such uses were reported for the other years.

Other fish have increased in 2020 compared to the previous years (2020: 42,504, 2019: 17,873 and 2018: 25,539). The large difference is due to a drastic increase in *Basic Research, Ethology/Animal Behaviour/Animal Biology* (25,005, 5,331 and 5,922 respectively). Most uses were recorded in *Basic research* (25,709, 6,010 and 11,850 respectively) but *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (8,208, 2,905 and 2,304) and *Translational and applied research* had many uses as well (5,883, 6,083 and 6,095), mostly within *Non-regulatory toxicology and ecotoxicology* (5,883, 5,619 and 5,530).

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

Overall, the uses are relatively steady. *Basic Research* has 202,547 uses (74%) in 2020, 190,709 uses (73%) in 2019 and 212,334 uses (77%) in 2018.
Most uses in *Basic Research* for 2020 are reported under *Nervous System* (37,926), an increase in actual numbers compared to 2019 (34,646) and 2018 (35,775). Increases are also seen in *Gastrointestinal System including Liver* (4,341 compared to 1,772 and 2,180), *Musculoskeletal System* (7,048 compared to 3,960 and 4,471), *Multisystemic* (11,308 compared to 9,689 and 7,257) as well as in *Ethology/Animal Behaviour/Animal Biology* (30,081 compared to 17,858 and 18,397). A large increase is visible in *Other basic research* in 2020 (10,193 5%) compared to 2019 (4,763 2%), but not as high as during 2018 (13,397 6%).

The use for *Cardiovascular Blood and Lymphatic System* decreased in 2020 (28,987) compared to both 2019 (38,876) and 2018 (47,707). Decreases were also observed in the use for *Urogenital/Reproductive System* (1,289 compared to 1,967 and 2,073), *Sensory Organs (skin, eyes and ears)* (833 compared to 2,206 and 2,262) as well as for *Endocrine System/Metabolism* (14,163 compared to 17,894 and 20,334).
The use for *Respiratory System* is lower in 2020 (2,597) compared to 2019 (3,045) but higher than in 2018 (1,697).

The number of uses in 2020 reported as *Translational and Applied Research* has decreased to 50,375 (18%) from 55,756 (21%) in 2019, but is similar to 2018 (46,257 17%). There have been more uses for *Human Infectious Disorders* in 2020 (1,527 compared to 1,056 and 1,350). Increases are seen also in *Human Respiratory Disorders* (6,401 compared to 5,065 and 4,279), in *Human Endocrine/Metabolism Disorders* (8,575 compared to 8,331 and 5,491), in *Human Sensory Organ Disorders (skin, eyes and ears)* (971 compared to 250 and 48) and in *Other Human Disorders* (1,616 compared to 1,559 and 1,020).

There is a clear decrease in use for *Human Nervous and Mental Disorders* (5,038 compared to 8,067 and 10,942) and for *Human Immune Disorders*, 1,106 in 2020 compared to 1,910 in 2019, however similar to 2018, 1,161. *Animal Welfare* use has decreased in 2020 (247) compared to 2019 (611) and 2018 (528). Some areas have decreased in relation to 2019, but increased related to 2018. This is the case for *Human Cancer* (2020: 10,046, 2019: 12,124 and 2018: 7,737), *Human Cardiovascular Disorders* (2020: 5,613, 2019: 5,890 and 2018: 4,660), *Non-regulatory toxicology and ecotoxicology* (2020: 6,462, 2019: 8,423 and 2018: 6,253) and *Diagnosis of diseases* (2020: 421, 2019: 500 and 2018: 355).
Human Musculoskeletal Disorders increased in 2020 (273) in relation to 2019 (75) but was lower

than in 2018 (504).

There is an increase in *Regulatory use and Routine production*, 2,080 uses for 2020 compared to 1,079 in 2019 and 1,306 in 2018. A decrease was seen in *Quality control (incl. batch safety and potency testing),* 547 compared to 1,070 and 1,080, all used in *batch potency testing*. A clear increase was seen in *Toxicity and other safety testing including pharmacology* (1,353 compared to 9 and 106), the increase due to use in *Acute and sub-acute, Non-lethal methods* and in *Routine production* (137 compared to zero use for 2019 and 2018), all *Blood based products*.

The category *Preservation of species* has continued to decrease, 1,834 in 2020 compared to 2,416 uses in 2019 and 6,295 uses in 2018. The use in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* has increased in actual numbers to 5,986 from 5,132 in 2019 and 4,958 in 2018.

There is a large increase in *Protection of the natural environment in the interests of the health or welfare of human beings or animals*, 10,201 for 2020 compared to 2019 (4,457) and 2018 (3,253). *Maintenance of colonies of established genetically altered animals, not used in other procedures* had 1,071 uses in 2020, a large increase from 2018 (69) but similar to 2019 (976).

There is a decrease in *Legislation on medicinal products for veterinary use and their residues*, 547 for 2020 compared to 1,070 in 2019 and 1,080 in 2018. However, there is a substantial increase in the category *Legislation on medicinal products for human use*, 1,396 for 2020 compared to 9 uses in 2019 and 226 uses in 2018.

It is not clear what the changes depend on, but it is possible that some changes are due to the effect of Covid-19, concerning both research not performed according to plan as well as research that was initiated due to the disease.

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

Severities
The actual severities were proportionally quite similar during the past years for *Non-recovery* 2020 (9,175, 3%), 2019 (9,370 4%) and 2018 (6,128, 2%). The proportion for *Mild* has decreased in 2020 (69,065 25%) compared to both 2019 (79,396 30%) and 2018 (88,646 32%). *Moderate* severity has increased in 2020 (172,068 63%) compared to both 2019 (144,917 56%) and 2018 (154,206 56%). *Severe* is constant in 2020 (23,768 9%), 2019 (26,842 10%) and 2018 (25,492 9%).

Mild
Most uses classified as *Mild* are reported as *Basic Research* during the past years, although decreasing in 2020 (53,757) compared to 2019 (69,540) and 2018 (72,992). There is also a decrease in the use in *Translational and applied research,* 6,091 compared to 6,482 and 8,712 for 2019 and 2018 respectively. In 2020, there is a large increase in the use under *Protection of the natural environment in the interests of the health or welfare of human beings or animals*, 6,611, compared to 2019 (469) and 2018 (776). *Higher education or training for the acquisition, maintenance or improvement of vocational skills* exhibits a decrease in 2020 (2,042) compared to 2019 (2,399) but an increase compared to 2018 (1,607). *Maintenance of colonies of established genetically altered animals, not used in other procedures* has 467 uses in *Mild* in 2020 to be compared with 500 in 2019 and zero in 2018. *Genetically altered with a harmful phenotype* have decreased in the severity category mild (2020: 4,851, 2019: 13,849 and 2018: 1,951).

Moderate

Most uses classified as *Moderate* are reported as *Basic Research* during the past years, increasing in 2020 (121,113) compared to 2019 (93,666) and 2018 (113,765). The increase is partly due to a higher use reported under *Ethology/Animal Behaviour/Animal Biology* (2020: 26,442, 2019: 8,042 and 2018: 7,297). Also, the use in *Gastrointestinal System including Liver* has increased to 3,723 in 2020 compared to 2019 (893) and 2018 (1,671). *Translational and applied research* remains at about half of the use in *Basic Research* (2020: 39,796, 2019: 40,823 and 2018: 31,838). The uses classified as moderate severity for *Creation of New Genetically Altered Line* is similar proportionally speaking in 2020 (8,349 5%) compared to 2019 (6,285 4%) but lower than 2018 (20,091 13%).

Severe
Most uses classified as *Severe* in 2020 were reported as *Basic Research* (88%), foremost in *Immune System* (9,672 uses) and *Nervous System* (4,451 uses). The number of *Severe* uses in the subcategory *Immune System* increased from 9,141 in 2019 and 7,306 uses in 2018, and for *Nervous System* compared to 2019 (2,863). However, the use in *Nervous System* was very similar to 2018 (4,398). The categories *Multisystemic*, *Oncology*, *Musculoskeletal System*, and *Cardiovascular Blood and Lymphatic System* contain rather large portions of the total in 2020: 2,122 (2019: 2,122 and 2018: 23), 1,623 (2019: 1,935 and 2018: 1,434), 846 (2019: 535 and 2018: 646) and 749 uses (decreasing from 2019: 1,974 and 2018: 1,694).

The number of uses classified as *Severe* has decreased for the category *Not genetically altered* (2020: 9,846, 2019: 13,830 uses, 2018: 12,895 uses), but similar between the years for *Genetically altered with a harmful phenotype* (2020: 970, 2019: 827 and 2018: 1,174 uses). The amount of uses for *Genetically altered without a harmful phenotype* but with *Severe* severity have increased from 2019 and 2018 (2020: 12,952 54%, 2019: 12,185 45%, and 2018: 11,423 45%). No uses are reported as *Severe* in the *Creation of New Genetically Altered Line* for 2020 and 2019, compared to 1,628 reported uses in 2018.

Non-recovery
Most uses classified as *Non-recovery* were reported as *Basic Research* during the past years, similar between 2020 (6,832 74%) and 2019 (7,099 76%) but higher than 2018 (4,011 65%). The use is diverse, but most are within *Immune System* (2020: 1,677, 2019: 1,482 and 2018: 668) and *Nervous System* (2020: 1,388, 2019: 1,872 and 2018: 1,094). *Translational and applied research* remains lower than the use in *Basic Research* (2020: 1,769, 2019: 2,014 and 2018: 1,781), with in total most uses under *Human Cardiovascular Disorders* (2020: 788, 2019: 712 and 2018: 436). *Higher education or training for the acquisition, maintenance or improvement of vocational skills* has an increase in 2020 (574) compared to 2019 (255) and 2018 (336).

It is unclear what the changes depend on in this part. However, minor fluctuations are commonly observed over the years.

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

The Swedish National Committee for the Protection of Animals Used for Scientific Purposes drives the Swedish national work with the 3Rs, with the Swedish 3Rs Center as its 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.

Projects
One of the largest projects during the year was the continuation and completion of a project concerning group housing of male mice, already mentioned in the 2019 report. The project has led

to seven concrete recommendations, which are available also as a poster to facilitate the uptake. In addition, the guide on marking and tagging of fish mentioned in the 2019 report was finalised. Further, during 2020, the 2019 work with the national replace network and the replace strategy continued, and a project about the ways in which mathematical modelling and artificial intelligence can replace and reduce the number of animals used was initiated.

Meetings and conferences
Covid-19 changed the playing field in many ways, but just before it put a stop to physical meetings, the Swedish 3Rs Center held a well-attended seminar on non-animal methods, with participants from the academy, the industry and different authorities. During the year, thanks to the rapid move into digital meetings the National Committee and the 3Rs Center has continued to promote the 3Rs through participating in conferences, workshops, seminars and meetings, as well as arranging such activities. One such activity was participating together with the non-profit organisation Public & Science in Researchers' Night. This posed an opportunity for high school students to meet with researchers and discuss animal experiments and non-animal method, with the aim of increasing the general knowledge on the subject.
In order to draw the attention to the progress in European 3Rs work and show the breadth of ongoing research in the field, the Swedish 3Rs Center together with five other 3Rs centres in Europe, arranged three webinars on the 3Rs and European research.

Focus on the 3Rs
Another important step for the visibility and dissemination of information for the Swedish 3Rs Center is the digital letter Focus on the 3Rs, which was initiated in 2019. During 2020, four issues were published: 3Rs in a Swedish context, Replacement, Fish in research and Authorities and the 3Rs.

Infographics
The Swedish 3Rs Center produced educational material in the form of infographics aimed primarily at high school students, but useful to anyone interested in learning more about the 3Rs and animals used for scientific purposes.

Group of Experts
To its aid, the Swedish National Committee has a Group of Experts to assist where particular expertise is needed. During 2020, the group has mainly worked with a compilation of knowledge regarding euthanization of zebrafish through hypothermic shock.

The National Committee and the Swedish 3Rs Center are continuously working to inspire researchers to use replace methods as well as to refine the methods they are using. It is, however, difficult to measure whether these actions have 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
119 (15%) of the uses of carnivores were recorded as other carnivores, to be compared with 115 in 2019 and 237 in 2018. They consist of brown bear (*Ursus arctos*, 66 uses), raccoon dog (*Nyctereutes procyonoides*, 35 uses), wolf (*Canis lupus,* 2 uses), wolverine (*Gulo gulo*, 8 uses) and lynx (*Lynx lynx*, 8 uses). All uses were reported as *Basic Research* with subcategory *Ethology/Animal Behaviour/Animal Biology*.

Other birds
3,906 (66%) of the birds were reported as *Other birds*. This is much lower than in previous years (2019: 10,810 and 2018: 10,625). They consist mostly of European pied flycatcher (*Ficedula hypoleuca*, 489 uses), great tit (*Parus major*, 486 uses), marsh tit (*Poecile palustris*, 461 uses), willow warbler (*Phylloscopus trochilus*, 363 uses), zebra finch (*Taeniopygia guttata,* 340 uses), Eurasian blue tit (*Cyanistes caeruleus*, 265 uses), common blackbird (*Turdus merula*, 235 uses) and the great reed warbler (*Acrocephalus arundinaceus*, 211 uses). Most uses of *Other birds* were reported under *Basic research* (3,592 uses, of which 3,524 were specified as *Ethology/Animal Behaviour/Animal Biology,* 52 under *Endocrine System/Metabolism* and 16 under *Cardiovascular Blood and Lymphatic System*). 314 uses were reported under *Protection of the natural environment in the interests of the health or welfare of human beings or animals*.

Other fish
42,504 (70%) of the reported uses of fish constitutes of *Other fish*, a large increase compared to both 2019 (17,873) and 2018 (25,539). Most *Other fish* are reported as Atlantic salmon (*Salmo salar*, 20,491), brown trout (*Salmo trutta*, 2,938), European perch (*Perca fluviatilis*, 2,624), Atlantic herring (*Clupea harengus*, 2,500), corkwing wrasse (*Symphodus melops*, 1,928), ninespine stickleback (*Pungitius pungitius*, 1606) and guppy (*Poecilia reticulata*, 1,586). Most uses of *Other fish* are reported under *Basic Research* (25,709 uses, of which 25,005 were in *Ethology/Animal Behaviour/Animal Biology*), *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (8,208) and *Translational and Applied Research* (5,883 uses, all in *Non-regulatory Toxicology and Ecotoxicology*).

Other amphibians
42% (1,256 uses) of the amphibians are reported as *Other amphibians*, which is lower compared to previous years (2019: 2,041 and 2018: 2,538 uses). The species used 2020 are Iberian ribbed newt (*Pleurodeles waltl,* 1,230 uses) and the eastern newt (*Notophthalmus viridescens*, 26 uses). All uses of *Other amphibians* were reported as *Basic Research*, of which 1,014 uses were in *Nervous System* and 242 uses in *Cardiovascular Blood and Lymphatic System*.

Other mammals
382 uses of *Other mammals* were reported, 145 wild boar (*Sus scrofa*), 118 elk (*Alces alces*), 38 roe deer (*Capreolus capreolus*), 34 Daubenton's bat (*Myotis daubentonii*), 33 soprano pipistrelle (*Pipistrellus pygmaeus*), 8 Brandt's bat (*Myotis brandtii*), 5 alpaca (*Vicugna pacos*) and 1 whiskered bat (*Myotis mystacinus*).

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 are no reports on any such cases in SE up to this date.

Appendix to Swedish Member State narrative

The European Commission noticed some irregularities in the Swedish statistics for 2018. As last year, this table contains the adjusted numbers after correcting reports following a contact with the relevant users.

Animal group	Animal species	2018	2019	2020
Rodents	Mice	173,815	168,194	176,073
	Rats	15,438	15,502	18,385
	Guinea-Pigs	623	437	409
	Hamsters (Syrian)	39	0	0
	Hamsters (Chinese)	0	0	0
	Mongolian gerbil	0	0	0
	Other rodents	181	304	82
Lagomorphs	Rabbits	1,738	2,765	3,181
Carnivores	Cats	4	288	147
	Dogs	531	364	494
	Ferrets	0	25	18
	Other carnivores	237	115	119
Ungulates	Horses, donkeys & cross-breeds	146	340	570
	Pigs	1,579	1,730	1,325
	Goats	261	53	59
	Sheep	46	442	167
	Cattle	2,394	1,621	2,908
Primates	Prosimians	0	0	0
	Marmosets and tamarins	0	0	0
	Cynomolgus monkey	10	20	4
	Rhesus monkey	10	8	19
	Vervets Chlorocebus spp.	0	0	0
	Baboons	0	0	0
	Squirrel monkey	0	0	0
	Other species of New World Monkeys (Ceboidea)	0	0	0
	Other species of Old World Monkeys (Cercopithecoidea)	0	0	0
	Other species of non-human primates	0	0	0
	Apes	0	0	0
Other mammals	Other mammals	260	200	382
Birds	Domestic fowl	1,153	1,994	1,988
	Other birds	10,625	10,810	3,906
Reptiles	Reptiles	529	139	34
Amphibians	Rana	2	0	0
	Xenopus	298	171	1,761

	Other amphibians	2,538	2,041	1,256
Fish	Zebra fish	36,476	35,089	18,285
	Other fish	25,539	17,873	42,504
Cephalopods	Cephalopods	0	0	0
	Total uses	**274,472**	**260,525**	**274,076**

Severity	**2018**		**2019**		**2020**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Non-recovery	6,128	2	9,370	4	9,175	3
Mild (up to and including)	88,646	32	79,396	30	69,065	25
Moderate	154,206	56	144,917	56	172,068	63
Severe	25,492	9	26,842	10	23,768	9
Totally	**274,472**	**100**	**260,525**	**100**	**274, 076**	**100**

Genetic Status	**2018**		**2019**		**2020**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Not genetically altered	132,537	48	128,070	49	146,036	53
Genetically altered without a harmful phenotype	114,594	42	106,496	41	113,621	41
Genetically altered with a harmful phenotype	27,341	10	25,959	10	14,419	5
Totally	***274,472***	***100***	***260,525***	***100***	***274,076***	***100***

Regulatory use and routine production	**2018**		**2019**		**2020**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Quality control (incl batch safety and potency testing)	1,080	83	1,070	99	547	26
Other efficacy and tolerance testing	120	9	0	0	43	2
Toxicity and other safety testing including pharmacology	106	8	9	1	1,353	65
Routine production	0	0	0	0	137	7
Totally	**1,306**	**100**	**1,079**	**100**	**2,080**	**100**

Re-use	**2018**		**2019**		**2020**	
	Number of	**%**	**Number of**	**%**	**Number of**	**%**
No	266,874	97	252,291	97	270,982	99
Yes	7,598	3	8,234	3	3,094	1
Totally	**274,472**	**100**	**260,525**	**100**	**2**	**100**

Basic research (first use and re-use)	**2018**		**2019**		**2020**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Oncology	24,836	12	21,733	11	20,806	10
Cardiovascular Blood and Lymphatic System	47,707	22	38,876	20	28,987	14
Nervous System	35,775	17	34,646	18	37,926	19
Respiratory System	1,697	1	3,045	2	2,597	1
Gastrointestinal System including Liver	2,180	1	1,772	1	4,341	2
Musculoskeletal System	4,471	2	3,960	2	7,048	3
Immune System	31,948	15	32,300	17	32,975	16
Urogenital/Reproductive System	2,073	1	1,967	1	1,289	1
Sensory Organs (skin, eyes and ears)	2,262	1	2,206	1	833	<1
Endocrine System/Metabolism	20,334	10	17,894	9	14,163	7
Multisystemic	7,257	3	9,689	5	11,308	6
Ethology / Animal Behaviour /Animal Biology	18,397	9	17,858	9	30,081	15
Other basic research	13,397	6	4,763	2	10,193	5
Totally	**212,334**	**100**	**190,709**	**100**	**202,547**	**100**

Translational and applied research (first use and re-use)	**2018**		**2019**		**2020**	
	Number of	***%***	***Number of***	***%***	***Number of***	***%***
Human Cancer	7,737	17	12,124	22	10,046	20
Human Infectious Disorders	1,350	3	1,056	2	1,527	3
Human Cardiovascular Disorders	4,660	10	5,890	11	5,613	11
Human Nervous and Mental Disorders	10,942	24	8,067	15	5,038	10
Human Respiratory Disorders	4,279	9	5,065	9	6,401	13
Human Gastrointestinal Disorders including Liver	56	<1	0	0	78	<1
Human Musculoskeletal Disorders	504	1	75	<1	273	1
Human Immune Disorders	1,161	3	1,910	3	1,106	2
Human Urogenital/Reproductive Disorders	74	<1	99	<1	157	<1
Human Sensory Organ Disorders (skin, eyes and ears)	48	<1	250	<1	971	2
Human Endocrine/Metabolism Disorders	5,491	12	8,331	15	8,575	17
Other Human Disorders	1,020	<1	1,559	3	1,616	3
Animal Diseases and Disorders	1,799	4	1,796	3	1,826	4
Animal Welfare	528	1	611	1	247	<1
Diagnosis of diseases	355	1	500	1	421	1
Plant diseases	0	0	0	0	0	0
Non-regulatory toxicology and ecotoxicology	6,253	14	8,423	15	6,462	13
Totally	**46,257**	**100**	**55,756**	**100**	**50,357**	**100**

Sweden: Statistical Data 2020

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	166,567	65.17%
Rats	18,369	7.19%
Guinea-Pigs	396	0.15%
Other rodents	82	0.03%
Rabbits	3,166	1.24%
Cats	147	0.06%
Dogs	366	0.14%
Ferrets	18	0.01%
Other carnivores	56	0.02%
Horses, donkeys and cross-breeds	391	0.15%
Pigs	767	0.3%
Goats	44	0.02%
Sheep	82	0.03%
Cattle	2,018	0.79%
Other mammals	364	0.14%
Domestic fowl	1,944	0.76%
Other birds	3,738	1.46%
Reptiles	34	0.01%
Xenopus	1,713	0.67%
Other amphibians	1,256	0.49%
Zebra fish	11,550	4.52%
Other fish	42,504	16.63%
Total	255,572	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	199,013	77.87%
Animals born in the EU but not at a registered breeder	55,003	21.52%
Animals born in rest of Europe	200	0.08%
Animals born in rest of world	1,356	0.53%
Total	255,572	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	166,567	764	167,331
Rats	18,369	16	18,385
Guinea-Pigs	396	13	409
Other rodents	82		82
Rabbits	3,166	15	3,181
Cats	147		147
Dogs	366	128	494
Ferrets	18		18
Other carnivores	56	63	119
Horses, donkeys and cross-breeds	391	179	570
Pigs	767	558	1,325
Goats	44	15	59
Sheep	82	85	167
Cattle	2,018	890	2,908
Cynomolgus monkey		4	4
Rhesus monkey		19	19
Other mammals	364	18	382
Domestic fowl	1,944	44	19,88
Other birds	3,738	168	3,906
Reptiles	34		34
Xenopus	1,713	48	1,761
Other amphibians	1,256		1,256
Zebra fish	11,550		11,550
Other fish	42,504		42,504
Total	255,572	3,027	258,599

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	188,663	72.96%
Translational and applied research	49,835	19.27%
Regulatory use and Routine production	2,080	0.8%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	10,201	3.94%
Preservation of species	1,834	0.71%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	5,986	2.31%
Total	258,599	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	20,331	10.78%
Cardiovascular Blood and Lymphatic System	24,805	13.15%
Nervous System	36,814	19.51%
Respiratory System	2,549	1.35%
Gastrointestinal System including Liver	4,341	2.3%
Musculoskeletal System	5,020	2.66%
Immune System	32,374	17.16%

Urogenital/Reproductive System	1,188	0.63%
Sensory Organs (skin, eyes and ears)	833	0.44%
Endocrine System/Metabolism	12,670	6.72%
Multisystemic	7,892	4.18%
Ethology / Animal Behaviour /Animal Biology	30,081	15.94%
Other basic research	9,765	5.18%
Total	188,663	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	10,045	20.16%
Human Infectious Disorders	1,527	3.06%
Human Cardiovascular Disorders	5,612	11.26%
Human Nervous and Mental Disorders	5,037	10.11%
Human Respiratory Disorders	6,395	12.83%
Human Gastrointestinal Disorders including Liver	78	0.16%
Human Musculoskeletal Disorders	273	0.55%
Human Immune Disorders	1,106	2.22%
Human Urogenital/Reproductive Disorders	157	0.32%
Human Sensory Organ Disorders (skin, eyes and ears)	458	0.92%
Human Endocrine/Metabolism Disorders	8,575	17.21%
Other Human Disorders	1,616	3.24%
Animal Diseases and Disorders	1,826	3.66%
Animal Welfare	247	0.5%
Diagnosis of diseases	421	0.84%
Non-regulatory toxicology and ecotoxicology	6,462	12.97%
Total	49,835	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	547	26.3%
Other efficacy and tolerance testing	43	2.07%
Toxicity and other safety testing including pharmacology	1,353	65.05%
Routine production	137	6.59%
Total	2,080	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	547	100.00%
Total	547	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	1,189	87.88%
Kinetics	164	12.12%
Total	1,353	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	1,189	100.00%
Total	1,189	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	1,396	71.85%
Legislation on medicinal products for veterinary use and their residues	547	28.15%
Total	1,943	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	1,943	100.00%
Total	1,943	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Blood based products	137	100.00%
Total	137	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	255,572	98.83%
Yes	3,027	1.17%
Total	258,599	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	9,062	3.5%
Mild [up to and including]	62,654	24.23%
Moderate	163,115	63.08%
Severe	23,768	9.19%
Total	258,599	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	144,698	55.95%
Genetically altered without a harmful phenotype	100,932	39.03%
Genetically altered with a harmful phenotype	12,969	5.02%
Total	258,599	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	7,669	2	7,671
Zebra fish	6,670	65	6,735
Total	14,339	67	14,406

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

Severity	Number of uses	Percentage
Non-recovery	113	0.78%
Mild [up to and including]	5,944	41.26%
Moderate	8,349	57.96%
Total	14,406	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	1,338	9.29%
Genetically altered without a harmful phenotype	12,486	86.67%
Genetically altered with a harmful phenotype	582	4.04%
Total	14,406	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	475	3.42%
Cardiovascular Blood and Lymphatic System	4,182	30.12%
Nervous System	1,112	8.01%
Respiratory System	48	0.35%
Musculoskeletal System	2,028	14.61%
Immune System	601	4.33%
Urogenital/Reproductive System	101	0.73%
Endocrine System/Metabolism	1,493	10.75%
Multisystemic	3,416	24.6%
Other basic research	428	3.08%
Total	13,884	100.00%

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

Translational and applied research	Number of uses	Percentage
Human Cancer	1	0.19%
Human Cardiovascular Disorders	1	0.19%
Human Nervous and Mental Disorders	1	0.19%
Human Respiratory Disorders	6	1.15%
Human Sensory Organ Disorders (skin, eyes and ears)	513	98.28%
Total	522	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	1,071		1,071
Total	1,071		1,071

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

Severity	Number of uses	Percentage
Mild [up to and including]	467	43.6%
Moderate	604	56.4%
Total	1,071	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	203	18.95%
Genetically altered with a harmful phenotype	868	81.05%
Total	1,071	100.00%

Norway

Noway: Narrative 2020

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

From 2020 all animals used in approved projects are reported. Before 2020 the number of used animals in 5-10 % of the approved projects were not reported.

There has been a slight decrease in the use of mammals for scientific purposes the last 3 years, but the number varies among species. The number of pigs and dogs was higher in 2020 than in 2019.

- In 2019 466 pigs were reported, while the number in 2020 was 696. Of these 696 pigs, 490 were used in terminal procedures. The remaining 206 pigs were used in procedures of mild severity, of which 194 were used in the testing of iron supplement in pig feed.

- In 2019 66 dogs were reported, while the number in 2020 was 201. 10 of these were used in terminal procedures. The remaining 191 dogs were used in procedures of mild severity, mainly blood sampling.

- The general trend over several years is a slight decline in the use of rats and an increase in the use of mice followed by a decline from 2018 till 2020. The reason for this decrease in the use of traditional lab animals is not clear, but for 2020 it might be a result of the corona pandemic and university lockdowns.

- Other rodents dropped to one third from 2019 till 2020, from 1,572 to 568. This is due to field projects with wild rodent species in 2018 which ended in 2019.

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

- The number of fish used in procedures in 2020 was around two million. This is a small increase from the three previous years. Normally the number of fish varies significantly from one year to another, due to variation of large projects in the fish farms.

- The purpose “preservation of species” has been used more frequently in 2020 than in 2019 while the number of projects with the purpose “protection of the natural environment” has decreased. These changes are probably due to research needs and financial opportunities that vary over years.

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 2019.

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

- We lecture about 3Rs in various meetings with researchers and user establishments.
- Due to a general ban on mink farming in Norway which will be effective from 2025, we have initiated a dialogue with a research group which uses minks in nutritional studies in order to find alternative models.
- We have requested from the Norwegian National Committee an evaluation of the possible alternatives to using mice for the testing of food samples and patient serum for botulinum toxin. We are in a dialogue with the lab performing these tests in Norway with the aim of replacing the use of mice with a chemical method.
- We have requested from the Norwegian National committee an evalution of the use of egg laying hens for the production of IgY antibodies without the need for blood sampling.
- We have requested from the Norwegian National committe an evaluation of «best practice» in experiments using cranial implants on rats and mice.
- We have implemented the mandatory use of multimodal analgesia for all surgical procedures on rats and mice. (General anaesthesia, local anaesthesia, preemptive and postoperative analgesia, preferrably using both NSAIDs and opioids). Removal of one or more components must be scientifically justified.
- We have also an extensive dialog with the applicant while evaluating the application, often resulting in refinements and sometimes also reductions.

All these efforts are 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.

For the group «Other mammals» 541 animals have been reported used in 2020. The distribution in species is like this:

186	whales
22	deer
83	seals
65	mooses
59	reindeer
126	bats

The main purpose of these kind of experiments is tagging of the animals (except bats) and tracking their movements. Other purposes include blood sampling and biopsies.

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 2020

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	,	2.98%
Rats	3,344	0.24%
Guinea-Pigs	296	0.02%
Hamsters (Syrian)	15	0%
Other rodents	568	0.04%
Rabbits	8	0%
Dogs	200	0.01%
Other carnivores	125	0.01%
Horses, donkeys and cross-breeds	54	0%
Pigs	696	0.05%
Sheep	712	0.05%
Cattle	14	0%
Other mammals	537	0.04%
Domestic fowl	1,298	0.09%
Other birds	11,435	0.81%
Reptiles	27	0%
Xenopus	13	0%
Zebra fish	37,094	2.63%
Other fish	1,311,675	93.02%
Total	1,410,152	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	1,026,325	72.78%
Animals born in the EU but not at a registered breeder	382,774	27.14%
Animals born in rest of Europe	723	0.05%
Animals born in rest of world	330	0.02%
Total	1,410,152	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	42,041	116	42,157
Rats	3,344		3,344
Guinea-Pigs	296		296
Hamsters (Syrian)	15		15
Other rodents	568		568
Rabbits	8		8
Dogs	200	1	201
Other carnivores	125		125
Horses, donkeys and cross-breeds	54	5	59
Pigs	696		696
Sheep	712	24	736
Cattle	14		14
Other mammals	537	4	541
Domestic fowl	1,298		1,298
Other birds	11,435		11,435
Reptiles	27		27
Xenopus	13		13
Zebra fish	3,7094	814	37,908
Other fish	1,311,675	490	1,312,165
Total	1,410,152	1,454	1,411,606

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	401,497	28.44%
Translational and applied research	838,268	59.38%
Regulatory use and Routine production	36,455	2.58%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	106,211	7.52%
Preservation of species	27,913	1.98%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	1,262	0.09%
Total	1,411,606	100.00%

Basic research related uses

Basic research	Number of uses	Percentage
Oncology	8,122	2.02%
Cardiovascular Blood and Lymphatic System	5,447	1.36%
Nervous System	37,177	9.26%
Respiratory System	823	0.2%
Gastrointestinal System including Liver	4,200	1.05%
Musculoskeletal System	1,404	0.35%
Immune System	28,302	7.05%
Urogenital/Reproductive System	1,168	0.29%
Sensory Organs (skin, eyes and ears)	1,842	0.46%
Endocrine System/Metabolism	5,831	1.45%
Multisystemic	6,292	1.57%
Ethology / Animal Behaviour /Animal Biology	300,758	74.91%

Other basic research	131	0.03%
Total	401,497	100.00%

Translational and applied research related uses

Translational and applied research	Number of uses	Percentage
Human Cancer	6,412	0.76%
Human Infectious Disorders	2,702	0.32%
Human Cardiovascular Disorders	1,687	0.2%
Human Nervous and Mental Disorders	1,862	0.22%
Human Respiratory Disorders	1	0%
Human Gastrointestinal Disorders including Liver	40	0%
Human Musculoskeletal Disorders	153	0.02%
Human Immune Disorders	152	0.02%
Human Urogenital/Reproductive Disorders	1	0%
Human Sensory Organ Disorders (skin, eyes and ears)	80	0.01%
Human Endocrine/Metabolism Disorders	660	0.08%
Other Human Disorders	54	0.01%
Animal Diseases and Disorders	250,865	29.93%
Animal Welfare	572,583	68.31%
Diagnosis of diseases	236	0.03%
Non-regulatory toxicology and ecotoxicology	780	0.09%
Total	838,268	100.00%

Regulatory uses and Routine production

Regulatory uses and Routine production	Number of uses	Percentage
Quality control (incl batch safety and potency testing)	22,160	60.79%
Toxicity and other safety testing including pharmacology	3,517	9.65%
Routine production	10,778	29.57%
Total	36,455	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	15,443	69.69%
Batch potency testing	5,732	25.87%
Other quality controls	985	4.44%
Total	22,160	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)	480	13.65%
Ecotoxicity	210	5.97%
Target animal safety	2,824	80.3%
Other toxicity/safety testing	3	0.09%
Total	3,517	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	210	100.00%
Total	210	100.00%

Regulatory uses by type of legislation

Type of legislation	Number of uses	Percentage
Legislation on medicinal products for human use	401	1.56%
Legislation on medicinal products for veterinary use and their residues	25,063	97.61%
Other legislation	213	0.83%
Total	25,677	100.00%

Regulatory uses by origin of regulatory requirement

Origin of legislative requirement	Number of uses	Percentage
Legislation satisfying EU requirements	25,674	99.99%
Legislation satisfying Non-EU requirements only	3	0.01%
Total	25,677	100.00%

Routine production uses by product type

Product type	Number of uses	Percentage
Other product types	10,778	100.00%
Total	10,778	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	1,410,152	99.9%
Yes	1,454	0.1%
Total	1,411,606	100.00%

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

Severity	Number of uses	Percentage
Non-recovery	8,644	0.61%
Mild [up to and including]	844,312	59.81%
Moderate	482,590	34.19%
Severe	76,060	5.39%
Total	1,411,606	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	1,352,928	95.84%
Genetically altered without a harmful phenotype	53830	3.81%
Genetically altered with a harmful phenotype	4,848	0.34%
Total	1,411,606	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	1,749		1,749
Zebra fish	287		287
Total	2036		2,036

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

Severity	Number of uses	Percentage
Non-recovery	220	10.81%
Mild [up to and including]	1,056	51.87%
Moderate	742	36.44%
Severe	18	0.88%
Total	2,036	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	1,545	75.88%
Genetically altered with a harmful phenotype	491	24.12%
Total	2,036	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	209	11.02%
Nervous System	239	12.6%
Gastrointestinal System including Liver	943	49.71%
Musculoskeletal System	209	11.02%
Immune System	56	2.95%
Multisystemic	241	12.7%
Total	1,897	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	139	100.00%
Total	139	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	6,316		6,316
Rats	11		11
Zebra fish	272	400	672
Other fish	1,400		1,400
Total	7,999	400	8,399

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

Severity	Number of uses	Percentage
Mild [up to and including]	3,990	47.51%
Moderate	3,709	44.16%
Severe	700	8.33%
Total	8,399	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	5,071	60.38%
Genetically altered with a harmful phenotype	3,328	39.62%
Total	8,399	100.00%

VII Member State comparative tables for 2020

Introduction

Based on the recalculated Member State data, three comparative tables are provided for 2020 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**

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) (2020)

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE
Mammals															
Rodents															
Mice	151,446	216,117	407	3,651	50,213	1,014,753	144,681	1,864	21,614	362,610	54,739	913,109	28,507	57,669	113,209
Rats	3,369	12,343	1,526	0	15,695	130,480	33,028	669	3,345	36,448	10,458	138,180	5,282	28,728	12,330
Guinea-Pigs	107	11,656	16	0	1,325	11,226	2,249	0	1	8,720	8	42,813	121	2,634	228
Hamsters (Syrian)	242	2,726	0	0	0	1,984	108	0	0	713	64	8,247	0	48	8
Hamsters (Chinese)	0	0	0	0	15	24	0	0	0	0	0	110	0	0	0
Mongolian gerbil	63	14	0	0	13	2,346	0	0	0	36	0	342	0	0	0
Other rodents	22	194	140	0	787	14,548	0	0	0	202	4,745	411	0	0	59
Rabbits															
Rabbits	1,250	70,724	203	90	6,613	69,718	2,344	52	192	17,336	92	142,318	148	1,524	1,043
Carnivores															
Cats	7	245	50	0	79	364	6	0	0	234	138	413	0	9	0
Dogs	143	428	0	0	215	1,361	527	0	0	401	1,210	2,385	0	427	24
Ferrets	0	0	0	0	56	155	0	0	0	109	0	169	0	0	186
Other carnivores	0	0	0	0	0	231	5,948	0	0	48	160	6	0	0	0
Farm animals															
Horses, donkeys and cross-breeds	98	162	0	0	145	2,000	11	0	0	219	56	164	0	12	238
Pigs	2,216	5,549	34	0	1,631	18,858	8,654	0	70	8,265	766	11,378	2	3,747	129
Goats	21	68	0	0	31	255	27	0	0	109	0	322	0	0	16
Sheep	103	473	320	0	394	7,567	62	0	0	1,511	422	2,280	13	4	1,239
Cattle	558	2,150	30	0	585	7,355	451	1,425	0	1,092	147	1,249	0	4	2,104
Non-human primates															
Prosimians	0	0	0	0	0	3	0	0	0	0	0	51	0	0	0
Marmoset and tamarins	0	0	0	0	0	127	0	0	0	0	0	44	0	0	0
Cynomolgus monkey	0	0	0	0	32	1,405	0	0	0	264	0	2,037	0	0	0
Rhesus monkey	0	6	0	0	4	39	0	0	0	0	0	37	0	2	0
Vervets Chlorocebus spp.	0	0	0	0	0	0	0	0	0	0	0	34	0	0	0
Baboons	0	0	0	0	0	6	0	0	0	0	0	47	0	0	0
Other mammals															
Other mammals	83	55	0	0	112	1,826	35	0	0	47	134	174	0	0	1
Birds															
Domestic fowl	3,658	40,870	4,000	0	20,100	17,682	621	79	1,690	129,061	5,033	74,379	2,335	32,597	129
Other birds	519	4,820	144	0	1,999	10,728	390	0	0	6,140	1,082	21,151	0	872	87
Reptiles															
Reptiles	0	14	0	0	460	392	21	0	0	240	0	524	0	0	0
Amphibians															
Rana	0	0	930	0	0	0	792	0	0	0	0	0	0	0	0
Xenopus	74	794	0	0	0	9,727	390	0	0	596	0	1,673	0	0	3
Other amphibians	4,894	54	305	0	0	4,095	6	0	0	5,067	5	322	0	2,200	0
Fish															
Zebra fish	7,197	18,527	0	5	5,228	82,062	7,731	0	678	33,330	6,062	28,245	0	1,861	3,357
Other fish	7,883	5,068	0	0	116,593	83,215	39,745	0	16,595	62,054	27,094	84,431	0	2,222	2,928
Cephalopods															
Cephalopods	0	0	0	0	0	31	0	0	0	970	0	299	0	0	0
Totals															
Total	**183,953**	**393,057**	**8,105**	**3,746**	**222,325**	**1,494,563**	**247,827**	**4,089**	**44,185**	**675,822**	**112,415**	**1,477,344**	**36,408**	**134,560**	**137,318**
%	**2.3**	**5**	**0.1**	**0**	**2.8**	**18.8**	**3.1**	**0.1**	**0.6**	**8.5**	**1.4**	**18.6**	**0.5**	**1.7**	**1.7**

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) (2020)

		IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	Total	%
Mammals																
	Rodents															
	Mice	265,357	2,395	4,775	2,178	0	136,611	42,041	62,679	46,715	4,999	166,567	4,498	6,287	**3,879,691**	**48.9**
	Rats	91,619	842	10	578	0	86,375	3,344	17,917	4,964	1,890	18,369	19	7,347	**665,155**	**8.4**
	Guinea-Pigs	14,017	36	0	0	0	8,509	296	6,325	0	198	396	0	291	**111,172**	**1.4**
	Hamsters (Syrian)	271	0	0	0	0	2,856	15	9	0	64	0	0	0	**17,355**	**0.2**
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	**149**	**0**
	Mongolian gerbil	0	0	0	0	0	109	0	38	0	0	0	0	17	**2,978**	**0**
	Other rodents	376	0	0	0	0	495	568	5,443	114	0	82	0	0	**28,186**	**0.4**
	Rabbits															
	Rabbits	10,060	114	0	2	0	15,337	8	698	14	295	3,166	0	180	**343,521**	**4.3**
	Carnivores															
	Cats	0	0	0	198	0	560	0	1	0	0	147	0	13	**2,464**	**0**
	Dogs	454	0	0	0	0	551	200	18	0	6	366	0	0	**8,716**	**0.1**
	Ferrets	20	0	0	0	0	537	0	0	0	0	18	0	0	**1,250**	**0**
	Other carnivores	0	0	0	0	0	25	125	268	0	0	56	0	0	**6,867**	**0.1**
	Farm animals															
	Horses, donkeys and cross-breeds	0	0	0	0	0	241	54	40	0	0	391	0	0	**3,831**	**0**
	Pigs	1,027	169	0	10	0	8,861	696	550	119	3	767	8	0	**73,509**	**0.9**
	Goats	5	0	0	0	0	99	0	1	0	0	44	0	0	**998**	**0**
	Sheep	80	12	0	0	0	2,076	712	119	0	20	82	0	0	**17,489**	**0.2**
	Cattle	156	0	0	0	0	2,604	14	233	0	0	2,018	0	0	**22,175**	**0.3**
	Non-human primates															
	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	**54**	**0**
	Marmoset and tamarins	0	0	0	0	0	25	0	0	0	0	0	0	0	**196**	**0**
	Cynomolgus monkey	454	0	0	0	0	28	0	0	0	0	0	0	0	**4,220**	**0.1**
	Rhesus monkey	2	0	0	0	0	137	0	0	0	0	0	0	0	**227**	**0**
	Vervets Chlorocebus spp.	0	0	0	0	0	0	0	0	0	0	0	0	0	**34**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0	**53**	**0**
	Other mammals															
	Other mammals	18	0	0	614	0	244	537	505	24	0	364	0	0	**4,773**	**0.1**
Birds																
	Domestic fowl	40,225	0	0	0	0	44,992	1,298	2,004	120	111	1,944	407	402	**423,737**	**5.3**
	Other birds	813	52	0	232	0	17,906	11,435	4,063	0	0	3,738	0	200	**86,371**	**1.1**
Reptiles																
	Reptiles	0	0	0	0	0	360	27	0	0	0	34	0	0	**2,072**	**0**
Amphibians																
	Rana	0	0	0	0	0	0	0	0	0	0	0	0	0	**1,722**	**0**
	Xenopus	144	0	0	0	0	2,641	13	0	38	0	1,713	0	0	**17,806**	**0.2**
	Other amphibians	0	0	0	0	0	74	0	15	0	0	1,256	0	0	**18,293**	**0.2**
Fish																
	Zebra fish	11,592	0	556	0	0	14,225	37,094	6,605	1,423	0	11,550	0	0	**277,328**	**3.5**
	Other fish	6,788	168	0	0	47,490	44,673	1,311,675	4,881	8,032	0	42,504	0	0	**1,914,039**	**24.1**
Cephalopods																
	Cephalopods	333	0	0	0	0	0	0	0	0	0	0	0	0	**1,633**	**0**
Totals																
	Total	**443,811**	**3,788**	**5,341**	**3,812**	**47,490**	**391,151**	**1,410,152**	**112,412**	**61,563**	**7,586**	**255,572**	**4,932**	**14,737**	**7,938,064**	**100**
	%	**5.6**	**0**	**0.1**	**0**	**0.6**	**4.9**	**17.8**	**1.4**	**0.8**	**0.1**	**3.2**	**0.1**	**0.2**	**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) (2020)

		AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE
Mammals																
	Rodents															
	Mice	151,718	216,682	407	3,651	51,285	1,041,769	145,890	1,864	21,614	363,402	54,809	933,171	28,507	57,782	113,209
	Rats	3,369	12,480	1,526	0	16,164	135,897	33,349	669	3,391	36,680	10,458	139,827	5,282	28,728	12,330
	Guinea-Pigs	107	11,656	16	0	1,331	11,365	2,249	0	1	9,028	8	42,841	122	2,778	228
	Hamsters (Syrian)	242	2,726	0	0	0	1,984	111	0	0	713	64	8,322	0	48	8
	Hamsters (Chinese)	0	0	0	0	15	24	0	0	0	0	0	110	0	0	0
	Mongolian gerbil	63	14	0	0	13	2,372	0	0	0	36	0	342	0	0	0
	Other rodents	22	213	140	0	787	14,548	0	0	0	202	4,745	1,037	0	0	59
	Rabbits															
	Rabbits	1,278	70,761	512	90	6,664	70,840	2,344	52	192	19,916	92	143,970	148	1,538	1,043
	Carnivores															
	Cats	7	253	50	0	115	644	6	0	3	779	138	970	0	11	20
	Dogs	176	1,519	0	0	463	2,560	589	0	10	789	1,283	4,047	0	485	64
	Ferrets	0	0	0	0	56	157	0	0	0	109	0	169	0	0	186
	Other carnivores	0	0	0	0	0	231	6,128	0	0	48	160	12	0	0	0
	Farm animals															
	Horses, donkeys and cross-breeds	141	199	0	0	153	2,219	16	0	0	235	114	473	16	17	248
	Pigs	2,219	5,767	34	0	1,643	19,421	8,816	0	78	8,273	772	11,843	2	3,810	129
	Goats	21	69	0	0	36	263	27	0	0	222	0	534	0	0	16
	Sheep	103	503	320	0	700	7,626	67	0	0	1,849	692	2,564	30	4	1,268
	Cattle	567	2,329	30	0	620	7,750	743	1,425	0	2,167	219	1,790	0	7	2,661
	Non-human primates															
	Prosimians	0	0	0	0	0	29	0	0	0	0	0	51	0	0	0
	Marmoset and tamarins	0	0	0	0	0	176	0	0	0	0	0	159	0	0	0
	Cynomolgus monkey	0	0	0	0	32	1,766	0	0	0	475	0	3,570	0	0	0
	Rhesus monkey	0	36	0	0	4	54	0	0	1	0	0	77	0	2	0
	Vervets Chlorocebus spp.	0	0	0	0	0	0	0	0	0	0	0	37	0	0	0
	Baboons	0	0	0	0	0	6	0	0	0	0	0	84	0	0	0
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	18	0	0	0
	Other mammals															
	Other mammals	83	110	0	0	119	1,870	36	0	0	80	134	181	0	0	1
Birds																
	Domestic fowl	3,658	41,115	4,000	0	20,138	18,515	621	79	1,690	129,142	5,039	75,108	2,335	32,597	143
	Other birds	539	4,831	144	0	2,025	10,816	401	0	0	6,259	1,082	21,272	0	872	87
Reptiles																
	Reptiles	0	105	0	0	540	395	24	0	0	240	0	1,638	0	0	0
Amphibians																
	Rana	0	0	930	0	0	0	792	0	0	0	0	0	0	0	0
	Xenopus	100	957	0	0	0	11,021	390	0	0	596	0	2,989	0	0	3
	Other amphibians	4,921	54	305	0	0	4,095	16	0	0	5,067	5	432	0	2,200	0
Fish																
	Zebra fish	7,197	18,527	0	5	5,228	82,096	7,731	0	678	33,330	6,062	28,682	0	3,144	3,357
	Other fish	7,898	5,322	0	0	117,450	86,294	39,781	0	16,691	67,288	27,100	84,936	0	2,522	2,928
Cephalopods																
	Cephalopods	0	0	0	0	0	31	0	0	0	970	0	299	0	0	0
Totals																
	Total	**184,429**	**396,228**	**8,414**	**3,746**	**225,581**	**1,536,834**	**250,127**	**4,089**	**44,349**	**687,895**	**112,976**	**1,511,555**	**36,442**	**136,545**	**137,988**
	%	**2.3**	**4.9**	**0.1**	**0**	**2.8**	**19.1**	**3.1**	**0.1**	**0.6**	**8.5**	**1.4**	**18.8**	**0.5**	**1.7**	**1.7**

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) (2020)

		IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	Total	%
Mammals																
	Rodents															
	Mice	265,595	2,395	4,775	2,223	0	137,737	42,157	62,679	46,719	4,999	167,331	5,290	6,287	**3,933,947**	**48.8**
	Rats	91,778	842	10	578	0	87,061	3,344	17,917	4,965	1,890	18,385	19	7,347	**674,286**	**8.4**
	Guinea-Pigs	14,131	36	0	0	0	8,537	296	6,325	0	198	409	0	291	**111,953**	**1.4**
	Hamsters (Syrian)	271	0	0	0	0	2,856	15	9	0	64	0	0	0	**17,433**	**0.2**
	Hamsters (Chinese)	0	0	0	0	0	0	0	0	0	0	0	0	0	**149**	**0**
	Mongolian gerbil	0	0	0	0	0	109	0	38	0	0	0	0	17	**3,004**	**0**
	Other rodents	376	0	0	0	0	495	568	5,443	116	0	82	0	0	**28,833**	**0.4**
	Rabbits															
	Rabbits	10,915	114	0	2	0	15,373	8	897	14	295	3,181	68	187	**350,494**	**4.4**
	Carnivores															
	Cats	0	0	0	198	0	604	0	1	0	0	147	0	13	**3,959**	**0**
	Dogs	552	0	0	0	0	803	201	23	0	6	494	0	0	**14,064**	**0.2**
	Ferrets	20	0	0	0	0	570	0	0	0	0	18	0	0	**1,285**	**0**
	Other carnivores	0	0	0	0	0	25	125	268	0	0	119	0	0	**7,116**	**0.1**
	Farm animals															
	Horses, donkeys and cross-breeds	15	0	0	0	0	310	59	40	0	2	570	2	0	**4,829**	**0.1**
	Pigs	1,101	169	0	10	0	9,192	696	550	119	3	1,325	8	0	**75,980**	**0.9**
	Goats	25	0	0	0	0	248	0	1	66	0	59	0	0	**1,587**	**0**
	Sheep	396	12	0	0	0	2,278	736	141	0	246	167	2	0	**19,704**	**0.2**
	Cattle	159	0	0	0	0	4,090	14	236	0	3	2,908	0	4	**27,722**	**0.3**
	Non-human primates															
	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	**80**	**0**
	Marmoset and tamarins	4	0	0	0	0	25	0	0	0	0	0	0	0	**364**	**0**
	Cynomolgus monkey	498	0	0	0	0	28	0	0	0	0	4	0	0	**6,373**	**0.1**
	Rhesus monkey	2	0	0	0	0	159	0	0	0	0	19	0	0	**354**	**0**
	Vervets Chlorocebus spp.	0	0	0	0	0	0	0	0	0	0	0	0	0	**37**	**0**
	Baboons	0	0	0	0	0	0	0	0	0	0	0	0	0	**90**	**0**
	Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	**18**	**0**
	Other mammals															
	Other mammals	23	0	0	614	0	244	541	517	24	0	382	0	0	**4,959**	**0.1**
Birds																
	Domestic fowl	40,677	0	0	0	0	45,268	1,298	2,004	120	160	1,988	407	411	**426,513**	**5.3**
	Other birds	917	52	0	232	0	18,046	11,435	4,125	0	8	3,906	0	200	**87,249**	**1.1**
Reptiles																
	Reptiles	0	0	0	0	0	360	27	0	0	0	34	0	0	**3,363**	**0**
Amphibians																
	Rana	0	0	0	0	0	0	0	0	0	0	0	0	0	**1,722**	**0**
	Xenopus	163	0	0	0	0	2,641	13	0	38	0	1,761	0	0	**20,672**	**0.3**
	Other amphibians	0	0	0	0	0	74	0	15	0	0	1,256	0	0	**18,440**	**0.2**
Fish																
	Zebra fish	11,961	0	556	0	0	14,225	37,908	6,605	1,893	0	11,550	0	0	**280,735**	**3.5**
	Other fish	6,962	168	0	0	47,490	44,683	1,312,165	4,881	8,920	0	42,504	0	0	**1,925,983**	**23.9**
Cephalopods																
	Cephalopods	333	0	0	0	0	0	0	0	0	0	0	0	0	**1,633**	**0**
Totals																
	Total	**446,874**	**3,788**	**5,341**	**3,857**	**47,490**	**396,041**	**1,411,606**	**112,715**	**62,994**	**7,874**	**258,599**	**5,796**	**14,757**	**8,054,930**	**100**
	%	**5.5**	**0**	**0.1**	**0**	**0.6**	**4.9**	**17.5**	**1.4**	**0.8**	**0.1**	**3.2**	**0.1**	**0.2**	**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)] (2020)

	Reuse[2)]	AT	BE	BG	CZ	DE	DK	EL	ES	FI	FR	HR	HU	IE	IT	LU	LV	NL	NO	PL	PT	SE	Total	%
Mice	No	14,993	20,766	2,800	10,110	111,373	2,983	6,258	15,892	6,366	78,859	367	263	104	4,378	0	145	5,343	1,749	137	296	7,669	**290,851**	**99.0**
	Yes	0	0	0	1,977	856	39	0	82	0	1	0	5	0	6	0	0	2	0	0	0	2	**2,970**	**1.0**
	Total	**14,993**	**20,766**	**2,800**	**12,087**	**112,229**	**3,022**	**6,258**	**15,974**	**6,366**	**78,860**	**367**	**268**	**104**	**4,384**	**0**	**145**	**5,345**	**1,749**	**137**	**296**	**7,671**	**293,821**	**100.0**
Rats	No	0	119	0	60	911	0	0	61	29	3,880	0	0	0	38	0	0	0	0	0	0	0	**5,098**	**99.2**
	Yes	0	0	0	0	0	0	0	0	0	40	0	0	0	0	0	0	0	0	0	0	0	**40**	**0.8**
	Total	**0**	**119**	**0**	**60**	**911**	**0**	**0**	**61**	**29**	**3,920**	**0**	**0**	**0**	**38**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	5,138	100.0
Hamsters (Syrian)	No	0	259	0	45	0	0	0	0	0	145	0	0	0	0	0	0	0	0	0	0	0	**449**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**259**	**0**	**45**	**0**	**0**	**0**	**0**	**0**	**145**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	449	100.0
Rabbits	No	0	0	0	0	0	0	0	9	0	220	0	48	0	0	0	0	0	0	0	0	0	**277**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**9**	**0**	**220**	**0**	**48**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	277	100.0
Dogs	No	0	0	0	0	0	0	0	0	0	18	0	0	0	0	0	0	0	0	0	0	0	**18**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**18**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	18	100.0
Other carnivores	No	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0	0	0	0	0	**6**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**6**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	6	100.0
Horses, donkeys and cross-breeds	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Yes	0	0	0	0	0	0	0	0	0	10	0	0	0	0	0	0	0	0	0	0	0	**10**	**100.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	10	100.0
Pigs	No	0	0	0	33	98	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**131**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**33**	**98**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	131	100.0
Sheep	No	0	0	0	0	0	0	0	0	0	245	0	0	0	0	0	0	0	0	0	0	0	**245**	**93.2**
	Yes	0	0	0	0	0	0	0	0	0	18	0	0	0	0	0	0	0	0	0	0	0	**18**	**6.8**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**263**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	263	100.0
Cattle	No	0	0	0	0	0	0	0	0	0	20	0	0	0	1	0	0	0	0	0	0	0	**21**	**75.0**
	Yes	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0	0	0	0	0	**7**	**25.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**27**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	28	100.0
Other mammals	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10	0	0	**10**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**10**	**0**	**0**	10	100.0
Domestic fowl	No	0	0	0	70	223	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**293**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**70**	**223**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	293	100.0
Other birds	No	0	0	0	0	183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**183**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**183**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	183	100.0
Reptiles	No	0	0	0	0	0	0	0	0	0	42	0	0	0	0	0	0	0	0	0	0	0	**42**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**42**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	42	100.0
Xenopus	No	0	0	0	0	759	0	0	0	0	60	0	0	0	0	0	0	0	0	0	0	0	**819**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**759**	**0**	**0**	**0**	**0**	**60**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	819	100.0
Other amphibians	No	0	0	0	0	368	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**368**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**0**	**0**	**368**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	368	100.0
Zebra fish	No	4,513	4,157	0	301	58,139	808	0	2,827	520	5,964	41	990	0	1,377	116	0	15	287	0	1,090	6,670	**87,815**	**97.8**
	Yes	0	0	0	0	0	0	0	127	0	20	0	1,335	0	80	0	0	0	0	0	345	65	**1,972**	**2.2**
	Total	**4,513**	**4,157**	**0**	**301**	**58,139**	**808**	**0**	**2,954**	**520**	**5,984**	**41**	**2,325**	**0**	**1,457**	**116**	**0**	**15**	**287**	**0**	**1,435**	**6,735**	89,787	100.0
Other fish	No	250	0	0	398	550	0	0	876	0	0	0	0	0	0	0	0	0	0	0	29	0	**2,103**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**250**	**0**	**0**	**398**	**550**	**0**	**0**	**876**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**29**	**0**	2,103	100.0
All Species	**No**	19,756	25,301	2,800	11,017	172,604	3,791	6,258	19,665	6,915	89,459	408	1,301	104	5,794	116	145	5,358	2,036	147	1,415	14,339	**388,729**	**98.7**
	Yes	**0**	**0**	**0**	**1,977**	**856**	**39**	**0**	**209**	**0**	**96**	**0**	**1,340**	**0**	**86**	**0**	**0**	**2**	**0**	**0**	**345**	**67**	**5,017**	**1.3**
	Total	19,756	25,301	2,800	12,994	173,460	3,830	6,258	19,874	6,915	89,555	408	2,641	104	5,880	116	145	5,360	2,036	147	1,760	14,406	393,746	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] (2020)

	Reuse[2]	AT	BE	DE	DK	EL	ES	FI	FR	HR	IE	IT	NL	NO	PL	PT	SE	SK	Total	%
Mice	No	2,284	14,448	178,586	7,793	2,384	25,062	95	36,833	1,186	491	2,386	5,145	6,316	443	1,345	1,071	318	**286,186**	**97.8**
	Yes	0	17	6,310	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**6,327**	**2.2**
	Total	**2,284**	**14,465**	**184,896**	**7,793**	**2,384**	**25,062**	**95**	**36,833**	**1,186**	**491**	**2,386**	**5,145**	**6,316**	**443**	**1,345**	**1,071**	**318**	**292,513**	**100.0**
Rats	No	0	1,159	1,441	0	0	0	0	5,321	0	0	0	108	11	36	0	0	136	**8,212**	**100.0**
	Yes	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**2**	**0.0**
	Total	**0**	**1,161**	**1,441**	**0**	**0**	**0**	**0**	**5,321**	**0**	**0**	**0**	**108**	**11**	**36**	**0**	**0**	**136**	**8,214**	**100.0**
Dogs	No	0	0	0	0	0	0	0	14	0	0	0	0	0	0	0	0	0	**14**	**100.0**
	Yes	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**	**14**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**14**	**100.0**
Pigs	No	0	0	92	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**92**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**92**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**92**	**100.0**
Zebra fish	No	0	120	523	0	0	0	0	509	0	107	0	70	272	0	0	0	0	**1,601**	**80.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	400	0	0	0	0	**400**	**20.0**
	Total	**0**	**120**	**523**	**0**	**0**	**0**	**0**	**509**	**0**	**107**	**0**	**70**	**672**	**0**	**0**	**0**	**0**	**2,001**	**100.0**
Other fish	No	0	0	394	0	0	0	0	0	0	0	0	0	1,400	0	0	0	0	**1,794**	**100.0**
	Yes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0.0**
	Total	**0**	**0**	**394**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1,400**	**0**	**0**	**0**	**0**	**1,794**	**100.0**
All Species	**No**	**2,284**	**15,727**	**181,036**	**7,793**	**2,384**	**25,062**	**95**	**42,677**	**1,186**	**598**	**2,386**	**5,323**	**7,999**	**479**	**1,345**	**1,071**	**454**	**297,899**	**97.8**
	Yes	**0**	**19**	**6,310**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**400**	**0**	**0**	**0**	**0**	**6,729**	**2.2**
	Total	**2,284**	**15,746**	**187,346**	**7,793**	**2,384**	**25,062**	**95**	**42,677**	**1,186**	**598**	**2,386**	**5,323**	**8,399**	**479**	**1,345**	**1,071**	**454**	**304,628**	**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.

Corrected Member State comparative tables for 2019

Introduction

Based on the recalculated Member State data, three 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**

This section presents the corrected Member State comparative tables for the year 2019. Due to an error, the Polish data were duplicated for 2019, and as a result their 2019 data had to be revised. The duplicate records have been removed resulting. The Public ALURES Statistical EU database has also been updated with the corrected data.

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**	**4.3**	**0.1**	**0**	**2.3**	**17.7**	**2.4**	**0**	**0.5**	**7.3**	**0.9**	**16.9**	**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	74,107	50,555	7,481	159,095	4,179	8,272	1,066,413	**5,385,326**	**52.5**
	Rats	100,936	886	117	717	0	79,937	3,159	23,334	6,273	4,551	15,472	91	8,517	162,227	**954,971**	**9.3**
	Guinea-Pigs	15,849	15	0	0	0	9,108	386	5,901	0	332	428	0	607	6,934	**118,586**	**1.2**
	Hamsters (Syrian)	434	0	0	0	0	684	0	121	0	50	0	0	0	1,583	**12,010**	**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	160	0	0	0	0	12	271	**3,943**	**0**
	Other rodents	642	0	0	0	0	1,066	1,572	5,486	7	0	304	0	0	904	**29,177**	**0.3**
	Rabbits																
	Rabbits	9,703	88	0	6	0	12,797	14	1,054	84	264	2,745	0	178	10,133	**352,777**	**3.4**
	Carnivores																
	Cats	0	0	0	0	0	52	1	12	0	0	288	0	13	28	**2,168**	**0**
	Dogs	542	0	0	0	0	235	22	9	0	0	215	0	0	2,679	**13,067**	**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	58	0	0	55	0	0	343	**4,668**	**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	1,044	208	39	1,144	8	0	4,371	**81,795**	**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	387	0	107	357	40	28	5,573	**21,355**	**0.2**
	Cattle	395	0	0	0	0	1,814	28	140	0	0	717	0	0	6,050	**25,109**	**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	510	3	0	153	0	0	576	**4,835**	**0**
Birds																	
	Domestic fowl	36,361	0	0	0	0	52,287	1,184	6,275	0	228	1,958	127	249	122,681	**513,021**	**5**
	Other birds	718	187	0	80	0	13,723	11,517	6,735	367	0	10,795	0	31	8,378	**116,256**	**1.1**
Reptiles																	
	Reptiles	0	0	0	0	0	1	26	40	0	0	139	0	0	0	**1,972**	**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	368	0	0	2,041	0	0	349	**20,293**	**0.2**
Fish																	
	Zebra fish	10,232	0	349	0	0	7,587	39,085	11,433	4,862	0	14,373	0	0	187,334	**505,760**	**4.9**
	Other fish	38,138	882	0	240	265	37,519	1,164,530	3,697	10,775	0	17,792	55	0	89,291	**2,038,642**	**19.9**
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**	**140,871**	**73,334**	**13,292**	**228,364**	**4,500**	**17,907**	**1,681,383**	**10,260,822**	**100**
	%	**5.3**	**0**	**0.1**	**0**	**0**	**3.7**	**12.4**	**1.4**	**0.7**	**0.1**	**2.2**	**0**	**0.2**	**16.4**	**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**	**2.3**	**17.7**	**2.4**	**0**	**0.5**	**7.2**	**0.9**	**17**	**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	74,128	50,589	7,581	160,174	4,932	8,272	1,066,711	**5,440,961**	**52**
	Rats	101,066	886	117	717	0	80,819	3,160	23,478	6,279	4,571	15,502	94	8,517	163,433	**969,189**	**9.3**
	Guinea-Pigs	16,102	15	0	0	0	9,108	386	5,901	0	332	437	0	607	6,934	**119,394**	**1.1**
	Hamsters (Syrian)	434	0	0	0	0	684	0	121	0	50	0	0	0	1,583	**12,015**	**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	160	0	0	0	0	12	271	**3,951**	**0**
	Other rodents	642	0	0	0	0	1,066	1,572	5,486	7	0	304	0	0	904	**29,399**	**0.3**
	Rabbits																
	Rabbits	11,156	88	0	6	0	12,964	14	1,222	84	264	2,765	51	190	10,190	**363,178**	**3.5**
	Carnivores																
	Cats	0	0	0	0	0	171	1	12	0	0	288	0	13	152	**3,696**	**0**
	Dogs	657	0	0	0	0	550	66	11	0	0	364	0	0	4,255	**20,630**	**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	58	0	0	115	0	0	373	**4,998**	**0**
	Farm animals																
	Horses, donkeys and cross-breeds	15	0	0	0	0	101	139	21	0	2	340	2	0	10,512	**13,378**	**0.1**
	Pigs	1,421	213	0	24	0	11,544	466	1,046	208	39	1,730	8	0	5,043	**86,090**	**0.8**
	Goats	23	0	0	0	0	321	0	13	84	0	53	0	0	83	**2,359**	**0**
	Sheep	294	5	0	0	0	393	517	453	0	246	442	42	28	53,972	**72,521**	**0.7**
	Cattle	397	0	0	0	0	4,207	110	145	0	2	1,621	0	0	6,786	**35,216**	**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	570	3	0	200	0	0	578	**5,217**	**0**
Birds																	
	Domestic fowl	38,578	0	0	0	0	52,430	1,184	6,275	0	283	1,994	127	249	122,766	**516,525**	**4.9**
	Other birds	718	187	0	80	0	13,864	11,570	6,790	422	6	10,810	0	31	8,730	**117,756**	**1.1**
Reptiles																	
	Reptiles	0	0	0	0	0	1	26	40	0	0	139	0	0	0	**8,209**	**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	368	0	0	2,041	0	0	355	**20,894**	**0.2**
Fish																	
	Zebra fish	12,375	0	349	0	0	7,587	39,129	11,433	5,312	0	18,350	0	0	188,244	**513,737**	**4.9**
	Other fish	38,142	882	0	240	265	37,519	1,164,991	3,697	12,125	0	17,873	55	0	91,599	**2,045,990**	**19.5**
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**	**141,428**	**75,360**	**13,616**	**235,766**	**5,311**	**17,919**	**1,752,132**	**10,467,356**	**100**
	%	**5.3**	**0**	**0.1**	**0**	**0**	**3.7**	**12.1**	**1.4**	**0.7**	**0.1**	**2.3**	**0.1**	**0.2**	**16.7**	**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	202	1,217	6,929	6	157,314	**370,710**	**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**	**202**	**1,217**	**7,044**	**6**	**157,679**	**371,757**	**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	6	0	0	0	1	**7**	**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**	**6**	**0**	**0**	**0**	**1**	**7**	**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	36	269	16,022	0	37,875	**126,530**	**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**	**36**	**269**	**16,739**	**0**	**39,111**	**128,503**	**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**	**244**	**1,486**	**22,951**	**6**	**196,362**	**508,076**	**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**	**244**	**1,486**	**23,783**	**6**	**197,963**	**511,104**	**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	405	2,571	19	976	353	282,818	**613,517**	**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**	**405**	**2,571**	**19**	**976**	**353**	**283,267**	619,694	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**	**405**	**2,601**	**19**	**976**	**478**	**352,525**	**699,580**	**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**	**405**	**2,601**	**19**	**976**	**478**	**354,366**	707,169	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.