

EUROPEAN COMMISSION

> Brussels, 5.2.2020 SWD(2020) 10 final

PART 4/5

# COMMISSION STAFF WORKING DOCUMENT

Accompanying the document

# REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017

{COM(2020) 16 final}

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# V.3. Recalculated presentation of Member State data for 2017

# Introduction

Member States submitted statistical data to the Commission grouped by the main categorisation of data attributes provided in the Annex II of Commission Implementing Decision 2012/707/EU (Section C, V.1.-2. of this Staff Working Document). However, the presentation of data at EU level was restructured to allow for an improved understanding of when and how animals are still used in science today: animals (and uses) in relation to research, testing, routine production and education/training separated from animals (and uses) for the creation and maintenance of genetically altered animals.

To allow for a similar presentation and correlation with the EU data for the year 2017, the Member State annual submissions for the year 2017 were recalculated.

The recalculation was made on the basis of the three Parts of this Staff Working Document:

- Numbers of animals used for purposes of research, testing, routine production and education (including training) Part 1 (III.1)
- **Details of all uses** (first and any subsequent reuse) of animals for the purposes of research, testing, routine production and education (including training) Part 2 (III.2)
- Numbers and uses of animals for the creation and maintenance of genetically altered animals in the EU Part 3 (III.3)

The main recalculation rules are explained below. As a result, some of the numbers may differ between the original Member Submission for the year 2017 compared to the corresponding table found in the recalculated report.

# - Part 1 – Numbers of animals used in research and testing

- Excludes records that were indicated as being carried out for the creation of a new genetically altered animal line;
- Excludes records for the purposes of maintenance of established genetically altered animal lines;
- Excludes reuses.
- Part 2 All animal uses for research and testing
  - Excludes records that were indicated as being carried out for the creation of a new genetically altered animal line;
  - Excludes records for the purposes of maintenance of established genetically altered animal lines;
  - Includes both the first use and any subsequent reuse;
  - Excludes legislative information (type and origin of legislative requirement) that is not related to regulatory use. For example, entries for the purposes of "Routine

production" have been submitted with legislative information as this requirement is included in the Commission Implementing Decision 2012/707/EU. However, since the adoption of the Decision, it has become clear that this link between routine production and legislative information is an error and the erroneous legislative data have been removed from purpose category "Routine production". This provides for a more accurate presentation of the type and origin of legislation that results in regulatory testing.

N.B. When products (produced by using of animals such as blood based products) are placed on the market, there may be requirements for testing their purity, efficacy etc. These are reported separately under regulatory use, and therefore linked correctly with the respective legislative information.

- Part 3 Animals (numbers and uses) used for the creation and maintenance of genetically altered animal lines
  - Includes records that were indicated as being carried out for the creation of a new genetically altered animal line;
  - Includes records for the purposes of maintenance of established genetically altered animal lines – other purposes excluded unless carried out for the creation of a new genetically altered animal line;
  - Includes both first and any subsequent reuse.

To reduce the length of the document, only those lines in which data were reported are included in the tables below.

# Member State: Austria, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 169345            | 80.19%     |
| Rats                             | 5309              | 2.51%      |
| Guinea-Pigs                      | 1127              | 0.53%      |
| Other Rodents                    | 998               | 0.47%      |
| Rabbits                          | 10367             | 4.91%      |
| Cats                             | 61                | 0.03%      |
| Dogs                             | 149               | 0.07%      |
| Horses, donkeys and cross-breeds | 349               | 0.17%      |
| Pigs                             | 2040              | 0.97%      |
| Goats                            | 20                | 0.01%      |
| Sheep                            | 139               | 0.07%      |
| Cattle                           | 904               | 0.43%      |
| Other Mammals                    | 102               | 0.05%      |
| Domestic fowl                    | 3895              | 1.84%      |
| Other birds                      | 1810              | 0.86%      |
| Xenopus                          | 941               | 0.45%      |
| Other Amphibians                 | 912               | 0.43%      |
| Zebra fish                       | 8112              | 3.84%      |
| Other Fish                       | 4596              | 2.18%      |
| Total                            | 211176            | 100.00%    |

Numbers of animals used for the first time by species

# 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         | 195266            | 92.47%     |
| Animals born in the EU but not at a registered breeder | 11909             | 5.64%      |
| Animals born in rest of Europe                         | 99                | 0.05%      |
| Animals born in rest of world                          | 3902              | 1.85%      |
| Total  | 211176            | 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

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species                   | First uses | Reuses | Total  |
|----------------------------------|------------|--------|--------|
| Mice                             | 169345     | 563    | 169908 |
| Rats                             | 5309       |        | 5309   |
| Guinea-Pigs                      | 1127       | 27     | 1154   |
| Hamsters (Syrian)                |            | 8      | 8      |
| Mongolian gerbil                 |            | 41     | 41     |
| Other Rodents                    | 998        |        | 998    |
| Rabbits                          | 10367      | 21     | 10388  |
| Cats                             | 61         |        | 61     |
| Dogs                             | 149        | 54     | 203    |
| Horses, donkeys and cross-breeds | 349        | 172    | 521    |
| Pigs                             | 2040       |        | 2040   |
| Goats                            | 20         | 2      | 22     |
| Sheep                            | 139        | 10     | 149    |
| Cattle                           | 904        | 4      | 908    |
| Other Mammals                    | 102        |        | 102    |
| Domestic fowl                    | 3895       |        | 3895   |
| Other birds                      | 1810       | 9      | 1819   |
| Xenopus                          | 941        | 31     | 972    |
| Other Amphibians                 | 912        |        | 912    |
| Zebra fish                       | 8112       |        | 8112   |
| Other Fish                       | 4596       | 34     | 4630   |
| Total                            | 211176     | 976    | 212152 |

#### First use versus reuses

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

# categories of scientific purposes

| Purpose Category   | Number of<br>uses | Percentage |
|--|-------------------|------------|
| Basic Research   | 105109            | 49.54%     |
| Translational and applied research   | 77138             | 36.36%     |
| Regulatory use and Routine production  | 26569             | 12.52%     |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 198               | 0.09%      |
| Preservation of species  | 30                | 0.01%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills          | 3108              | 1.46%      |
| Total  | 212152            | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 21077          | 20.05%     |
| Cardiovascular Blood and Lymphatic System   | 8833           | 8.4%       |
| Nervous System                              | 12522          | 11.91%     |
| Respiratory System                          | 316            | 0.3%       |
| Gastrointestinal System including Liver     | 1997           | 1.9%       |
| Musculoskeletal System                      | 4947           | 4.71%      |
| Immune System                               | 25168          | 23.94%     |
| Urogenital/Reproductive System              | 1128           | 1.07%      |
| Sensory Organs (skin, eyes and ears)        | 1208           | 1.15%      |
| Endocrine System/Metabolism                 | 1304           | 1.24%      |
| Multisystemic                               | 7835           | 7.45%      |
| Ethology / Animal Behaviour /Animal Biology | 5799           | 5.52%      |
| Other basic research                        | 12975          | 12.34%     |
| Total                                       | 105109         | 100.00%    |

# Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 14506          | 18.81%     |
| Human Infectious Disorders                          | 42202          | 54.71%     |
| Human Cardiovascular Disorders                      | 5109           | 6.62%      |
| Human Nervous and Mental Disorders                  | 5487           | 7.11%      |
| Human Respiratory Disorders                         | 285            | 0.37%      |
| Human Gastrointestinal Disorders including Liver    | 151            | 0.2%       |
| Human Musculoskeletal Disorders                     | 260            | 0.34%      |
| Human Immune Disorders                              | 785            | 1.02%      |
| Human Urogenital/Reproductive Disorders             | 201            | 0.26%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 300            | 0.39%      |
| Human Endocrine/Metabolism Disorders                | 1138           | 1.48%      |
| Other Human Disorders                               | 576            | 0.75%      |
| Animal Diseases and Disorders                       | 4816           | 6.24%      |
| Animal Welfare                                      | 542            | 0.7%       |
| Diagnosis of diseases                               | 715            | 0.93%      |
| Non-regulatory toxicology and ecotoxicology         | 65             | 0.08%      |
| Total   | 77138          | 100.00%    |

# Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 25823          | 97.19%     |
| Toxicity and other safety testing including pharmacology | 740            | 2.79%      |
| Routine production                                       | 6              | 0.02%      |
| Total  | 26569          | 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   | 2700           | 10.46%     |
| Pyrogenicity testing   | 9125           | 35.34%     |
| Batch potency testing  | 13554          | 52.49%     |
| Other quality controls   | 444            | 1.72%      |
| Total  | 25823          | 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   | 43             | 5.81%      |
| Neurotoxicity  | 32             | 4.32%      |
| Target animal safety   | 665            | 89.86%     |
| Total  | 740            | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
|   |           |            |

#### 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| 29 - 90 days   | 43        | 100%       |
| Total  | 43        | 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 | 25864          | 97.37%     |
| Medical devices legislation                     | 2              | 0.01%      |
| Plant protection product legislation            | 665            | 2.5%       |
| Other legislation                               | 32             | 0.12%      |
| Total   | 26563          | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement               | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements          | 23031          | 86.7%      |
| Legislation satisfying Non-EU requirements only | 3532           | 13.3%      |
| Total   | 26563          | 100.00%    |

#### Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 6              | 100%       |
| Total                | 6              | 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    | 211176         | 99.54%     |
| Yes   | 976            | 0.46%      |
| Total | 212152         | 100.00%    |

| Uses of animals in research, | tecting  | routine product  | ion and education | (including training)  | by covority |
|------------------------------|----------|------------------|-------------------|-----------------------|-------------|
| Uses of animals in research, | iesting, | i outine product | lon and Education | i (including training | by sevenity |

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 5087           | 2.4%       |
| Mild [up to and including] | 125863         | 59.33%     |
| Moderate                   | 60095          | 28.33%     |
| Severe                     | 21107          | 9.95%      |
| Total                      | 212152         | 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                         | 135474         | 63.86%     |
| Genetically altered without a harmful phenotype | 56923          | 26.83%     |
| Genetically altered with a harmful phenotype    | 19755          | 9.31%      |
| Total   | 212152         | 100.00%    |

# Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 14373      |        | 14373 |
| Zebra fish     | 8185       |        | 8185  |
| Total          | 22558      |        | 22558 |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 20298          | 89.98%     |
| Moderate                   | 2040           | 9.04%      |
| Severe                     | 220            | 0.98%      |
| Total                      | 22558          | 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                         | 2545           | 11.28%     |
| Genetically altered without a harmful phenotype | 7059           | 31.29%     |
| Genetically altered with a harmful phenotype    | 12954          | 57.43%     |
| Total   | 22558          | 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                                  | 4329           | 19.19%     |
| Cardiovascular Blood and Lymphatic System | 1439           | 6.38%      |
| Nervous System                            | 4069           | 18.04%     |
| Gastrointestinal System including Liver   | 232            | 1.03%      |
| Immune System                             | 115            | 0.51%      |
| Endocrine System/Metabolism               | 390            | 1.73%      |
| Multisystemic                             | 4970           | 22.03%     |
| Other basic research                      | 7014           | 31.09%     |
| Total                                     | 22558          | 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           | 28632      |        | 28632      |
| Rats           | 729        |        | 729        |
| Total          | 29361      |        | 29361      |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 66             | 0.22%      |
| Mild [up to and including] | 28861          | 98.3%      |
| Moderate                   | 381            | 1.3%       |
| Severe                     | 53             | 0.18%      |
| Total                      | 29361          | 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                         | 7912           | 26.95%     |
| Genetically altered without a harmful phenotype | 18527          | 63.1%      |
| Genetically altered with a harmful phenotype    | 2922           | 9.95%      |
| Total   | 29361          | 100.00%    |

# Member State: Belgium, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 306605            | 60.46%     |
| Rats                             | 23207             | 4.58%      |
| Guinea-Pigs                      | 15539             | 3.06%      |
| Hamsters (Syrian)                | 1147              | 0.23%      |
| Mongolian gerbil                 | 174               | 0.03%      |
| Other Rodents                    | 115               | 0.02%      |
| Rabbits                          | 57849             | 11.41%     |
| Cats                             | 53                | 0.01%      |
| Dogs                             | 334               | 0.07%      |
| Ferrets                          | 26                | 0.01%      |
| Horses, donkeys and cross-breeds | 135               | 0.03%      |
| Pigs                             | 4847              | 0.96%      |
| Goats                            | 77                | 0.02%      |
| Sheep                            | 628               | 0.12%      |
| Cattle                           | 1354              | 0.27%      |
| Rhesus monkey                    | 9                 | 0%         |
| Other Mammals                    | 77                | 0.02%      |
| Domestic fowl                    | 39661             | 7.82%      |
| Other birds                      | 6887              | 1.36%      |
| Reptiles                         | 42                | 0.01%      |
| Xenopus                          | 866               | 0.17%      |
| Other Amphibians                 | 71                | 0.01%      |
| Zebra fish                       | 23912             | 4.71%      |
| Other Fish                       | 23538             | 4.64%      |
| Total                            | 507153            | 100.00%    |

Numbers of animals used for the first time by species

# 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         | 483302            | 95.3%      |
| Animals born in the EU but not at a registered breeder | 19519             | 3.85%      |
| Animals born in rest of Europe                         | 903               | 0.18%      |
| Animals born in rest of world                          | 3420              | 0.67%      |
| Total  | 507144            | 100.00%    |

# Source of non-human primates

| NHP Source (origin)                            | Number of animals | Percentage |
|--|-------------------|------------|
| Animals born at a registered breeder within EU | 9                 | 100%       |
| Total  | 9                 | 100.00%    |

# Generation of non-human primates

| NHP Generation | Number of animals | Percentage |
|----------------|-------------------|------------|
| F2 or greater  | 9                 | 100%       |
| Total          | 9                 | 100.00%    |

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

|                                  |            | _      |        |
|----------------------------------|------------|--------|--------|
| Animal species                   | First uses | Reuses | Total  |
| Mice                             | 306605     | 314    | 306919 |
| Rats                             | 23207      | 397    | 23604  |
| Guinea-Pigs                      | 15539      | 2      | 15541  |
| Hamsters (Syrian)                | 1147       |        | 1147   |
| Mongolian gerbil                 | 174        |        | 174    |
| Other Rodents                    | 115        |        | 115    |
| Rabbits                          | 57849      | 39     | 57888  |
| Cats                             | 53         | 8      | 61     |
| Dogs                             | 334        | 1522   | 1856   |
| Ferrets                          | 26         |        | 26     |
| Horses, donkeys and cross-breeds | 135        | 99     | 234    |
| Pigs                             | 4847       | 123    | 4970   |
| Goats                            | 77         | 1      | 78     |
| Sheep                            | 628        | 38     | 666    |
| Cattle                           | 1354       | 204    | 1558   |
| Rhesus monkey                    | 9          | 35     | 44     |
| Other Mammals                    | 77         | 63     | 140    |
| Domestic fowl                    | 39661      | 13     | 39674  |
| Other birds                      | 6887       | 251    | 7138   |
| Reptiles                         | 42         | 139    | 181    |
| Xenopus                          | 866        | 52     | 918    |
| Other Amphibians                 | 71         | 252    | 323    |
| Zebra fish                       | 23912      |        | 23912  |
| Other Fish                       | 23538      | 489    | 24027  |
| Total                            | 507153     | 4041   | 511194 |

#### First use versus reuses

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

# categories of scientific purposes

| Purpose Category   | Number of<br>uses | Percentage |
|--|-------------------|------------|
| Basic Research   | 243476            | 47.63%     |
| Translational and applied research   | 116957            | 22.88%     |
| Regulatory use and Routine production  | 141853            | 27.75%     |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 706               | 0.14%      |
| Preservation of species  | 151               | 0.03%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills          | 8051              | 1.57%      |
| Total  | 511194            | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 49489          | 20.33%     |
| Cardiovascular Blood and Lymphatic System   | 10890          | 4.47%      |
| Nervous System                              | 37566          | 15.43%     |
| Respiratory System                          | 3403           | 1.4%       |
| Gastrointestinal System including Liver     | 14181          | 5.82%      |
| Musculoskeletal System                      | 4058           | 1.67%      |
| Immune System                               | 68939          | 28.31%     |
| Urogenital/Reproductive System              | 5450           | 2.24%      |
| Sensory Organs (skin, eyes and ears)        | 4674           | 1.92%      |
| Endocrine System/Metabolism                 | 10658          | 4.38%      |
| Multisystemic                               | 2599           | 1.07%      |
| Ethology / Animal Behaviour /Animal Biology | 14701          | 6.04%      |
| Other basic research                        | 16868          | 6.93%      |
| Total                                       | 243476         | 100.00%    |

# Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 12720          | 10.88%     |
| Human Infectious Disorders                          | 15691          | 13.42%     |
| Human Cardiovascular Disorders                      | 1573           | 1.34%      |
| Human Nervous and Mental Disorders                  | 28677          | 24.52%     |
| Human Respiratory Disorders                         | 5945           | 5.08%      |
| Human Gastrointestinal Disorders including Liver    | 977            | 0.84%      |
| Human Musculoskeletal Disorders                     | 783            | 0.67%      |
| Human Immune Disorders                              | 2039           | 1.74%      |
| Human Urogenital/Reproductive Disorders             | 503            | 0.43%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 5441           | 4.65%      |
| Human Endocrine/Metabolism Disorders                | 3722           | 3.18%      |
| Other Human Disorders                               | 40             | 0.03%      |
| Animal Diseases and Disorders                       | 17918          | 15.32%     |
| Animal Welfare                                      | 3525           | 3.01%      |
| Diagnosis of diseases                               | 4292           | 3.67%      |
| Non-regulatory toxicology and ecotoxicology         | 13111          | 11.21%     |
| Total   | 116957         | 100.00%    |

# Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 68615          | 48.37%     |
| Other efficacy and tolerance testing                     | 17201          | 12.13%     |
| Toxicity and other safety testing including pharmacology | 4133           | 2.91%      |
| Routine production                                       | 51904          | 36.59%     |
| Total  | 141853         | 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   | 8016           | 11.68%     |
| Batch potency testing  | 57716          | 84.12%     |
| Other quality controls   | 2883           | 4.2%       |
| Total  | 68615          | 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  | 1037           | 25.09%     |
| Repeated dose toxicity   | 672            | 16.26%     |
| Reproductive toxicity  | 290            | 7.02%      |
| Developmental toxicity   | 11             | 0.27%      |
| Neurotoxicity  | 20             | 0.48%      |
| Kinetics   | 399            | 9.65%      |
| Ecotoxicity  | 1418           | 34.31%     |
| Safety testing in food and feed area                                       | 150            | 3.63%      |
| Target animal safety   | 136            | 3.29%      |
| Total  | 4133           | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 50        | 4.82%      |
| Non lethal methods  | 987       | 95.18%     |
| Total   | 1037      | 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<br>uses | Percentage |
|---|-------------------|------------|
| up to 28 days   | 505               | 75.15%     |
| 29 - 90 days  | 42                | 6.25%      |
| > 90 days   | 125               | 18.6%      |
| Total   | 672               | 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   | 1202           | 84.77%     |
| Chronic toxicity   | 216            | 15.23%     |
| Total  | 1418           | 100.00%    |

#### Regulatory uses by type of legislation

| Type of legislation   | Number of uses | Percentage |
|---|----------------|------------|
| Legislation on medicinal products for human use                         | 62092          | 69.03%     |
| Legislation on medicinal products for veterinary use and their residues | 25534          | 28.39%     |
| Medical devices legislation   | 779            | 0.87%      |
| Industrial chemicals legislation  | 216            | 0.24%      |
| Plant protection product legislation                                    | 52             | 0.06%      |
| Food legislation including food contact material                        | 74             | 0.08%      |
| Other legislation   | 1202           | 1.34%      |
| Total   | 89949          | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 76304          | 84.83%     |
| Legislation satisfying national requirements only [within EU] | 50             | 0.06%      |
| Legislation satisfying Non-EU requirements only               | 13595          | 15.11%     |
| Total   | 89949          | 100.00%    |

#### Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 51804          | 99.81%     |
| Other product types  | 100            | 0.19%      |
| Total                | 51904          | 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    | 507153         | 99.21%     |
| Yes   | 4041           | 0.79%      |
| Total | 511194         | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 25003          | 4.89%      |
| Mild [up to and including] | 275109         | 53.82%     |
| Moderate                   | 128546         | 25.15%     |
| Severe                     | 82536          | 16.15%     |
| Total                      | 511194         | 100.00%    |

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

# Genetic statusNumber of usesPercentageNot genetically altered39518877.31%Genetically altered without a harmful phenotype10021819.6%Genetically altered with a harmful phenotype157883.09%Total511194100.00%

# Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 24875      |        | 24875 |
| Rats           | 222        |        | 222   |
| Zebra fish     | 3544       | 979    | 4523  |
| Total          | 28641      | 979    | 29620 |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 1543           | 5.21%      |
| Mild [up to and including] | 20452          | 69.05%     |
| Moderate                   | 5403           | 18.24%     |
| Severe                     | 2222           | 7.5%       |
| Total                      | 29620          | 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                         | 7096           | 23.96%     |
| Genetically altered without a harmful phenotype | 16407          | 55.39%     |
| Genetically altered with a harmful phenotype    | 6117           | 20.65%     |
| Total   | 29620          | 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                                  | 8598           | 29.33%     |
| Cardiovascular Blood and Lymphatic System | 2572           | 8.77%      |
| Nervous System                            | 5408           | 18.45%     |
| Respiratory System                        | 180            | 0.61%      |
| Gastrointestinal System including Liver   | 2594           | 8.85%      |
| Musculoskeletal System                    | 909            | 3.1%       |
| Immune System                             | 1166           | 3.98%      |
| Urogenital/Reproductive System            | 402            | 1.37%      |
| Sensory Organs (skin, eyes and ears)      | 111            | 0.38%      |
| Endocrine System/Metabolism               | 4203           | 14.34%     |
| Multisystemic                             | 3001           | 10.24%     |
| Other basic research                      | 175            | 0.6%       |
| Total                                     | 29319          | 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 | 259            | 86.05%     |
| Animal Diseases and Disorders      | 42             | 13.95%     |
| Total                              | 301            | 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           | 2249       | 11     | 2260       |
| Total          | 2249       | 11     | 2260       |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 1628           | 72.04%     |
| Moderate                   | 628            | 27.79%     |
| Severe                     | 4              | 0.18%      |
| Total                      | 2260           | 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                         | 5              | 0.22%      |
| Genetically altered without a harmful phenotype | 1701           | 75.27%     |
| Genetically altered with a harmful phenotype    | 554            | 24.51%     |
| Total   | 2260           | 100.00%    |

# Member State: Bulgaria, 2017

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

| Animal species | Number of animals | Percentage |
|----------------|-------------------|------------|
| Mice           | 989               | 11.39%     |
| Rats           | 1892              | 21.79%     |
| Guinea-Pigs    | 1841              | 21.21%     |
| Rabbits        | 568               | 6.54%      |
| Cats           | 30                | 0.35%      |
| Pigs           | 20                | 0.23%      |
| Sheep          | 340               | 3.92%      |
| Cattle         | 15                | 0.17%      |
| Domestic fowl  | 680               | 7.83%      |
| Rana           | 2306              | 26.56%     |
| Total          | 8681              | 100.00%    |

#### Numbers of animals used for the first time by species

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         | 8651              | 99.65%     |
| Animals born in the EU but not at a registered breeder | 30                | 0.35%      |
| Total  | 8681              | 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

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 989        |        | 989   |
| Rats           | 1892       |        | 1892  |
| Guinea-Pigs    | 1841       |        | 1841  |
| Rabbits        | 568        |        | 568   |
| Cats           | 30         |        | 30    |
| Pigs           | 20         |        | 20    |
| Sheep          | 340        |        | 340   |
| Cattle         | 15         |        | 15    |
| Domestic fowl  | 680        |        | 680   |
| Rana           | 2306       |        | 2306  |
| Total          | 8681       |        | 8681  |

First use versus reuses

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

# categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 2246      | 25.87%     |
| Translational and applied research   | 19        | 0.22%      |
| Regulatory use and Routine production  | 4126      | 47.53%     |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 2290      | 26.38%     |
| skills   |           |            |
| Total  | 8681      | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Nervous System                              | 1651           | 73.51%     |
| Gastrointestinal System including Liver     | 11             | 0.49%      |
| Musculoskeletal System                      | 74             | 3.29%      |
| Immune System                               | 42             | 1.87%      |
| Urogenital/Reproductive System              | 45             | 2%         |
| Endocrine System/Metabolism                 | 56             | 2.49%      |
| Multisystemic                               | 62             | 2.76%      |
| Ethology / Animal Behaviour /Animal Biology | 235            | 10.46%     |
| Other basic research                        | 70             | 3.12%      |
| Total                                       | 2246           | 100.00%    |

# Translational and applied research related uses

| Translational and applied research | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Human Nervous and Mental Disorders | 19             | 100%       |
| Total                              | 19             | 100.00%    |

#### Regulatory uses and Routine production

| Regulatory uses and Routine production                  | Number of uses | Percentage |
|---|----------------|------------|
| Quality control (incl batch safety and potency testing) | 2843           | 68.9%      |

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Toxicity and other safety testing including pharmacology | 238            | 5.77%      |
| Routine production                                       | 1045           | 25.33%     |
| Total  | 4126           | 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   | 2843           | 100%       |
| Total  | 2843           | 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  | 38             | 15.97%     |
| Pharmaco-dynamics (incl safety pharmacology)                               | 150            | 63.03%     |
| Ecotoxicity  | 50             | 21.01%     |
| Total  | 238            | 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-<br>acute toxicity testing methods | Number of<br>uses | Percentage |
|---|-------------------|------------|
| LD50, LC50  | 38                | 100%       |
| Total   | 38                | 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 | Number of | Percentage |
|--|-----------|------------|
| 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 |
|--|----------------|------------|
| Chronic toxicity   | 50             | 100%       |
| Total  | 50             | 100.00%    |

Regulatory uses by type of legislation

| Type of legislation                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation on medicinal products for human use | 3081           | 100%       |
| Total   | 3081           | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement      | Number of uses | Percentage |
|--|----------------|------------|
| Legislation satisfying EU requirements | 3081           | 100%       |
| Total                                  | 3081           | 100.00%    |

#### Routine production uses by product type

| Product type        | Number of uses | Percentage |
|---------------------|----------------|------------|
| Other product types | 1045           | 100%       |
| Total               | 1045           | 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    | 8681           | 100%       |
| Total | 8681           | 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] | 4547           | 52.38%     |
| Moderate                   | 3869           | 44.57%     |
| Severe                     | 265            | 3.05%      |
| Total                      | 8681           | 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 | 8681           | 100%       |
| Total                   | 8681           | 100.00%    |

# Part 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

# Member State: Croatia, 2017

Part 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           | 19710             | 70.13%     |
| Rats           | 7638              | 27.18%     |
| Guinea-Pigs    | 16                | 0.06%      |
| Rabbits        | 426               | 1.52%      |
| Pigs           | 2                 | 0.01%      |
| Sheep          | 28                | 0.1%       |
| Cattle         | 30                | 0.11%      |
| Domestic fowl  | 255               | 0.91%      |
| Total          | 28105             | 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         | 27966             | 99.51%     |
| Animals born in the EU but not at a registered breeder | 60                | 0.21%      |
| Animals born in rest of world                          | 79                | 0.28%      |
| Total  | 28105             | 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

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| That use versus reuses           |            |        |       |
|----------------------------------|------------|--------|-------|
| Animal species                   | First uses | Reuses | Total |
| Mice                             | 19710      |        | 19710 |
| Rats                             | 7638       | 62     | 7700  |
| Guinea-Pigs                      | 16         | 5      | 21    |
| Rabbits                          | 426        |        | 426   |
| Horses, donkeys and cross-breeds |            | 25     | 25    |
| Pigs                             | 2          |        | 2     |
| Sheep                            | 28         | 11     | 39    |
| Cattle                           | 30         |        | 30    |
| Domestic fowl                    | 255        |        | 255   |
| Total                            | 28105      | 103    | 28208 |

#### First use versus reuses

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

# categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 22067     | 78.23%     |
| Translational and applied research   | 2531      | 8.97%      |
| Regulatory use and Routine production  | 2182      | 7.74%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 1428      | 5.06%      |
| skills   |           |            |
| Total  | 28208     | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 1345           | 6.1%       |
| Cardiovascular Blood and Lymphatic System   | 378            | 1.71%      |
| Nervous System                              | 1428           | 6.47%      |
| Respiratory System                          | 5721           | 25.93%     |
| Gastrointestinal System including Liver     | 2069           | 9.38%      |
| Musculoskeletal System                      | 30             | 0.14%      |
| Immune System                               | 3764           | 17.06%     |
| Urogenital/Reproductive System              | 234            | 1.06%      |
| Sensory Organs (skin, eyes and ears)        | 688            | 3.12%      |
| Endocrine System/Metabolism                 | 384            | 1.74%      |
| Multisystemic                               | 4582           | 20.76%     |
| Ethology / Animal Behaviour /Animal Biology | 122            | 0.55%      |
| Other basic research                        | 1322           | 5.99%      |
| Total                                       | 22067          | 100.00%    |

# Translational and applied research related uses

| Translational and applied research | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Human Cancer                       | 230            | 9.09%      |
| Human Infectious Disorders         | 1394           | 55.08%     |
| Human Cardiovascular Disorders     | 510            | 20.15%     |
| Human Nervous and Mental Disorders | 214            | 8.46%      |
| Human Musculoskeletal Disorders    | 28             | 1.11%      |

| Translational and applied research          | Number of uses | Percentage |
|---|----------------|------------|
| Human Endocrine/Metabolism Disorders        | 60             | 2.37%      |
| Animal Diseases and Disorders               | 30             | 1.19%      |
| Non-regulatory toxicology and ecotoxicology | 65             | 2.57%      |
| Total                                       | 2531           | 100.00%    |

**Regulatory uses and Routine production** 

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 1585           | 72.64%     |
| Toxicity and other safety testing including pharmacology | 556            | 25.48%     |
| Routine production                                       | 41             | 1.88%      |
| Total  | 2182           | 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   | 262            | 16.53%     |
| Batch potency testing  | 128            | 8.08%      |
| Other quality controls   | 1195           | 75.39%     |
| Total  | 1585           | 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  | 556            | 100%       |
| l | Total  | 556            | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| Non lethal methods  | 556       | 100%       |
| Total   | 556       | 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| No data reported   |           |            |

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                         | 1758           | 82.11%     |
| Legislation on medicinal products for veterinary use and their residues | 383            | 17.89%     |
| Total   | 2141           | 100.00%    |

Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement      | Number of uses | Percentage |
|--|----------------|------------|
| Legislation satisfying EU requirements | 2141           | 100%       |

| Origin of legislative requirement | Number of uses | Percentage |
|-----------------------------------|----------------|------------|
| Total                             | 2141           | 100.00%    |

Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 41             | 100%       |
| Total                | 41             | 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    | 28105          | 99.63%     |
| Yes   | 103            | 0.37%      |
| Total | 28208          | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 2965           | 10.51%     |
| Mild [up to and including] | 8242           | 29.22%     |
| Moderate                   | 11403          | 40.42%     |
| Severe                     | 5598           | 19.85%     |
| Total                      | 28208          | 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                         | 25797          | 91.45%     |
| Genetically altered without a harmful phenotype | 2356           | 8.35%      |
| Genetically altered with a harmful phenotype    | 55             | 0.19%      |
| Total   | 28208          | 100.00%    |

# Part 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     | 230        |        | 230   |
| Total          | 230        |        | 230   |

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

| Severity     | Number of uses | Percentage |
|--------------|----------------|------------|
| Non-recovery | 40             | 17.39%     |
| Moderate     | 190            | 82.61%     |
| Total        | 230            | 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 | 230            | 100%       |
| Total                   | 230            | 100.00%    |

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

No data reported

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

| Translational and applied research          | Number of uses | Percentage |
|---|----------------|------------|
| Non-regulatory toxicology and ecotoxicology | 230            | 100%       |
| Total                                       | 230            | 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           | 96         |        | 96         |
| Total          | 96         |        | 96         |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 96             | 100%       |
| Total                      | 96             | 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 | 96             | 100%       |
| Total   | 96             | 100.00%    |

# Member State: Cyprus, 2017

Part 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           | 1209              | 100%       |
| Total          | 1209              | 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 | 1209              | 100%       |
| Total  | 1209              | 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

Part 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           | 1209       |        | 1209  |
| Total          | 1209       |        | 1209  |

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                     | 839            | 69.4%      |
| Translational and applied research | 370            | 30.6%      |
| Total                              | 1209           | 100.00%    |

#### Basic research related uses

| Basic research                            | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                  | 129            | 15.38%     |
| Cardiovascular Blood and Lymphatic System | 17             | 2.03%      |
| Nervous System                            | 368            | 43.86%     |
| Musculoskeletal System                    | 275            | 32.78%     |
| Sensory Organs (skin, eyes and ears)      | 50             | 5.96%      |
| Total                                     | 839            | 100.00%    |

#### Translational and applied research related uses

| Translational and applied research | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Human Cancer                       | 370            | 100%       |
| Total                              | 370            | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| - Nie dete versied  | -         |            |

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 | Number of | Percentage |
|--|-----------|------------|
| 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    | 1209           | 100%       |
| Total | 1209           | 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] | 1197           | 99.01%     |
| Moderate                   | 12             | 0.99%      |
| Total                      | 1209           | 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                         | 623            | 51.53%     |
| Genetically altered without a harmful phenotype | 586            | 48.47%     |
| Total   | 1209           | 100.00%    |

## Part 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

## Member State: Czechia, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 71954             | 33.92%     |
| Rats                             | 24809             | 11.69%     |
| Guinea-Pigs                      | 1377              | 0.65%      |
| Hamsters (Syrian)                | 15                | 0.01%      |
| Mongolian gerbil                 | 46                | 0.02%      |
| Other Rodents                    | 635               | 0.3%       |
| Rabbits                          | 2031              | 0.96%      |
| Cats                             | 121               | 0.06%      |
| Dogs                             | 437               | 0.21%      |
| Ferrets                          | 1                 | 0%         |
| Other carnivores                 | 1                 | 0%         |
| Horses, donkeys and cross-breeds | 90                | 0.04%      |
| Pigs                             | 1893              | 0.89%      |
| Goats                            | 91                | 0.04%      |
| Sheep                            | 524               | 0.25%      |
| Cattle                           | 1413              | 0.67%      |
| Domestic fowl                    | 21166             | 9.98%      |
| Other birds                      | 4234              | 2%         |
| Reptiles                         | 558               | 0.26%      |
| Xenopus                          | 50                | 0.02%      |
| Other Amphibians                 | 531               | 0.25%      |
| Zebra fish                       | 5414              | 2.55%      |
| Other Fish                       | 74753             | 35.24%     |
| Total                            | 212144            | 100.00%    |

Numbers of animals used for the first time by species

#### 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         | 202387            | 95.4%      |
| Animals born in the EU but not at a registered breeder | 9222              | 4.35%      |
| Animals born in rest of world                          | 535               | 0.25%      |
| Total  | 212144            | 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

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

|                                  |            | _      |        |
|----------------------------------|------------|--------|--------|
| Animal species                   | First uses | Reuses | Total  |
| Mice                             | 71954      | 1042   | 72996  |
| Rats                             | 24809      | 46     | 24855  |
| Guinea-Pigs                      | 1377       | 6      | 1383   |
| Hamsters (Syrian)                | 15         |        | 15     |
| Mongolian gerbil                 | 46         |        | 46     |
| Other Rodents                    | 635        |        | 635    |
| Rabbits                          | 2031       | 102    | 2133   |
| Cats                             | 121        | 11     | 132    |
| Dogs                             | 437        | 200    | 637    |
| Ferrets                          | 1          |        | 1      |
| Other carnivores                 | 1          |        | 1      |
| Horses, donkeys and cross-breeds | 90         | 15     | 105    |
| Pigs                             | 1893       | 554    | 2447   |
| Goats                            | 91         | 6      | 97     |
| Sheep                            | 524        | 394    | 918    |
| Cattle                           | 1413       | 1321   | 2734   |
| Domestic fowl                    | 21166      | 51     | 21217  |
| Other birds                      | 4234       | 26     | 4260   |
| Reptiles                         | 558        |        | 558    |
| Xenopus                          | 50         |        | 50     |
| Other Amphibians                 | 531        |        | 531    |
| Zebra fish                       | 5414       |        | 5414   |
| Other Fish                       | 74753      | 108    | 74861  |
| Total                            | 212144     | 3882   | 216026 |

#### First use versus reuses

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

### categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 74438     | 34.46%     |
| Translational and applied research   | 27640     | 12.79%     |
| Regulatory use and Routine production  | 54133     | 25.06%     |
| Protection of the natural environment in the interests of the health or welfare of human   | 47646     | 22.06%     |
| beings or animals  |           |            |
| Preservation of species  | 6437      | 2.98%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 5732      | 2.65%      |
| skills   |           |            |
| Total  | 216026    | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 7593           | 10.2%      |
| Cardiovascular Blood and Lymphatic System   | 6413           | 8.62%      |
| Nervous System                              | 8951           | 12.02%     |
| Respiratory System                          | 503            | 0.68%      |
| Gastrointestinal System including Liver     | 1727           | 2.32%      |
| Musculoskeletal System                      | 484            | 0.65%      |
| Immune System                               | 11401          | 15.32%     |
| Urogenital/Reproductive System              | 6488           | 8.72%      |
| Sensory Organs (skin, eyes and ears)        | 525            | 0.71%      |
| Endocrine System/Metabolism                 | 3777           | 5.07%      |
| Multisystemic                               | 6311           | 8.48%      |
| Ethology / Animal Behaviour /Animal Biology | 7542           | 10.13%     |
| Other basic research                        | 12723          | 17.09%     |
| Total                                       | 74438          | 100.00%    |

## Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 3761           | 13.61%     |
| Human Infectious Disorders                          | 1309           | 4.74%      |
| Human Cardiovascular Disorders                      | 1308           | 4.73%      |
| Human Nervous and Mental Disorders                  | 2009           | 7.27%      |
| Human Gastrointestinal Disorders including Liver    | 861            | 3.12%      |
| Human Musculoskeletal Disorders                     | 114            | 0.41%      |
| Human Immune Disorders                              | 303            | 1.1%       |
| Human Urogenital/Reproductive Disorders             | 496            | 1.79%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 112            | 0.41%      |
| Human Endocrine/Metabolism Disorders                | 2066           | 7.47%      |
| Other Human Disorders                               | 379            | 1.37%      |
| Animal Diseases and Disorders                       | 3643           | 13.18%     |
| Animal Welfare                                      | 3897           | 14.1%      |
| Diagnosis of diseases                               | 7373           | 26.68%     |
| Non-regulatory toxicology and ecotoxicology         | 9              | 0.03%      |
| Total   | 27640          | 100.00%    |

## Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 12209          | 22.55%     |
| Other efficacy and tolerance testing                     | 326            | 0.6%       |
| Toxicity and other safety testing including pharmacology | 25293          | 46.72%     |
| Routine production                                       | 16305          | 30.12%     |
| Total  | 54133          | 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            | 4.28%      |
| Pyrogenicity testing   | 81             | 0.66%      |
| Batch potency testing  | 11397          | 93.35%     |
| Other quality controls   | 208            | 1.7%       |
| Total  | 12209          | 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  | 4646           | 18.37%     |
| Skin sensitisation   | 637            | 2.52%      |
| Eye irritation/corrosion   | 18             | 0.07%      |
| Repeated dose toxicity   | 1440           | 5.69%      |
| Reproductive toxicity  | 3136           | 12.4%      |
| Developmental toxicity   | 274            | 1.08%      |
| Kinetics   | 144            | 0.57%      |
| Pharmaco-dynamics (incl safety pharmacology)                               | 24             | 0.09%      |
| Ecotoxicity  | 14374          | 56.83%     |
| Safety testing in food and feed area                                       | 438            | 1.73%      |
| Target animal safety   | 50             | 0.2%       |
| Other toxicity/safety testing  | 112            | 0.44%      |
| Total  | 25293          | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 994       | 21.39%     |
| Other lethal methods  | 3652      | 78.61%     |
| Total   | 4646      | 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<br>uses | Percentage |
|---|-------------------|------------|
| up to 28 days   | 482               | 33.47%     |
| 29 - 90 days  | 552               | 38.33%     |
| > 90 days   | 406               | 28.19%     |
| Total   | 1440              | 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   | 12714          | 88.45%     |
| Other ecotoxicity  | 1660           | 11.55%     |
| Total  | 14374          | 100.00%    |

#### Regulatory uses by type of legislation

| Type of legislation  | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Legislation on medicinal products for human use                                      | 2682      | 7.09%      |
| Legislation on medicinal products for veterinary use and their residues              | 12127     | 32.06%     |
| Medical devices legislation  | 719       | 1.9%       |
| Industrial chemicals legislation   | 4345      | 11.49%     |
| Food legislation including food contact material                                     | 170       | 0.45%      |
| Feed legislation including legislation for the safety of target animals, workers and | 525       | 1.39%      |
| environment  |           |            |
| Other legislation  | 17260     | 45.63%     |
| Total  | 37828     | 100.00%    |

### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 28179          | 74.49%     |
| Legislation satisfying national requirements only [within EU] | 9649           | 25.51%     |
| Total   | 37828          | 100.00%    |

#### Routine production uses by product type

| Product type                                | Number of uses | Percentage |
|---|----------------|------------|
| Blood based products                        | 777            | 4.77%      |
| Monoclonal antibody by mouse ascites method | 230            | 1.41%      |
| Other product types                         | 15298          | 93.82%     |
| Total                                       | 16305          | 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    | 212144         | 98.2%      |
| Yes   | 3882           | 1.8%       |
| Total | 216026         | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 13419          | 6.21%      |
| Mild [up to and including] | 93112          | 43.1%      |
| Moderate                   | 93344          | 43.21%     |
| Severe                     | 16151          | 7.48%      |
| Total                      | 216026         | 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                         | 199255         | 92.24%     |
| Genetically altered without a harmful phenotype | 13888          | 6.43%      |
| Genetically altered with a harmful phenotype    | 2883           | 1.33%      |
| Total   | 216026         | 100.00%    |

## Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 9007       | 216    | 9223  |
| Rats           | 2112       |        | 2112  |
| Zebra fish     |            | 14351  | 14351 |
| Total          | 11119      | 14567  | 25686 |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 5695           | 22.17%     |
| Mild [up to and including] | 17018          | 66.25%     |
| Moderate                   | 2973           | 11.57%     |
| Total                      | 25686          | 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 | 25686          | 100%       |
| Total   | 25686          | 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                                  | 1325           | 5.16%      |
| Cardiovascular Blood and Lymphatic System | 16566          | 64.54%     |
| Nervous System                            | 155            | 0.6%       |
| Immune System                             | 1726           | 6.72%      |
| Urogenital/Reproductive System            | 5617           | 21.88%     |
| Other basic research                      | 280            | 1.09%      |
| Total                                     | 25669          | 100.00%    |

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

research purposes

| Translational and applied research | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Animal Welfare                     | 17             | 100%       |
| Total                              | 17             | 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

## Member State: Denmark, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 159566            | 68.84%     |
| Rats                             | 37955             | 16.37%     |
| Guinea-Pigs                      | 2932              | 1.26%      |
| Hamsters (Syrian)                | 282               | 0.12%      |
| Other Rodents                    | 3                 | 0%         |
| Rabbits                          | 2439              | 1.05%      |
| Dogs                             | 69                | 0.03%      |
| Ferrets                          | 4                 | 0%         |
| Other carnivores                 | 935               | 0.4%       |
| Horses, donkeys and cross-breeds | 55                | 0.02%      |
| Pigs                             | 5481              | 2.36%      |
| Goats                            | 1                 | 0%         |
| Sheep                            | 56                | 0.02%      |
| Cattle                           | 3663              | 1.58%      |
| Other Mammals                    | 28                | 0.01%      |
| Domestic fowl                    | 402               | 0.17%      |
| Other birds                      | 408               | 0.18%      |
| Reptiles                         | 269               | 0.12%      |
| Xenopus                          | 75                | 0.03%      |
| Other Amphibians                 | 47                | 0.02%      |
| Zebra fish                       | 1587              | 0.68%      |
| Other Fish                       | 15538             | 6.7%       |
| Total                            | 231795            | 100.00%    |

Numbers of animals used for the first time by species

## 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         | 201515            | 86.94%     |
| Animals born in the EU but not at a registered breeder | 24528             | 10.58%     |
| Animals born in rest of Europe                         | 537               | 0.23%      |
| Animals born in rest of world                          | 5215              | 2.25%      |
| Total  | 231795            | 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

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species                   | First uses | Reuses | Total  |
|----------------------------------|------------|--------|--------|
| Mice                             | 159566     | 856    | 160422 |
| Rats                             | 37955      | 543    | 38498  |
| Guinea-Pigs                      | 2932       | 15     | 2947   |
| Hamsters (Syrian)                | 282        |        | 282    |
| Other Rodents                    | 3          |        | 3      |
| Rabbits                          | 2439       | 4      | 2443   |
| Dogs                             | 69         | 145    | 214    |
| Ferrets                          | 4          |        | 4      |
| Other carnivores                 | 935        | 100    | 1035   |
| Horses, donkeys and cross-breeds | 55         | 64     | 119    |
| Pigs                             | 5481       | 320    | 5801   |
| Goats                            | 1          |        | 1      |
| Sheep                            | 56         | 10     | 66     |
| Cattle                           | 3663       | 14     | 3677   |
| Other Mammals                    | 28         |        | 28     |
| Domestic fowl                    | 402        | 64     | 466    |
| Other birds                      | 408        |        | 408    |
| Reptiles                         | 269        | 20     | 289    |
| Rana                             |            | 4      | 4      |
| Xenopus                          | 75         | 210    | 285    |
| Other Amphibians                 | 47         |        | 47     |
| Zebra fish                       | 1587       |        | 1587   |
| Other Fish                       | 15538      | 68     | 15606  |
| Total                            | 231795     | 2437   | 234232 |

First use versus reuses

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

## categories of scientific purposes

| Purpose Category   | Number of<br>uses | Percentage |
|--|-------------------|------------|
| Basic Research   | 79399             | 33.9%      |
| Translational and applied research   | 121977            | 52.08%     |
| Regulatory use and Routine production  | 19865             | 8.48%      |
| Protection of the natural environment in the interests of the health or welfare of human   | 2875              | 1.23%      |
| beings or animals  |                   |            |
| Preservation of species  | 5637              | 2.41%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 4463              | 1.91%      |
| skills   |                   |            |
| Forensic enquiries   | 16                | 0.01%      |
| Total  | 234232            | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 6469           | 8.15%      |
| Cardiovascular Blood and Lymphatic System   | 4268           | 5.38%      |
| Nervous System                              | 18149          | 22.86%     |
| Respiratory System                          | 2444           | 3.08%      |
| Gastrointestinal System including Liver     | 2478           | 3.12%      |
| Musculoskeletal System                      | 2462           | 3.1%       |
| Immune System                               | 22727          | 28.62%     |
| Urogenital/Reproductive System              | 2220           | 2.8%       |
| Sensory Organs (skin, eyes and ears)        | 77             | 0.1%       |
| Endocrine System/Metabolism                 | 12359          | 15.57%     |
| Multisystemic                               | 485            | 0.61%      |
| Ethology / Animal Behaviour /Animal Biology | 2363           | 2.98%      |
| Other basic research                        | 2898           | 3.65%      |
| Total                                       | 79399          | 100.00%    |

## Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 18429          | 15.11%     |
| Human Infectious Disorders                          | 7665           | 6.28%      |
| Human Cardiovascular Disorders                      | 2016           | 1.65%      |
| Human Nervous and Mental Disorders                  | 31340          | 25.69%     |
| Human Respiratory Disorders                         | 176            | 0.14%      |
| Human Gastrointestinal Disorders including Liver    | 762            | 0.62%      |
| Human Musculoskeletal Disorders                     | 378            | 0.31%      |
| Human Immune Disorders                              | 4959           | 4.07%      |
| Human Urogenital/Reproductive Disorders             | 647            | 0.53%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 336            | 0.28%      |
| Human Endocrine/Metabolism Disorders                | 37015          | 30.35%     |
| Other Human Disorders                               | 9168           | 7.52%      |
| Animal Diseases and Disorders                       | 5708           | 4.68%      |
| Animal Welfare                                      | 1568           | 1.29%      |
| Diagnosis of diseases                               | 1023           | 0.84%      |
| Non-regulatory toxicology and ecotoxicology         | 787            | 0.65%      |
| Total   | 121977         | 100.00%    |

## Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 8139           | 40.97%     |
| Other efficacy and tolerance testing                     | 725            | 3.65%      |
| Toxicity and other safety testing including pharmacology | 10257          | 51.63%     |
| Routine production                                       | 744            | 3.75%      |
| Total  | 19865          | 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   | 2504           | 30.77%     |
| Batch potency testing  | 5601           | 68.82%     |
| Other quality controls   | 34             | 0.42%      |
| Total  | 8139           | 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  | 3968           | 38.69%     |
| Skin irritation/corrosion  | 28             | 0.27%      |
| Skin sensitisation   | 177            | 1.73%      |
| Repeated dose toxicity   | 2205           | 21.5%      |
| Reproductive toxicity  | 935            | 9.12%      |
| Kinetics   | 818            | 7.98%      |
| Pharmaco-dynamics (incl safety pharmacology)                               | 26             | 0.25%      |
| Ecotoxicity  | 2100           | 20.47%     |
| Total  | 10257          | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 3968      | 100%       |
| Total   | 3968      | 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| up to 28 days  | 1382      | 62.68%     |
| 29 - 90 days   | 586       | 26.58%     |
| > 90 days  | 237       | 10.75%     |
| Total  | 2205      | 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   | 120            | 5.71%      |
| Chronic toxicity   | 1800           | 85.71%     |
| Bioaccumulation  | 180            | 8.57%      |
| Total  | 2100           | 100.00%    |

### Regulatory uses by type of legislation

| Type of legislation                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation on medicinal products for human use | 16100          | 84.2%      |
| Industrial chemicals legislation                | 2987           | 15.62%     |
| Other legislation                               | 34             | 0.18%      |
| Total   | 19121          | 100.00%    |

### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 19021          | 99.48%     |
| Legislation satisfying national requirements only [within EU] | 100            | 0.52%      |
| Total   | 19121          | 100.00%    |

#### Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 288            | 38.71%     |
| Other product types  | 456            | 61.29%     |
| Total                | 744            | 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
 231795
 98.96%

 Yes
 2437
 1.04%

 Total
 234232
 100.00%

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 22792          | 9.73%      |
| Mild [up to and including] | 123841         | 52.87%     |
| Moderate                   | 85837          | 36.65%     |
| Severe                     | 1762           | 0.75%      |
| Total                      | 234232         | 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                         | 195240         | 83.35%     |
| Genetically altered without a harmful phenotype | 27228          | 11.62%     |
| Genetically altered with a harmful phenotype    | 11764          | 5.02%      |
| Total   | 234232         | 100.00%    |

## Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 3686       |        | 3686  |
| Pigs           | 2          |        | 2     |
| Total          | 3688       |        | 3688  |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 79             | 2.14%      |
| Mild [up to and including] | 3143           | 85.22%     |
| Moderate                   | 466            | 12.64%     |
| Total                      | 3688           | 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                         | 2803           | 76%        |
| Genetically altered without a harmful phenotype | 679            | 18.41%     |
| Genetically altered with a harmful phenotype    | 206            | 5.59%      |
| Total   | 3688           | 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                                    | 258            | 7.33%      |
| Cardiovascular Blood and Lymphatic System   | 2              | 0.06%      |
| Nervous System                              | 92             | 2.61%      |
| Musculoskeletal System                      | 818            | 23.25%     |
| Endocrine System/Metabolism                 | 273            | 7.76%      |
| Ethology / Animal Behaviour /Animal Biology | 91             | 2.59%      |
| Other basic research                        | 1985           | 56.41%     |
| Total                                       | 3519           | 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 | 169            | 100%       |
| Total                              | 169            | 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           | 29         |        | 29         |
| Total          | 29         |        | 29         |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 29             | 100%       |
| Total                      | 29             | 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 | 29             | 100%       |
| Total  | 29             | 100.00%    |

## Member State: Estonia, 2017

Part 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           | 2168              | 81.38%     |
| Rats           | 296               | 11.11%     |
| Pigs           | 4                 | 0.15%      |
| Cattle         | 16                | 0.6%       |
| Other birds    | 180               | 6.76%      |
| Total          | 2664              | 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         | 2484              | 93.24%     |
| Animals born in the EU but not at a registered breeder | 180               | 6.76%      |
| Total  | 2664              | 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

# Part 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           | 2168       |        | 2168  |
| Rats           | 296        |        | 296   |
| Pigs           | 4          |        | 4     |
| Cattle         | 16         |        | 16    |
| Other birds    | 180        |        | 180   |
| Total          | 2664       |        | 2664  |

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

#### categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 2304      | 86.49%     |
| Translational and applied research   | 210       | 7.88%      |
| Regulatory use and Routine production  | 112       | 4.2%       |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 38        | 1.43%      |
| skills   |           |            |
| Total  | 2664      | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 985            | 42.75%     |
| Cardiovascular Blood and Lymphatic System   | 93             | 4.04%      |
| Nervous System                              | 407            | 17.66%     |
| Gastrointestinal System including Liver     | 32             | 1.39%      |
| Musculoskeletal System                      | 88             | 3.82%      |
| Immune System                               | 99             | 4.3%       |
| Sensory Organs (skin, eyes and ears)        | 32             | 1.39%      |
| Endocrine System/Metabolism                 | 219            | 9.51%      |
| Multisystemic                               | 153            | 6.64%      |
| Ethology / Animal Behaviour /Animal Biology | 180            | 7.81%      |
| Other basic research                        | 16             | 0.69%      |
| Total                                       | 2304           | 100.00%    |

#### Translational and applied research related uses

| Translational and applied research | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Human Respiratory Disorders        | 210            | 100%       |
| Total                              | 210            | 100.00%    |

#### Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Toxicity and other safety testing including pharmacology | 112            | 100%       |
| Total  | 112            | 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 |
|--|----------------|------------|
| Repeated dose toxicity   | 38             | 33.93%     |
| Carcinogenicity  | 74             | 66.07%     |
| Total  | 112            | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
|   |           |            |

#### 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| up to 28 days  | 38        | 100%       |
| Total  | 38        | 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 | 112            | 100%       |
| Total   | 112            | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement      | Number of uses | Percentage |
|--|----------------|------------|
| Legislation satisfying EU requirements | 112            | 100%       |
| Total                                  | 112            | 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    | 2664           | 100%       |
| Total | 2664           | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 122            | 4.58%      |
| Mild [up to and including] | 955            | 35.85%     |
| Moderate                   | 1312           | 49.25%     |
| Severe                     | 275            | 10.32%     |
| Total                      | 2664           | 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                         | 1940           | 72.82%     |
| Genetically altered without a harmful phenotype | 724            | 27.18%     |
| Total   | 2664           | 100.00%    |

## Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 16         |        | 16    |
| Rats           | 72         |        | 72    |
| Total          | 88         |        | 88    |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 10             | 11.36%     |
| Mild [up to and including] | 36             | 40.91%     |
| Moderate                   | 42             | 47.73%     |
| Total                      | 88             | 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                         | 16             | 18.18%     |
| Genetically altered without a harmful phenotype | 72             | 81.82%     |
| Total   | 88             | 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 | 88             | 100%       |
| Total          | 88             | 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           | 394        |        | 394        |
| Total          | 394        |        | 394        |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 394            | 100%       |
| Total                      | 394            | 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 | 394            | 100%       |
| Total   | 394            | 100.00%    |

## Member State: Finland, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 48580             | 49.9%      |
| Rats                             | 13467             | 13.83%     |
| Guinea-Pigs                      | 9                 | 0.01%      |
| Hamsters (Syrian)                | 149               | 0.15%      |
| Other Rodents                    | 690               | 0.71%      |
| Rabbits                          | 223               | 0.23%      |
| Cats                             | 311               | 0.32%      |
| Dogs                             | 3035              | 3.12%      |
| Other carnivores                 | 107               | 0.11%      |
| Horses, donkeys and cross-breeds | 30                | 0.03%      |
| Pigs                             | 632               | 0.65%      |
| Sheep                            | 1319              | 1.35%      |
| Cattle                           | 207               | 0.21%      |
| Other Mammals                    | 1521              | 1.56%      |
| Domestic fowl                    | 8485              | 8.72%      |
| Other birds                      | 404               | 0.41%      |
| Zebra fish                       | 6454              | 6.63%      |
| Other Fish                       | 11729             | 12.05%     |
| Total                            | 97352             | 100.00%    |

Numbers of animals used for the first time by species

#### 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         | 71217             | 73.15%     |
| Animals born in the EU but not at a registered breeder | 23562             | 24.2%      |
| Animals born in rest of Europe                         | 5                 | 0.01%      |
| Animals born in rest of world                          | 2568              | 2.64%      |
| Total  | 97352             | 100.00%    |

#### Source of non-human primates

NHP Source (origin) Number of animals Percentage

No data reported

Generation of non-human primates

NHP GenerationNumber of animalsPercentageNo data reported

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species                   | First uses | Reuses | Total |
|----------------------------------|------------|--------|-------|
| Mice                             | 48580      | 51     | 48631 |
| Rats                             | 13467      |        | 13467 |
| Guinea-Pigs                      | 9          |        | 9     |
| Hamsters (Syrian)                | 149        |        | 149   |
| Other Rodents                    | 690        |        | 690   |
| Rabbits                          | 223        | 4      | 227   |
| Cats                             | 311        |        | 311   |
| Dogs                             | 3035       | 26     | 3061  |
| Other carnivores                 | 107        |        | 107   |
| Horses, donkeys and cross-breeds | 30         | 47     | 77    |
| Pigs                             | 632        |        | 632   |
| Sheep                            | 1319       |        | 1319  |
| Cattle                           | 207        | 9      | 216   |
| Other Mammals                    | 1521       | 12     | 1533  |
| Domestic fowl                    | 8485       |        | 8485  |
| Other birds                      | 404        |        | 404   |
| Zebra fish                       | 6454       |        | 6454  |
| Other Fish                       | 11729      |        | 11729 |
| Total                            | 97352      | 149    | 97501 |

#### First use versus reuses

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

## categories of scientific purposes

| Purpose Category  | Number of | Percentage |
|---|-----------|------------|
|   | uses      |            |
| Basic Research  | 54625     | 56.03%     |
| Translational and applied research  | 33315     | 34.17%     |
| Regulatory use and Routine production   | 7895      | 8.1%       |
| Preservation of species   | 60        | 0.06%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1606      | 1.65%      |
| Skilis  |           |            |
| Total   | 97501     | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 6529           | 11.95%     |
| Cardiovascular Blood and Lymphatic System   | 5098           | 9.33%      |
| Nervous System                              | 10383          | 19.01%     |
| Respiratory System                          | 80             | 0.15%      |
| Gastrointestinal System including Liver     | 545            | 1%         |
| Musculoskeletal System                      | 337            | 0.62%      |
| Immune System                               | 10325          | 18.9%      |
| Urogenital/Reproductive System              | 181            | 0.33%      |
| Sensory Organs (skin, eyes and ears)        | 268            | 0.49%      |
| Endocrine System/Metabolism                 | 900            | 1.65%      |
| Multisystemic                               | 6005           | 10.99%     |
| Ethology / Animal Behaviour /Animal Biology | 7546           | 13.81%     |
| Other basic research                        | 6428           | 11.77%     |
| Total                                       | 54625          | 100.00%    |

## Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 5016           | 15.06%     |
| Human Infectious Disorders                          | 860            | 2.58%      |
| Human Cardiovascular Disorders                      | 662            | 1.99%      |
| Human Nervous and Mental Disorders                  | 19579          | 58.77%     |
| Human Gastrointestinal Disorders including Liver    | 117            | 0.35%      |
| Human Musculoskeletal Disorders                     | 605            | 1.82%      |
| Human Immune Disorders                              | 71             | 0.21%      |
| Human Urogenital/Reproductive Disorders             | 8              | 0.02%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 470            | 1.41%      |
| Human Endocrine/Metabolism Disorders                | 371            | 1.11%      |
| Other Human Disorders                               | 755            | 2.27%      |
| Animal Diseases and Disorders                       | 4384           | 13.16%     |
| Animal Welfare                                      | 226            | 0.68%      |
| Diagnosis of diseases                               | 123            | 0.37%      |
| Non-regulatory toxicology and ecotoxicology         | 68             | 0.2%       |
| Total   | 33315          | 100.00%    |

## Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 3395           | 43%        |
| Other efficacy and tolerance testing                     | 156            | 1.98%      |
| Toxicity and other safety testing including pharmacology | 2868           | 36.33%     |
| Routine production                                       | 1476           | 18.7%      |
| Total  | 7895           | 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  | 3395           | 100%       |
| Total  | 3395           | 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   | 134            | 4.67%      |
| Kinetics   | 1171           | 40.83%     |
| Pharmaco-dynamics (incl safety pharmacology)                               | 1556           | 54.25%     |
| Other toxicity/safety testing  | 7              | 0.24%      |
| Total  | 2868           | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |

#### 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| up to 28 days  | 134       | 100%       |
| Total  | 134       | 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 | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Legislation on medicinal products for human use                                      | 2992      | 46.61%     |
| Legislation on medicinal products for veterinary use and their residues              | 3395      | 52.89%     |
| Feed legislation including legislation for the safety of target animals, workers and | 32        | 0.5%       |
| environment  |           |            |
| Total  | 6419      | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement      | Number of uses | Percentage |
|--|----------------|------------|
| Legislation satisfying EU requirements | 6419           | 100%       |
| Total                                  | 6419           | 100.00%    |

#### Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 296            | 20.05%     |
| Other product types  | 1180           | 79.95%     |
| Total                | 1476           | 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    | 97352          | 99.85%     |
| Yes   | 149            | 0.15%      |
| Total | 97501          | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 8735           | 8.96%      |
| Mild [up to and including] | 46758          | 47.96%     |
| Moderate                   | 33282          | 34.14%     |
| Severe                     | 8726           | 8.95%      |
| Total                      | 97501          | 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                         | 71470          | 73.3%      |
| Genetically altered without a harmful phenotype | 17743          | 18.2%      |
| Genetically altered with a harmful phenotype    | 8288           | 8.5%       |
| Total   | 97501          | 100.00%    |

## Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 4155       |        | 4155  |
| Rats           | 5          |        | 5     |
| Zebra fish     | 699        |        | 699   |
| Total          | 4859       |        | 4859  |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 347            | 7.14%      |
| Mild [up to and including] | 2805           | 57.73%     |
| Moderate                   | 1694           | 34.86%     |
| Severe                     | 13             | 0.27%      |
| Total                      | 4859           | 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                         | 1607           | 33.07%     |
| Genetically altered without a harmful phenotype | 2756           | 56.72%     |
| Genetically altered with a harmful phenotype    | 496            | 10.21%     |
| Total   | 4859           | 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                                  | 262            | 5.63%      |
| Cardiovascular Blood and Lymphatic System | 47             | 1.01%      |
| Nervous System                            | 1522           | 32.71%     |
| Immune System                             | 699            | 15.02%     |
| Endocrine System/Metabolism               | 487            | 10.47%     |
| Multisystemic                             | 1582           | 34%        |
| Other basic research                      | 54             | 1.16%      |
| Total                                     | 4653           | 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                  | 124            | 60.19%     |
| Human Sensory Organ Disorders (skin, eyes and ears) | 7              | 3.4%       |
| Human Endocrine/Metabolism Disorders                | 71             | 34.47%     |
| Other Human Disorders                               | 4              | 1.94%      |
| Total   | 206            | 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           | 215        |        | 215        |
| Total          | 215        |        | 215        |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 207            | 96.28%     |
| Moderate                   | 8              | 3.72%      |
| Total                      | 215            | 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                         | 3              | 1.4%       |
| Genetically altered without a harmful phenotype | 179            | 83.26%     |
| Genetically altered with a harmful phenotype    | 33             | 15.35%     |
| Total   | 215            | 100.00%    |

## Member State: France, 2017

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

| Animal species  | Number of animals | Percentage |
|---|-------------------|------------|
| Mice  | 1011925           | 57.57%     |
| Rats  | 173535            | 9.87%      |
| Guinea-Pigs   | 44976             | 2.56%      |
| Hamsters (Syrian)                                     | 6529              | 0.37%      |
| Hamsters (Chinese)                                    | 167               | 0.01%      |
| Mongolian gerbil                                      | 429               | 0.02%      |
| Other Rodents   | 857               | 0.05%      |
| Rabbits   | 124544            | 7.09%      |
| Cats  | 315               | 0.02%      |
| Dogs  | 2752              | 0.16%      |
| Ferrets   | 148               | 0.01%      |
| Other carnivores                                      | 24                | 0%         |
| Horses, donkeys and cross-breeds                      | 109               | 0.01%      |
| Pigs  | 9261              | 0.53%      |
| Goats   | 311               | 0.02%      |
| Sheep   | 2633              | 0.15%      |
| Cattle  | 956               | 0.05%      |
| Prosimians  | 86                | 0%         |
| Marmoset and tamarins                                 | 131               | 0.01%      |
| Cynomolgus monkey                                     | 2001              | 0.11%      |
| Rhesus monkey   | 26                | 0%         |
| Vervets (Chlorocebus spp.)                            | 33                | 0%         |
| Baboons   | 11                | 0%         |
| Squirrel monkey                                       | 7                 | 0%         |
| Other species of Old World Monkeys (Cercopithecoidea) | 9                 | 0%         |
| Other Mammals   | 18125             | 1.03%      |
| Domestic fowl   | 42582             | 2.42%      |
| Other birds   | 26997             | 1.54%      |
| Reptiles  | 14                | 0%         |
| Rana  | 118               | 0.01%      |
| Xenopus   | 3570              | 0.2%       |
| Other Amphibians                                      | 742               | 0.04%      |
| Zebra fish  | 16199             | 0.92%      |
| Other Fish  | 267714            | 15.23%     |
| Cephalopods   | 1                 | 0%         |
| Total   | 1757837           | 100.00%    |

Numbers of animals used for the first time by species

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         | 1501087           | 85.51%     |
| Animals born in the EU but not at a registered breeder | 152224            | 8.67%      |
| Animals born in rest of Europe                         | 48610             | 2.77%      |
| Animals born in rest of world                          | 53612             | 3.05%      |
| Total  | 1755533           | 100.00%    |

## Source of non-human primates

| NHP Source (origin)                            | Number of animals | Percentage |
|--|-------------------|------------|
| Animals born at a registered breeder within EU | 236               | 10.24%     |
| Animals born in rest of Europe                 | 5                 | 0.22%      |
| Animals born in Asia                           | 130               | 5.64%      |
| Animals born in America                        | 35                | 1.52%      |
| Animals born in Africa                         | 1729              | 75.04%     |
| Animals born elsewhere                         | 169               | 7.34%      |
| Total  | 2304              | 100.00%    |

Generation of non-human primates

| NHP Generation         | Number of animals | Percentage |
|------------------------|-------------------|------------|
| F1                     | 885               | 38.41%     |
| F2 or greater          | 1285              | 55.77%     |
| Self-sustaining colony | 134               | 5.82%      |
| Total                  | 2304              | 100.00%    |

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species  | First uses | Reuses | Total   |
|---|------------|--------|---------|
| Mice  | 1011925    | 16158  | 1028083 |
| Rats  | 173535     | 6078   | 179613  |
| Guinea-Pigs   | 44976      | 58     | 45034   |
| Hamsters (Syrian)                                     | 6529       |        | 6529    |
| Hamsters (Chinese)                                    | 167        |        | 167     |
| Mongolian gerbil                                      | 429        |        | 429     |
| Other Rodents   | 857        | 100    | 957     |
| Rabbits   | 124544     | 2354   | 126898  |
| Cats  | 315        | 552    | 867     |
| Dogs  | 2752       | 1344   | 4096    |
| Ferrets   | 148        |        | 148     |
| Other carnivores                                      | 24         | 3      | 27      |
| Horses, donkeys and cross-breeds                      | 109        | 196    | 305     |
| Pigs  | 9261       | 1085   | 10346   |
| Goats   | 311        | 527    | 838     |
| Sheep   | 2633       | 2763   | 5396    |
| Cattle  | 956        | 821    | 1777    |
| Prosimians  | 86         |        | 86      |
| Marmoset and tamarins                                 | 131        | 93     | 224     |
| Cynomolgus monkey                                     | 2001       | 1278   | 3279    |
| Rhesus monkey   | 26         | 45     | 71      |
| Vervets (Chlorocebus spp.)                            | 33         | 5      | 38      |
| Baboons   | 11         | 21     | 32      |
| Squirrel monkey                                       | 7          |        | 7       |
| Other species of Old World Monkeys (Cercopithecoidea) | 9          |        | 9       |
| Other Mammals   | 18125      | 400    | 18525   |
| Domestic fowl   | 42582      | 562    | 43144   |
| Other birds   | 26997      | 228    | 27225   |
| Reptiles  | 14         | 3448   | 3462    |
| Rana  | 118        |        | 118     |
| Xenopus   | 3570       | 1327   | 4897    |
| Other Amphibians                                      | 742        |        | 742     |
| Zebra fish  | 16199      | 600    | 16799   |
| Other Fish  | 267714     | 360    | 268074  |
| Cephalopods   | 1          |        | 1       |
| Total   | 1757837    | 40406  | 1798243 |

First use versus reuses

## Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

| Purpose Category   | Number of<br>uses | Percentage |
|--|-------------------|------------|
| Basic Research   | 687105            | 38.21%     |
| Translational and applied research   | 477884            | 26.58%     |
| Regulatory use and Routine production  | 574030            | 31.92%     |
| Protection of the natural environment in the interests of the health or welfare of human   | 4918              | 0.27%      |
| beings or animals  |                   |            |
| Preservation of species  | 18786             | 1.04%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 35512             | 1.97%      |
| skills   |                   |            |
| Forensic enquiries   | 8                 | 0%         |
| Total  | 1798243           | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 92211          | 13.42%     |
| Cardiovascular Blood and Lymphatic System   | 32298          | 4.7%       |
| Nervous System                              | 123850         | 18.02%     |
| Respiratory System                          | 12314          | 1.79%      |
| Gastrointestinal System including Liver     | 27363          | 3.98%      |
| Musculoskeletal System                      | 17391          | 2.53%      |
| Immune System                               | 90438          | 13.16%     |
| Urogenital/Reproductive System              | 18745          | 2.73%      |
| Sensory Organs (skin, eyes and ears)        | 5415           | 0.79%      |
| Endocrine System/Metabolism                 | 40474          | 5.89%      |
| Multisystemic                               | 7270           | 1.06%      |
| Ethology / Animal Behaviour /Animal Biology | 161945         | 23.57%     |
| Other basic research                        | 57391          | 8.35%      |
| Total                                       | 687105         | 100.00%    |

## Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 120252         | 25.16%     |
| Human Infectious Disorders                          | 52555          | 11%        |
| Human Cardiovascular Disorders                      | 14990          | 3.14%      |
| Human Nervous and Mental Disorders                  | 46285          | 9.69%      |
| Human Respiratory Disorders                         | 6669           | 1.4%       |
| Human Gastrointestinal Disorders including Liver    | 12366          | 2.59%      |
| Human Musculoskeletal Disorders                     | 13833          | 2.89%      |
| Human Immune Disorders                              | 19048          | 3.99%      |
| Human Urogenital/Reproductive Disorders             | 2240           | 0.47%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 7750           | 1.62%      |
| Human Endocrine/Metabolism Disorders                | 12181          | 2.55%      |
| Other Human Disorders                               | 9642           | 2.02%      |
| Animal Diseases and Disorders                       | 37908          | 7.93%      |
| Animal Welfare                                      | 216            | 0.05%      |
| Diagnosis of diseases                               | 97413          | 20.38%     |
| Plant diseases                                      | 89             | 0.02%      |
| Non-regulatory toxicology and ecotoxicology         | 24447          | 5.12%      |
| Total   | 477884         | 100.00%    |

### Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 201610         | 35.12%     |
| Other efficacy and tolerance testing                     | 83928          | 14.62%     |
| Toxicity and other safety testing including pharmacology | 113238         | 19.73%     |
| Routine production                                       | 175254         | 30.53%     |
| Total  | 574030         | 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   | 20294          | 10.07%     |
| Pyrogenicity testing   | 6191           | 3.07%      |
| Batch potency testing  | 138017         | 68.46%     |
| Other quality controls   | 37108          | 18.41%     |
| Total  | 201610         | 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  | 3294           | 2.91%      |
| Skin irritation/corrosion  | 1754           | 1.55%      |
| Skin sensitisation   | 14019          | 12.38%     |
| Eye irritation/corrosion   | 253            | 0.22%      |
| Repeated dose toxicity   | 24250          | 21.42%     |
| Carcinogenicity  | 2295           | 2.03%      |
| Genotoxicity   | 486            | 0.43%      |
| Reproductive toxicity  | 14165          | 12.51%     |
| Developmental toxicity   | 7483           | 6.61%      |
| Kinetics   | 18338          | 16.19%     |
| Pharmaco-dynamics (incl safety pharmacology)                               | 9821           | 8.67%      |
| Phototoxicity  | 521            | 0.46%      |
| Ecotoxicity  | 13533          | 11.95%     |
| Safety testing in food and feed area                                       | 1570           | 1.39%      |
| Target animal safety   | 171            | 0.15%      |
| Other toxicity/safety testing  | 1285           | 1.13%      |
| Total  | 113238         | 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- |             | Percentage |
|---|-------------|------------|
| acute toxicity testing methods LD50. LC50   | uses<br>702 | 21.31%     |
| Other lethal methods  | 561         | 17.03%     |
| Non lethal methods  | 2031        | 61.66%     |
| Total   | 3294        | 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| up to 28 days  | 12892     | 53.16%     |
| 29 - 90 days   | 6543      | 26.98%     |
| > 90 days  | 4815      | 19.86%     |
| Total  | 24250     | 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   | 10955          | 80.95%     |
| Chronic toxicity   | 1107           | 8.18%      |
| Bioaccumulation  | 846            | 6.25%      |
| Other ecotoxicity  | 625            | 4.62%      |
| Total  | 13533          | 100.00%    |

## Regulatory uses by type of legislation

| Type of legislation  | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Legislation on medicinal products for human use                                      | 226886    | 56.9%      |
| Legislation on medicinal products for veterinary use and their residues              | 55686     | 13.96%     |
| Medical devices legislation  | 25090     | 6.29%      |
| Industrial chemicals legislation   | 12737     | 3.19%      |
| Plant protection product legislation   | 4541      | 1.14%      |
| Biocides legislation   | 757       | 0.19%      |
| Food legislation including food contact material                                     | 698       | 0.18%      |
| Feed legislation including legislation for the safety of target animals, workers and | 72087     | 18.08%     |
| environment  |           |            |
| Other legislation  | 294       | 0.07%      |
| Total  | 398776    | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 392531         | 98.43%     |
| Legislation satisfying national requirements only [within EU] | 1470           | 0.37%      |
| Legislation satisfying Non-EU requirements only               | 4775           | 1.2%       |
| Total   | 398776         | 100.00%    |

#### Routine production uses by product type

| Product type                                | Number of uses | Percentage |
|---|----------------|------------|
| Blood based products                        | 74243          | 42.36%     |
| Monoclonal antibody by mouse ascites method | 44198          | 25.22%     |
| Other product types                         | 56813          | 32.42%     |
| Total                                       | 175254         | 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    | 1757837        | 97.75%     |
| Yes   | 40406          | 2.25%      |
| Total | 1798243        | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 99949          | 5.56%      |
| Mild [up to and including] | 636482         | 35.39%     |
| Moderate                   | 739008         | 41.1%      |
| Severe                     | 322804         | 17.95%     |
| Total                      | 1798243        | 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                         | 1469131        | 81.7%      |
| Genetically altered without a harmful phenotype | 285514         | 15.88%     |
| Genetically altered with a harmful phenotype    | 43598          | 2.42%      |
| Total   | 1798243        | 100.00%    |
|   |                |            |

## Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 36512      | 180    | 36692 |
| Rats           | 3346       |        | 3346  |
| Rabbits        | 306        |        | 306   |
| Zebra fish     | 5080       |        | 5080  |
| Total          | 45244      | 180    | 45424 |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 3145           | 6.92%      |
| Mild [up to and including] | 18783          | 41.35%     |
| Moderate                   | 22237          | 48.95%     |
| Severe                     | 1259           | 2.77%      |
| Total                      | 45424          | 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                         | 16437          | 36.19%     |
| Genetically altered without a harmful phenotype | 23553          | 51.85%     |
| Genetically altered with a harmful phenotype    | 5434           | 11.96%     |
| Total   | 45424          | 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                                    | 2002           | 4.56%      |
| Cardiovascular Blood and Lymphatic System   | 279            | 0.64%      |
| Nervous System                              | 17558          | 39.96%     |
| Gastrointestinal System including Liver     | 713            | 1.62%      |
| Musculoskeletal System                      | 110            | 0.25%      |
| Immune System                               | 1755           | 3.99%      |
| Urogenital/Reproductive System              | 1161           | 2.64%      |
| Sensory Organs (skin, eyes and ears)        | 20             | 0.05%      |
| Endocrine System/Metabolism                 | 234            | 0.53%      |
| Multisystemic                               | 13626          | 31.01%     |
| Ethology / Animal Behaviour /Animal Biology | 2511           | 5.72%      |
| Other basic research                        | 3967           | 9.03%      |
| Total                                       | 43936          | 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  | 91             | 6.12%      |
| Human Cardiovascular Disorders                      | 213            | 14.31%     |
| Human Nervous and Mental Disorders                  | 63             | 4.23%      |
| Human Gastrointestinal Disorders including Liver    | 7              | 0.47%      |
| Human Musculoskeletal Disorders                     | 648            | 43.55%     |
| Human Sensory Organ Disorders (skin, eyes and ears) | 10             | 0.67%      |
| Human Endocrine/Metabolism Disorders                | 321            | 21.57%     |
| Other Human Disorders                               | 100            | 6.72%      |
| Animal Diseases and Disorders                       | 35             | 2.35%      |
| Total   | 1488           | 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           | 69742      |        | 69742      |
| Rats           | 755        |        | 755        |
| Dogs           | 10         |        | 10         |
| Total          | 70507      |        | 70507      |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 48518          | 68.81%     |
| Moderate                   | 19608          | 27.81%     |
| Severe                     | 2381           | 3.38%      |
| Total                      | 70507          | 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 | 66463          | 94.26%     |
| Genetically altered with a harmful phenotype    | 4044           | 5.74%      |
| Total   | 70507          | 100.00%    |

## Member State: Germany, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 1171550           | 65.33%     |
| Rats                             | 245998            | 13.72%     |
| Guinea-Pigs                      | 14349             | 0.8%       |
| Hamsters (Syrian)                | 1217              | 0.07%      |
| Hamsters (Chinese)               | 8                 | 0%         |
| Mongolian gerbil                 | 4154              | 0.23%      |
| Other Rodents                    | 9950              | 0.55%      |
| Rabbits                          | 89147             | 4.97%      |
| Cats                             | 431               | 0.02%      |
| Dogs                             | 1720              | 0.1%       |
| Ferrets                          | 172               | 0.01%      |
| Other carnivores                 | 535               | 0.03%      |
| Horses, donkeys and cross-breeds | 1013              | 0.06%      |
| Pigs                             | 16069             | 0.9%       |
| Goats                            | 195               | 0.01%      |
| Sheep                            | 2832              | 0.16%      |
| Cattle                           | 5842              | 0.33%      |
| Prosimians                       | 12                | 0%         |
| Marmoset and tamarins            | 197               | 0.01%      |
| Cynomolgus monkey                | 2387              | 0.13%      |
| Rhesus monkey                    | 67                | 0%         |
| Baboons                          | 14                | 0%         |
| Squirrel monkey                  | 1                 | 0%         |
| Other Mammals                    | 1259              | 0.07%      |
| Domestic fowl                    | 24463             | 1.36%      |
| Other birds                      | 11339             | 0.63%      |
| Reptiles                         | 351               | 0.02%      |
| Rana                             | 377               | 0.02%      |
| Xenopus                          | 3405              | 0.19%      |
| Other Amphibians                 | 2652              | 0.15%      |
| Zebra fish                       | 87413             | 4.87%      |
| Other Fish                       | 94180             | 5.25%      |
| Total                            | 1793299           | 100.00%    |

Numbers of animals used for the first time by species

## 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         | 1663522           | 92.9%      |
| Animals born in the EU but not at a registered breeder | 98960             | 5.53%      |
| Animals born in rest of Europe                         | 15127             | 0.84%      |
| Animals born in rest of world                          | 13012             | 0.73%      |
| Total  | 1790621           | 100.00%    |

## Source of non-human primates

| NHP Source (origin)                            | Number of animals | Percentage |
|--|-------------------|------------|
| Animals born at a registered breeder within EU | 350               | 13.07%     |
| Animals born in Asia                           | 1699              | 63.44%     |
| Animals born in Africa                         | 628               | 23.45%     |
| Animals born elsewhere                         | 1                 | 0.04%      |
| Total  | 2678              | 100.00%    |

Generation of non-human primates

| NHP Generation         | Number of animals | Percentage |
|------------------------|-------------------|------------|
| F1                     | 338               | 12.62%     |
| F2 or greater          | 1786              | 66.69%     |
| Self-sustaining colony | 554               | 20.69%     |
| Total                  | 2678              | 100.00%    |

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species  |            |        |         |
|---|------------|--------|---------|
| Annuarspecies   | First uses | Reuses | Total   |
| Mice  | 1171550    | 17159  | 1188709 |
| Rats  | 245998     | 4481   | 250479  |
| Guinea-Pigs   | 14349      | 502    | 14851   |
| Hamsters (Syrian)                                     | 1217       | 5      | 1222    |
| Hamsters (Chinese)                                    | 8          |        | 8       |
| Mongolian gerbil                                      | 4154       | 101    | 4255    |
| Other Rodents   | 9950       |        | 9950    |
| Rabbits   | 89147      | 3497   | 92644   |
| Cats  | 431        | 287    | 718     |
| Dogs  | 1720       | 1610   | 3330    |
| Ferrets   | 172        | 24     | 196     |
| Other carnivores                                      | 535        |        | 535     |
| Horses, donkeys and cross-breeds                      | 1013       | 196    | 1209    |
| Pigs  | 16069      | 1214   | 17283   |
| Goats   | 195        | 17     | 212     |
| Sheep   | 2832       | 221    | 3053    |
| Cattle  | 5842       | 490    | 6332    |
| Prosimians  | 12         | 75     | 87      |
| Marmoset and tamarins                                 | 197        | 17     | 214     |
| Cynomolgus monkey                                     | 2387       | 615    | 3002    |
| Rhesus monkey   | 67         | 50     | 117     |
| Vervets (Chlorocebus spp.)                            |            | 15     | 15      |
| Baboons   | 14         |        | 14      |
| Squirrel monkey                                       | 1          |        | 1       |
| Other species of Old World Monkeys (Cercopithecoidea) |            | 12     | 12      |
| Other Mammals   | 1259       | 93     | 1352    |
| Domestic fowl   | 24463      | 457    | 24920   |
| Other birds   | 11339      | 661    | 12000   |
| Reptiles  | 351        | 18     | 369     |
| Rana  | 377        |        | 377     |
| Xenopus   | 3405       | 1141   | 4546    |
| Other Amphibians                                      | 2652       |        | 2652    |
| Zebra fish  | 87413      |        | 87413   |
| Other Fish  | 94180      | 30     | 94210   |
| Total   | 1793299    | 32988  | 1826287 |

First use versus reuses

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

## categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 875421    | 47.93%     |
| Translational and applied research   | 291152    | 15.94%     |
| Regulatory use and Routine production  | 556946    | 30.5%      |
| Protection of the natural environment in the interests of the health or welfare of human   | 8491      | 0.46%      |
| beings or animals  |           |            |
| Preservation of species  | 41156     | 2.25%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 53121     | 2.91%      |
| skills   |           |            |
| Total  | 1826287   | 100.00%    |

## Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 85330          | 9.75%      |
| Cardiovascular Blood and Lymphatic System   | 84382          | 9.64%      |
| Nervous System                              | 194683         | 22.24%     |
| Respiratory System                          | 23256          | 2.66%      |
| Gastrointestinal System including Liver     | 30152          | 3.44%      |
| Musculoskeletal System                      | 16529          | 1.89%      |
| Immune System                               | 183041         | 20.91%     |
| Urogenital/Reproductive System              | 14651          | 1.67%      |
| Sensory Organs (skin, eyes and ears)        | 20387          | 2.33%      |
| Endocrine System/Metabolism                 | 50807          | 5.8%       |
| Multisystemic                               | 42693          | 4.88%      |
| Ethology / Animal Behaviour /Animal Biology | 46171          | 5.27%      |
| Other basic research                        | 83339          | 9.52%      |
| Total                                       | 875421         | 100.00%    |

## Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 124509         | 42.76%     |
| Human Infectious Disorders                          | 17913          | 6.15%      |
| Human Cardiovascular Disorders                      | 15246          | 5.24%      |
| Human Nervous and Mental Disorders                  | 36680          | 12.6%      |
| Human Respiratory Disorders                         | 13197          | 4.53%      |
| Human Gastrointestinal Disorders including Liver    | 13424          | 4.61%      |
| Human Musculoskeletal Disorders                     | 3926           | 1.35%      |
| Human Immune Disorders                              | 11314          | 3.89%      |
| Human Urogenital/Reproductive Disorders             | 4613           | 1.58%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 5491           | 1.89%      |
| Human Endocrine/Metabolism Disorders                | 8031           | 2.76%      |
| Other Human Disorders                               | 1223           | 0.42%      |
| Animal Diseases and Disorders                       | 17368          | 5.97%      |
| Animal Welfare                                      | 6271           | 2.15%      |
| Diagnosis of diseases                               | 2488           | 0.85%      |
| Plant diseases                                      | 69             | 0.02%      |
| Non-regulatory toxicology and ecotoxicology         | 9389           | 3.22%      |
| Total   | 291152         | 100.00%    |

## Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 188089         | 33.77%     |
| Other efficacy and tolerance testing                     | 32991          | 5.92%      |
| Toxicity and other safety testing including pharmacology | 260473         | 46.77%     |
| Routine production                                       | 75393          | 13.54%     |
| Total  | 556946         | 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   | 19382          | 10.3%      |
| Pyrogenicity testing   | 5591           | 2.97%      |
| Batch potency testing  | 161272         | 85.74%     |
| Other quality controls   | 1844           | 0.98%      |
| Total  | 188089         | 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  | 10357          | 3.98%      |
| Skin irritation/corrosion  | 884            | 0.34%      |
| Skin sensitisation   | 8711           | 3.34%      |
| Eye irritation/corrosion   | 171            | 0.07%      |
| Repeated dose toxicity   | 19136          | 7.35%      |
| Carcinogenicity  | 1961           | 0.75%      |
| Genotoxicity   | 3522           | 1.35%      |
| Reproductive toxicity  | 21926          | 8.42%      |
| Developmental toxicity   | 35887          | 13.78%     |
| Neurotoxicity  | 86             | 0.03%      |
| Kinetics   | 31782          | 12.2%      |
| Pharmaco-dynamics (incl safety pharmacology)                               | 79250          | 30.43%     |
| Ecotoxicity  | 38843          | 14.91%     |
| Safety testing in food and feed area                                       | 1721           | 0.66%      |
| Target animal safety   | 3423           | 1.31%      |
| Other toxicity/safety testing  | 2813           | 1.08%      |
| Total  | 260473         | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 4136      | 39.93%     |
| Other lethal methods  | 182       | 1.76%      |
| Non lethal methods  | 6039      | 58.31%     |
| Total   | 10357     | 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| up to 28 days  | 13183     | 68.89%     |
| 29 - 90 days   | 4136      | 21.61%     |
| > 90 days  | 1817      | 9.5%       |
| Total  | 19136     | 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   | 6957           | 17.91%     |
| Chronic toxicity   | 16704          | 43%        |
| Reproductive ecotoxicity   | 904            | 2.33%      |
| Endocrine activity   | 5840           | 15.03%     |
| Bioaccumulation  | 1807           | 4.65%      |
| Other ecotoxicity  | 6631           | 17.07%     |
| Total  | 38843          | 100.00%    |

## Regulatory uses by type of legislation

| Type of legislation  | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Legislation on medicinal products for human use                                      | 340657    | 70.74%     |
| Legislation on medicinal products for veterinary use and their residues              | 23605     | 4.9%       |
| Medical devices legislation  | 12591     | 2.61%      |
| Industrial chemicals legislation   | 50430     | 10.47%     |
| Plant protection product legislation   | 46143     | 9.58%      |
| Biocides legislation   | 2284      | 0.47%      |
| Food legislation including food contact material                                     | 14        | 0%         |
| Feed legislation including legislation for the safety of target animals, workers and | 3554      | 0.74%      |
| environment  |           |            |
| Other legislation  | 2275      | 0.47%      |
| Total  | 481553    | 100.00%    |

## Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 470469         | 97.7%      |
| Legislation satisfying national requirements only [within EU] | 2083           | 0.43%      |
| Legislation satisfying Non-EU requirements only               | 9001           | 1.87%      |
| Total   | 481553         | 100.00%    |

## Routine production uses by product type

| Product type                                | Number of uses | Percentage |
|---|----------------|------------|
| Blood based products                        | 73520          | 97.52%     |
| Monoclonal antibody by mouse ascites method | 384            | 0.51%      |
| Other product types                         | 1489           | 1.97%      |
| Total                                       | 75393          | 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    | 1793299        | 98.19%     |
| Yes   | 32988          | 1.81%      |
| Total | 1826287        | 100.00%    |

| Uses of animals in research, testing, ro | outine production and education ( | (including training) by severity |
|--|-----------------------------------|----------------------------------|
|--|-----------------------------------|----------------------------------|

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 166236         | 9.1%       |
| Mild [up to and including] | 1040646        | 56.98%     |
| Moderate                   | 507633         | 27.8%      |
| Severe                     | 111772         | 6.12%      |
| Total                      | 1826287        | 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                         | 1241283        | 67.97%     |
| Genetically altered without a harmful phenotype | 465516         | 25.49%     |
| Genetically altered with a harmful phenotype    | 119488         | 6.54%      |
| Total   | 1826287        | 100.00%    |

## Part 3: Creation and maintenance of genetically altered animal lines

| Animal species        | First uses | Reuses | Total  |
|-----------------------|------------|--------|--------|
| Mice                  | 117993     | 432    | 118425 |
| Rats                  | 3396       |        | 3396   |
| Rabbits               | 17         |        | 17     |
| Pigs                  | 61         | 3      | 64     |
| Marmoset and tamarins | 10         |        | 10     |
| Zebra fish            | 48540      | 3451   | 51991  |
| Other Fish            | 3348       |        | 3348   |
| Total                 | 173365     | 3886   | 177251 |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 11592          | 6.54%      |
| Mild [up to and including] | 143868         | 81.17%     |
| Moderate                   | 21251          | 11.99%     |
| Severe                     | 540            | 0.3%       |
| Total                      | 177251         | 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 | 159047         | 89.73%     |
| Genetically altered with a harmful phenotype    | 18204          | 10.27%     |
| Total   | 177251         | 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                                    | 6057           | 3.7%       |
| Cardiovascular Blood and Lymphatic System   | 24671          | 15.06%     |
| Nervous System                              | 21445          | 13.09%     |
| Respiratory System                          | 323            | 0.2%       |
| Gastrointestinal System including Liver     | 2935           | 1.79%      |
| Musculoskeletal System                      | 9128           | 5.57%      |
| Immune System                               | 19540          | 11.93%     |
| Urogenital/Reproductive System              | 8775           | 5.36%      |
| Sensory Organs (skin, eyes and ears)        | 7414           | 4.53%      |
| Endocrine System/Metabolism                 | 7078           | 4.32%      |
| Multisystemic                               | 14782          | 9.02%      |
| Ethology / Animal Behaviour /Animal Biology | 135            | 0.08%      |
| Other basic research                        | 41521          | 25.35%     |
| Total                                       | 163804         | 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  | 1105           | 8.22%      |
| Human Infectious Disorders                          | 475            | 3.53%      |
| Human Cardiovascular Disorders                      | 1677           | 12.47%     |
| Human Nervous and Mental Disorders                  | 1893           | 14.08%     |
| Human Respiratory Disorders                         | 174            | 1.29%      |
| Human Gastrointestinal Disorders including Liver    | 2474           | 18.4%      |
| Human Musculoskeletal Disorders                     | 13             | 0.1%       |
| Human Immune Disorders                              | 345            | 2.57%      |
| Human Urogenital/Reproductive Disorders             | 171            | 1.27%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 1009           | 7.5%       |
| Human Endocrine/Metabolism Disorders                | 4107           | 30.54%     |
| Other Human Disorders                               | 4              | 0.03%      |
| Total   | 13447          | 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           | 61184      | 129    | 61313      |
| Rats           | 1574       |        | 1574       |
| Zebra fish     | 2272       |        | 2272       |
| Other Fish     | 116        |        | 116        |
| Total          | 65146      | 129    | 65275      |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 267            | 0.41%      |
| Mild [up to and including] | 42476          | 65.07%     |
| Moderate                   | 19737          | 30.24%     |
| Severe                     | 2795           | 4.28%      |
| Total                      | 65275          | 100.00%    |

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

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|-----|----------|-----|
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| Genetic status                                  | Number of uses | Percentage |
|---|----------------|------------|
| Genetically altered without a harmful phenotype | 34238          | 52.45%     |
| Genetically altered with a harmful phenotype    | 31037          | 47.55%     |
| Total   | 65275          | 100.00%    |

## Member State: Greece, 2017

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

| Animal species | Number of animals | Percentage |
|----------------|-------------------|------------|
| Mice           | 21190             | 50.08%     |
| Rats           | 2435              | 5.76%      |
| Guinea-Pigs    | 6                 | 0.01%      |
| Rabbits        | 213               | 0.5%       |
| Dogs           | 23                | 0.05%      |
| Pigs           | 283               | 0.67%      |
| Sheep          | 8                 | 0.02%      |
| Cattle         | 3                 | 0.01%      |
| Domestic fowl  | 6                 | 0.01%      |
| Zebra fish     | 1859              | 4.39%      |
| Other Fish     | 16250             | 38.41%     |
| Cephalopods    | 33                | 0.08%      |
| Total          | 42309             | 100.00%    |

#### Numbers of animals used for the first time by species

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         | 41636             | 98.41%     |
| Animals born in the EU but not at a registered breeder | 33                | 0.08%      |
| Animals born in rest of world                          | 640               | 1.51%      |
| Total  | 42309             | 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

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species | First uses | Reuses | Total |  |
|----------------|------------|--------|-------|--|
| Mice           | 21190      | 329    | 21519 |  |
| Rats           | 2435       | 3      | 2438  |  |
| Guinea-Pigs    | 6          |        | 6     |  |
| Rabbits        | 213        |        | 213   |  |
| Cats           |            | 8      | 8     |  |
| Dogs           | 23         | 18     | 41    |  |
| Pigs           | 283        | 6      | 289   |  |
| Sheep          | 8          |        | 8     |  |
| Cattle         | 3          |        | 3     |  |
| Rhesus monkey  |            | 1      | 1     |  |
| Domestic fowl  | 6          |        | 6     |  |
| Zebra fish     | 1859       |        | 1859  |  |
| Other Fish     | 16250      | 96     | 16346 |  |
| Cephalopods    | 33         |        | 33    |  |
| Total          | 42309      | 461    | 42770 |  |

First use versus reuses

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

## categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 23613     | 55.21%     |
| Translational and applied research   | 8058      | 18.84%     |
| Regulatory use and Routine production  | 6887      | 16.1%      |
| Protection of the natural environment in the interests of the health or welfare of human   | 3093      | 7.23%      |
| beings or animals  |           |            |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 1119      | 2.62%      |
| skills   |           |            |
| Total  | 42770     | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 923            | 3.91%      |
| Cardiovascular Blood and Lymphatic System   | 1315           | 5.57%      |
| Nervous System                              | 1204           | 5.1%       |
| Gastrointestinal System including Liver     | 428            | 1.81%      |
| Musculoskeletal System                      | 520            | 2.2%       |
| Immune System                               | 2225           | 9.42%      |
| Urogenital/Reproductive System              | 242            | 1.02%      |
| Sensory Organs (skin, eyes and ears)        | 988            | 4.18%      |
| Endocrine System/Metabolism                 | 843            | 3.57%      |
| Multisystemic                               | 99             | 0.42%      |
| Ethology / Animal Behaviour /Animal Biology | 14686          | 62.19%     |
| Other basic research                        | 140            | 0.59%      |
| Total                                       | 23613          | 100.00%    |

#### Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 2487           | 30.86%     |
| Human Infectious Disorders                          | 271            | 3.36%      |
| Human Cardiovascular Disorders                      | 967            | 12%        |
| Human Nervous and Mental Disorders                  | 1372           | 17.03%     |
| Human Respiratory Disorders                         | 291            | 3.61%      |
| Human Gastrointestinal Disorders including Liver    | 363            | 4.5%       |
| Human Musculoskeletal Disorders                     | 710            | 8.81%      |
| Human Immune Disorders                              | 200            | 2.48%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 381            | 4.73%      |
| Human Endocrine/Metabolism Disorders                | 34             | 0.42%      |
| Other Human Disorders                               | 648            | 8.04%      |
| Animal Welfare                                      | 40             | 0.5%       |
| Diagnosis of diseases                               | 230            | 2.85%      |
| Non-regulatory toxicology and ecotoxicology         | 64             | 0.79%      |
| Total   | 8058           | 100.00%    |

#### **Regulatory uses and Routine production**

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Toxicity and other safety testing including pharmacology | 6887           | 100%       |
| Total  | 6887           | 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 |
|--|----------------|------------|
| Pharmaco-dynamics (incl safety pharmacology)                               | 10             | 0.15%      |
| Safety testing in food and feed area                                       | 6877           | 99.85%     |
| Total  | 6887           | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
|   | -         |            |

#### 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 | Number of | Percentage |
|--|-----------|------------|
| 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

| Type of legislation                              | Number of uses | Percentage |
|--|----------------|------------|
| Legislation on medicinal products for human use  | 10             | 0.15%      |
| Food legislation including food contact material | 6877           | 99.85%     |
| Total  | 6887           | 100.00%    |

Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement      | Number of uses | Percentage |
|--|----------------|------------|
| Legislation satisfying EU requirements | 6887           | 100%       |
| Total                                  | 6887           | 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    | 42309          | 98.92%     |
| Yes   | 461            | 1.08%      |
| Total | 42770          | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 3646           | 8.52%      |
| Mild [up to and including] | 25432          | 59.46%     |
| Moderate                   | 9198           | 21.51%     |
| Severe                     | 4494           | 10.51%     |
| Total                      | 42770          | 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                         | 31622          | 73.94%     |
| Genetically altered without a harmful phenotype | 9022           | 21.09%     |
| Genetically altered with a harmful phenotype    | 2126           | 4.97%      |
| Total   | 42770          | 100.00%    |

## Part 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           | 3960       |        | 3960  |
| Total          | 3960       |        | 3960  |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 3960           | 100%       |
| Total                      | 3960           | 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 | 3960           | 100%       |
| Total   | 3960           | 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 |
|----------------------|----------------|------------|
| Other basic research | 3960           | 100%       |
| Total                | 3960           | 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

## Member State: Hungary, 2017

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

| Animal species | Number of animals | Percentage |
|----------------|-------------------|------------|
| Mice           | 65368             | 49.18%     |
| Rats           | 33255             | 25.02%     |
| Guinea-Pigs    | 5731              | 4.31%      |
| Rabbits        | 1343              | 1.01%      |
| Cats           | 16                | 0.01%      |
| Dogs           | 359               | 0.27%      |
| Ferrets        | 4                 | 0%         |
| Pigs           | 2078              | 1.56%      |
| Cattle         | 12                | 0.01%      |
| Rhesus monkey  | 2                 | 0%         |
| Domestic fowl  | 20575             | 15.48%     |
| Other birds    | 2084              | 1.57%      |
| Zebra fish     | 928               | 0.7%       |
| Other Fish     | 1174              | 0.88%      |
| Total          | 132929            | 100.00%    |

#### Numbers of animals used for the first time by species

#### 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         | 126369            | 95.07%     |
| Animals born in the EU but not at a registered breeder | 5062              | 3.81%      |
| Animals born in rest of Europe                         | 1187              | 0.89%      |
| Animals born in rest of world                          | 309               | 0.23%      |
| Total  | 132927            | 100.00%    |

## Source of non-human primates

| NHP Source (origin)                            | Number of animals | Percentage |
|--|-------------------|------------|
| Animals born at a registered breeder within EU | 2                 | 100%       |
| Total  | 2                 | 100.00%    |

Generation of non-human primates

| NHP Generation | Number of animals | Percentage |
|----------------|-------------------|------------|
| F2 or greater  | 2                 | 100%       |
| Total          | 2                 | 100.00%    |

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species | First uses | Reuses | Total  |  |
|----------------|------------|--------|--------|--|
| Mice           | 65368      | 346    | 65714  |  |
| Rats           | 33255      | 691    | 33946  |  |
| Guinea-Pigs    | 5731       | 34     | 5765   |  |
| Rabbits        | 1343       | 88     | 1431   |  |
| Cats           | 16         |        | 16     |  |
| Dogs           | 359        | 104    | 463    |  |
| Ferrets        | 4          |        | 4      |  |
| Pigs           | 2078       | 327    | 2405   |  |
| Cattle         | 12         | 21     | 33     |  |
| Rhesus monkey  | 2          |        | 2      |  |
| Domestic fowl  | 20575      | 4594   | 25169  |  |
| Other birds    | 2084       |        | 2084   |  |
| Zebra fish     | 928        | 748    | 1676   |  |
| Other Fish     | 1174       |        | 1174   |  |
| Total          | 132929     | 6953   | 139882 |  |

#### First use versus reuses

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

## categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 37658     | 26.92%     |
| Translational and applied research   | 41847     | 29.92%     |
| Regulatory use and Routine production  | 58007     | 41.47%     |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 2370      | 1.69%      |
| skills   |           |            |
| Total  | 139882    | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 3346           | 8.89%      |
| Cardiovascular Blood and Lymphatic System   | 3342           | 8.87%      |
| Nervous System                              | 16376          | 43.49%     |
| Respiratory System                          | 718            | 1.91%      |
| Gastrointestinal System including Liver     | 1865           | 4.95%      |
| Musculoskeletal System                      | 189            | 0.5%       |
| Immune System                               | 4412           | 11.72%     |
| Urogenital/Reproductive System              | 1678           | 4.46%      |
| Sensory Organs (skin, eyes and ears)        | 488            | 1.3%       |
| Endocrine System/Metabolism                 | 1417           | 3.76%      |
| Multisystemic                               | 1802           | 4.79%      |
| Ethology / Animal Behaviour /Animal Biology | 526            | 1.4%       |
| Other basic research                        | 1499           | 3.98%      |
| Total                                       | 37658          | 100.00%    |

## Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 4919           | 11.75%     |
| Human Infectious Disorders                          | 581            | 1.39%      |
| Human Cardiovascular Disorders                      | 293            | 0.7%       |
| Human Nervous and Mental Disorders                  | 20172          | 48.2%      |
| Human Gastrointestinal Disorders including Liver    | 211            | 0.5%       |
| Human Musculoskeletal Disorders                     | 79             | 0.19%      |
| Human Immune Disorders                              | 89             | 0.21%      |
| Human Urogenital/Reproductive Disorders             | 8              | 0.02%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 40             | 0.1%       |
| Other Human Disorders                               | 224            | 0.54%      |
| Animal Diseases and Disorders                       | 9410           | 22.49%     |
| Animal Welfare                                      | 4573           | 10.93%     |
| Diagnosis of diseases                               | 788            | 1.88%      |
| Non-regulatory toxicology and ecotoxicology         | 460            | 1.1%       |
| Total   | 41847          | 100.00%    |

## Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 27156          | 46.82%     |
| Other efficacy and tolerance testing                     | 329            | 0.57%      |
| Toxicity and other safety testing including pharmacology | 29813          | 51.4%      |
| Routine production                                       | 709            | 1.22%      |
| Total  | 58007          | 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   | 10102          | 37.2%      |
| Pyrogenicity testing   | 29             | 0.11%      |
| Batch potency testing  | 16682          | 61.43%     |
| Other quality controls   | 343            | 1.26%      |
| Total  | 27156          | 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  | 17639          | 59.17%     |
| Skin irritation/corrosion  | 293            | 0.98%      |
| Skin sensitisation   | 4629           | 15.53%     |
| Eye irritation/corrosion   | 137            | 0.46%      |
| Repeated dose toxicity   | 1125           | 3.77%      |
| Carcinogenicity  | 40             | 0.13%      |
| Genotoxicity   | 562            | 1.89%      |
| Reproductive toxicity  | 833            | 2.79%      |
| Developmental toxicity   | 1286           | 4.31%      |
| Kinetics   | 1207           | 4.05%      |
| Pharmaco-dynamics (incl safety pharmacology)                               | 569            | 1.91%      |
| Ecotoxicity  | 1028           | 3.45%      |
| Other toxicity/safety testing  | 465            | 1.56%      |
| Total  | 29813          | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 14255     | 80.82%     |
| Non lethal methods  | 3384      | 19.18%     |
| Total   | 17639     | 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<br>uses | Percentage |
|---|-------------------|------------|
| up to 28 days   | 438               | 38.93%     |
| 29 - 90 days  | 75                | 6.67%      |
| > 90 days   | 612               | 54.4%      |
| Total   | 1125              | 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   | 1028           | 100%       |
| Total  | 1028           | 100.00%    |

#### Regulatory uses by type of legislation

| Type of legislation   | Number of uses | Percentage |
|---|----------------|------------|
| Legislation on medicinal products for human use                         | 24550          | 42.85%     |
| Legislation on medicinal products for veterinary use and their residues | 28770          | 50.21%     |
| Medical devices legislation   | 516            | 0.9%       |
| Industrial chemicals legislation  | 834            | 1.46%      |
| Plant protection product legislation                                    | 2167           | 3.78%      |
| Food legislation including food contact material                        | 461            | 0.8%       |
| Total   | 57298          | 100.00%    |

## Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement               | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements          | 56022          | 97.77%     |
| Legislation satisfying Non-EU requirements only | 1276           | 2.23%      |
| Total   | 57298          | 100.00%    |

#### Routine production uses by product type

| Product type                                | Number of uses | Percentage |
|---|----------------|------------|
| Blood based products                        | 40             | 5.64%      |
| Monoclonal antibody by mouse ascites method | 157            | 22.14%     |
| Other product types                         | 512            | 72.21%     |
| Total                                       | 709            | 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    | 132929         | 95.03%     |
| Yes   | 6953           | 4.97%      |
| Total | 139882         | 100.00%    |

| Uses of animals in research, | tecting  | routine product   | ion and education | (including training)   | hy soverity |
|------------------------------|----------|-------------------|-------------------|------------------------|-------------|
| Uses of animals in research, | iesting, | , routine product | ion and Education | i (including training) | by sevenity |

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 12314          | 8.8%       |
| Mild [up to and including] | 69792          | 49.89%     |
| Moderate                   | 39760          | 28.42%     |
| Severe                     | 18016          | 12.88%     |
| Total                      | 139882         | 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                         | 131890         | 94.29%     |
| Genetically altered without a harmful phenotype | 7386           | 5.28%      |
| Genetically altered with a harmful phenotype    | 606            | 0.43%      |
| Total   | 139882         | 100.00%    |

## Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 162        |        | 162   |
| Rabbits        | 152        |        | 152   |
| Zebra fish     |            | 567    | 567   |
| Total          | 314        | 567    | 881   |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 96             | 10.9%      |
| Mild [up to and including] | 591            | 67.08%     |
| Moderate                   | 194            | 22.02%     |
| Total                      | 881            | 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                         | 339            | 38.48%     |
| Genetically altered without a harmful phenotype | 512            | 58.12%     |
| Genetically altered with a harmful phenotype    | 30             | 3.41%      |
| Total   | 881            | 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 | 64             | 7.26%      |
| Nervous System                            | 122            | 13.85%     |
| Multisystemic                             | 567            | 64.36%     |
| Other basic research                      | 128            | 14.53%     |
| Total                                     | 881            | 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

## Member State: Ireland, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 205849            | 85.57%     |
| Rats                             | 16858             | 7.01%      |
| Guinea-Pigs                      | 518               | 0.22%      |
| Rabbits                          | 400               | 0.17%      |
| Dogs                             | 46                | 0.02%      |
| Ferrets                          | 442               | 0.18%      |
| Horses, donkeys and cross-breeds | 59                | 0.02%      |
| Pigs                             | 1519              | 0.63%      |
| Goats                            | 11                | 0%         |
| Sheep                            | 1189              | 0.49%      |
| Cattle                           | 2805              | 1.17%      |
| Domestic fowl                    | 40                | 0.02%      |
| Other birds                      | 823               | 0.34%      |
| Xenopus                          | 18                | 0.01%      |
| Zebra fish                       | 236               | 0.1%       |
| Other Fish                       | 9755              | 4.05%      |
| Total                            | 240568            | 100.00%    |

Numbers of animals used for the first time by species

#### 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         | 226935            | 94.33%     |
| Animals born in the EU but not at a registered breeder | 13065             | 5.43%      |
| Animals born in rest of Europe                         | 121               | 0.05%      |
| Animals born in rest of world                          | 447               | 0.19%      |
| Total  | 240568            | 100.00%    |

Source of non-human primates

NHP Source (origin)Number of animalsPercentageNo data reported

Generation of non-human primates

NHP Generation Number of animals Percentage

No data reported

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species                   | First uses | Reuses | Total  |
|----------------------------------|------------|--------|--------|
| Mice                             | 205849     |        | 205849 |
| Rats                             | 16858      |        | 16858  |
| Guinea-Pigs                      | 518        |        | 518    |
| Rabbits                          | 400        |        | 400    |
| Dogs                             | 46         | 43     | 89     |
| Ferrets                          | 442        |        | 442    |
| Horses, donkeys and cross-breeds | 59         | 1      | 60     |
| Pigs                             | 1519       | 28     | 1547   |
| Goats                            | 11         |        | 11     |
| Sheep                            | 1189       | 132    | 1321   |
| Cattle                           | 2805       | 439    | 3244   |
| Domestic fowl                    | 40         |        | 40     |
| Other birds                      | 823        |        | 823    |
| Xenopus                          | 18         |        | 18     |
| Zebra fish                       | 236        |        | 236    |
| Other Fish                       | 9755       | 32     | 9787   |
| Total                            | 240568     | 675    | 241243 |

#### First use versus reuses

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

## categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 8492      | 3.52%      |
| Translational and applied research   | 29295     | 12.14%     |
| Regulatory use and Routine production  | 194816    | 80.76%     |
| Protection of the natural environment in the interests of the health or welfare of human   | 8366      | 3.47%      |
| beings or animals  |           |            |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 274       | 0.11%      |
| skills   |           |            |
| Total  | 241243    | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 391            | 4.6%       |
| Cardiovascular Blood and Lymphatic System   | 5              | 0.06%      |
| Nervous System                              | 2068           | 24.35%     |
| Respiratory System                          | 658            | 7.75%      |
| Gastrointestinal System including Liver     | 1111           | 13.08%     |
| Musculoskeletal System                      | 192            | 2.26%      |
| Immune System                               | 991            | 11.67%     |
| Urogenital/Reproductive System              | 238            | 2.8%       |
| Sensory Organs (skin, eyes and ears)        | 54             | 0.64%      |
| Endocrine System/Metabolism                 | 139            | 1.64%      |
| Multisystemic                               | 6              | 0.07%      |
| Ethology / Animal Behaviour /Animal Biology | 2635           | 31.03%     |
| Other basic research                        | 4              | 0.05%      |
| Total                                       | 8492           | 100.00%    |

## Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 754            | 2.57%      |
| Human Infectious Disorders                          | 780            | 2.66%      |
| Human Cardiovascular Disorders                      | 1129           | 3.85%      |
| Human Nervous and Mental Disorders                  | 9381           | 32.02%     |
| Human Respiratory Disorders                         | 277            | 0.95%      |
| Human Gastrointestinal Disorders including Liver    | 1114           | 3.8%       |
| Human Musculoskeletal Disorders                     | 734            | 2.51%      |
| Human Immune Disorders                              | 7789           | 26.59%     |
| Human Urogenital/Reproductive Disorders             | 50             | 0.17%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 2057           | 7.02%      |
| Human Endocrine/Metabolism Disorders                | 444            | 1.52%      |
| Animal Diseases and Disorders                       | 2115           | 7.22%      |
| Animal Welfare                                      | 2553           | 8.71%      |
| Diagnosis of diseases                               | 118            | 0.4%       |
| Total   | 29295          | 100.00%    |

#### Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 194247         | 99.71%     |
| Toxicity and other safety testing including pharmacology | 540            | 0.28%      |
| Routine production                                       | 29             | 0.01%      |
| Total  | 194816         | 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   | 1920           | 0.99%      |
| Pyrogenicity testing   | 312            | 0.16%      |
| Batch potency testing  | 192015         | 98.85%     |
| Total  | 194247         | 100.00%    |

#### Regulatory uses - Toxicity and other safety testing including pharmacology

| Regulatory uses - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
|--|----------------|------------|
| Ecotoxicity  | 500            | 92.59%     |
| Target animal safety   | 40             | 7.41%      |
| Total  | 540            | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
|   |           |            |

#### 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 | Number of | Percentage |
|--|-----------|------------|
| 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 |
|--|----------------|------------|
| Acute toxicity   | 500            | 100%       |
| Total  | 500            | 100.00%    |

#### Regulatory uses by type of legislation

| Type of legislation   | Number of uses | Percentage |
|---|----------------|------------|
| Legislation on medicinal products for human use                         | 185698         | 95.33%     |
| Legislation on medicinal products for veterinary use and their residues | 8589           | 4.41%      |
| Other legislation   | 500            | 0.26%      |
| Total   | 194787         | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 194755         | 99.98%     |
| Legislation satisfying national requirements only [within EU] | 32             | 0.02%      |
| Total   | 194787         | 100.00%    |

#### Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 29             | 100%       |
| Total                | 29             | 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    | 240568         | 99.72%     |
| Yes   | 675            | 0.28%      |
| Total | 241243         | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 2283           | 0.95%      |
| Mild [up to and including] | 113244         | 46.94%     |
| Moderate                   | 55158          | 22.86%     |
| Severe                     | 70558          | 29.25%     |
| Total                      | 241243         | 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                         | 234363         | 97.15%     |
| Genetically altered without a harmful phenotype | 5121           | 2.12%      |
| Genetically altered with a harmful phenotype    | 1759           | 0.73%      |
| Total   | 241243         | 100.00%    |

## Part 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           | 586        |        | 586   |
| Total          | 586        |        | 586   |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 548            | 93.52%     |
| Severe                     | 38             | 6.48%      |
| Total                      | 586            | 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 | 586            | 100%       |
| Total   | 586            | 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 |
|---------------------------|----------------|------------|
| <b>Respiratory System</b> | 66             | 100%       |
| Total                     | 66             | 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     | 66             | 12.69%     |
| Human Musculoskeletal Disorders    | 13             | 2.5%       |
| Human Immune Disorders             | 441            | 84.81%     |
| Total                              | 520            | 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           | 473        |        | 473        |
| Total          | 473        |        | 473        |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 469            | 99.15%     |
| Moderate                   | 4              | 0.85%      |
| Total                      | 473            | 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                         | 443            | 93.66%     |
| Genetically altered without a harmful phenotype | 30             | 6.34%      |
| Total   | 473            | 100.00%    |

## Member State: Italy, 2017

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

| Animal species    | Number of animals | Percentage |
|-------------------|-------------------|------------|
| Mice              | 347361            | 61.54%     |
| Rats              | 117203            | 20.76%     |
| Guinea-Pigs       | 14246             | 2.52%      |
| Hamsters (Syrian) | 277               | 0.05%      |
| Other Rodents     | 647               | 0.11%      |
| Rabbits           | 18146             | 3.21%      |
| Dogs              | 373               | 0.07%      |
| Ferrets           | 42                | 0.01%      |
| Pigs              | 1559              | 0.28%      |
| Sheep             | 120               | 0.02%      |
| Cattle            | 270               | 0.05%      |
| Cynomolgus monkey | 545               | 0.1%       |
| Rhesus monkey     | 3                 | 0%         |
| Other Mammals     | 24                | 0%         |
| Domestic fowl     | 33358             | 5.91%      |
| Other birds       | 420               | 0.07%      |
| Xenopus           | 371               | 0.07%      |
| Zebra fish        | 19415             | 3.44%      |
| Other Fish        | 10079             | 1.79%      |
| Cephalopods       | 10                | 0%         |
| Total             | 564469            | 100.00%    |

Numbers of animals used for the first time by species

## 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         | 497349            | 88.19%     |
| Animals born in the EU but not at a registered breeder | 64411             | 11.42%     |
| Animals born in rest of Europe                         | 840               | 0.15%      |
| Animals born in rest of world                          | 1321              | 0.23%      |
| Total  | 563921            | 100.00%    |

## Source of non-human primates

| NHP Source (origin)                            | Number of animals | Percentage |
|--|-------------------|------------|
| Animals born at a registered breeder within EU | 1                 | 0.18%      |
| Animals born in Asia                           | 57                | 10.4%      |
| Animals born in Africa                         | 490               | 89.42%     |
| Total  | 548               | 100.00%    |

## Generation of non-human primates

| NHP Generation | Number of animals | Percentage |
|----------------|-------------------|------------|
| F1             | 137               | 25%        |
| F2 or greater  | 411               | 75%        |
| Total          | 548               | 100.00%    |

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

|                                  |            | _      |        |
|----------------------------------|------------|--------|--------|
| Animal species                   | First uses | Reuses | Total  |
| Mice                             | 347361     | 483    | 347844 |
| Rats                             | 117203     | 338    | 117541 |
| Guinea-Pigs                      | 14246      | 111    | 14357  |
| Hamsters (Syrian)                | 277        |        | 277    |
| Other Rodents                    | 647        |        | 647    |
| Rabbits                          | 18146      | 1179   | 19325  |
| Dogs                             | 373        | 266    | 639    |
| Ferrets                          | 42         |        | 42     |
| Horses, donkeys and cross-breeds |            | 17     | 17     |
| Pigs                             | 1559       | 62     | 1621   |
| Goats                            |            | 23     | 23     |
| Sheep                            | 120        | 72     | 192    |
| Cattle                           | 270        | 9      | 279    |
| Marmoset and tamarins            |            | 1      | 1      |
| Cynomolgus monkey                | 545        | 24     | 569    |
| Rhesus monkey                    | 3          | 1      | 4      |
| Other Mammals                    | 24         | 6      | 30     |
| Domestic fowl                    | 33358      | 1357   | 34715  |
| Other birds                      | 420        |        | 420    |
| Xenopus                          | 371        | 30     | 401    |
| Zebra fish                       | 19415      | 93     | 19508  |
| Other Fish                       | 10079      | 636    | 10715  |
| Cephalopods                      | 10         |        | 10     |
| Total                            | 564469     | 4708   | 569177 |

First use versus reuses

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

## categories of scientific purposes

| Purpose Category   | Number of<br>uses | Percentage |
|--|-------------------|------------|
| Basic Research   | 187054            | 32.86%     |
| Translational and applied research   | 152986            | 26.88%     |
| Regulatory use and Routine production  | 225842            | 39.68%     |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 1697              | 0.3%       |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills          | 1598              | 0.28%      |
| Total  | 569177            | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 57091          | 30.52%     |
| Cardiovascular Blood and Lymphatic System   | 8534           | 4.56%      |
| Nervous System                              | 69030          | 36.9%      |
| Respiratory System                          | 1384           | 0.74%      |
| Gastrointestinal System including Liver     | 5792           | 3.1%       |
| Musculoskeletal System                      | 6922           | 3.7%       |
| Immune System                               | 13588          | 7.26%      |
| Urogenital/Reproductive System              | 2830           | 1.51%      |
| Sensory Organs (skin, eyes and ears)        | 3892           | 2.08%      |
| Endocrine System/Metabolism                 | 4459           | 2.38%      |
| Multisystemic                               | 3513           | 1.88%      |
| Ethology / Animal Behaviour /Animal Biology | 5028           | 2.69%      |
| Other basic research                        | 4991           | 2.67%      |
| Total                                       | 187054         | 100.00%    |

## Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 46470          | 30.38%     |
| Human Infectious Disorders                          | 21902          | 14.32%     |
| Human Cardiovascular Disorders                      | 1844           | 1.21%      |
| Human Nervous and Mental Disorders                  | 18352          | 12%        |
| Human Respiratory Disorders                         | 16658          | 10.89%     |
| Human Gastrointestinal Disorders including Liver    | 2644           | 1.73%      |
| Human Musculoskeletal Disorders                     | 5955           | 3.89%      |
| Human Immune Disorders                              | 3734           | 2.44%      |
| Human Urogenital/Reproductive Disorders             | 2989           | 1.95%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 2447           | 1.6%       |
| Human Endocrine/Metabolism Disorders                | 3064           | 2%         |
| Other Human Disorders                               | 4953           | 3.24%      |
| Animal Diseases and Disorders                       | 7228           | 4.72%      |
| Animal Welfare                                      | 918            | 0.6%       |
| Diagnosis of diseases                               | 13483          | 8.81%      |
| Non-regulatory toxicology and ecotoxicology         | 345            | 0.23%      |
| Total   | 152986         | 100.00%    |

## Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 111851         | 49.53%     |
| Other efficacy and tolerance testing                     | 45856          | 20.3%      |
| Toxicity and other safety testing including pharmacology | 63786          | 28.24%     |
| Routine production                                       | 4349           | 1.93%      |
| Total  | 225842         | 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   | 21535          | 19.25%     |
| Pyrogenicity testing   | 2717           | 2.43%      |
| Batch potency testing  | 84520          | 75.56%     |
| Other quality controls   | 3079           | 2.75%      |
| Total  | 111851         | 100.00%    |

| Regulatory uses - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
|--|----------------|------------|
| Acute and sub-acute  | 10612          | 16.64%     |
| Skin irritation/corrosion  | 820            | 1.29%      |
| Skin sensitisation   | 11983          | 18.79%     |
| Eye irritation/corrosion   | 93             | 0.15%      |
| Repeated dose toxicity   | 8757           | 13.73%     |
| Genotoxicity   | 291            | 0.46%      |
| Reproductive toxicity  | 628            | 0.98%      |
| Developmental toxicity   | 5554           | 8.71%      |
| Neurotoxicity  | 300            | 0.47%      |
| Kinetics   | 5976           | 9.37%      |
| Pharmaco-dynamics (incl safety pharmacology)                               | 1154           | 1.81%      |
| Ecotoxicity  | 4224           | 6.62%      |
| Safety testing in food and feed area                                       | 10807          | 16.94%     |
| Target animal safety   | 1212           | 1.9%       |
| Other toxicity/safety testing  | 1375           | 2.16%      |
| Total  | 63786          | 100.00%    |

## Regulatory uses - Toxicity and other safety testing including pharmacology

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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 1211      | 11.41%     |
| Other lethal methods  | 755       | 7.11%      |
| Non lethal methods  | 8646      | 81.47%     |
| Total   | 10612     | 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<br>uses | Percentage |
|---|-------------------|------------|
| up to 28 days   | 4157              | 47.47%     |
| 29 - 90 days  | 2782              | 31.77%     |
| > 90 days   | 1818              | 20.76%     |
| Total   | 8757              | 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   | 3930           | 93.04%     |
| Other ecotoxicity  | 294            | 6.96%      |
| Total  | 4224           | 100.00%    |

#### Regulatory uses by type of legislation

| Type of legislation   | Number of | Percentage |
|---|-----------|------------|
|   | uses      |            |
| Legislation on medicinal products for human use   | 143853    | 64.95%     |
| Legislation on medicinal products for veterinary use and their residues                             | 35700     | 16.12%     |
| Medical devices legislation   | 16869     | 7.62%      |
| Industrial chemicals legislation  | 8715      | 3.93%      |
| Plant protection product legislation  | 595       | 0.27%      |
| Biocides legislation  | 624       | 0.28%      |
| Food legislation including food contact material  | 11492     | 5.19%      |
| Feed legislation including legislation for the safety of target animals, workers and<br>environment | 1074      | 0.48%      |
| Other legislation   | 2571      | 1.16%      |
| Total   | 221493    | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 204920         | 92.52%     |
| Legislation satisfying national requirements only [within EU] | 3268           | 1.48%      |
| Legislation satisfying Non-EU requirements only               | 13305          | 6.01%      |
| Total   | 221493         | 100.00%    |

#### Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 2861           | 65.79%     |
| Other product types  | 1488           | 34.21%     |
| Total                | 4349           | 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    | 564469         | 99.17%     |
| Yes   | 4708           | 0.83%      |
| Total | 569177         | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 29618          | 5.2%       |
| Mild [up to and including] | 275143         | 48.34%     |
| Moderate                   | 175666         | 30.86%     |
| Severe                     | 88750          | 15.59%     |
| Total                      | 569177         | 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                         | 448298         | 78.76%     |
| Genetically altered without a harmful phenotype | 103778         | 18.23%     |
| Genetically altered with a harmful phenotype    | 17101          | 3%         |
| Total   | 569177         | 100.00%    |

## Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 7799       |        | 7799  |
| Rats           | 510        |        | 510   |
| Pigs           | 36         |        | 36    |
| Total          | 8345       |        | 8345  |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 2257           | 27.05%     |
| Mild [up to and including] | 3751           | 44.95%     |
| Moderate                   | 1470           | 17.62%     |
| Severe                     | 867            | 10.39%     |
| Total                      | 8345           | 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                         | 399            | 4.78%      |
| Genetically altered without a harmful phenotype | 7598           | 91.05%     |
| Genetically altered with a harmful phenotype    | 348            | 4.17%      |
| Total   | 8345           | 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                                  | 1422           | 18.74%     |
| Cardiovascular Blood and Lymphatic System | 101            | 1.33%      |
| Nervous System                            | 5313           | 70.02%     |
| Musculoskeletal System                    | 11             | 0.14%      |
| Immune System                             | 79             | 1.04%      |
| Endocrine System/Metabolism               | 317            | 4.18%      |
| Multisystemic                             | 345            | 4.55%      |
| Total                                     | 7588           | 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                      | 8              | 1.06%      |
| Human Nervous and Mental Disorders                  | 146            | 19.29%     |
| Human Gastrointestinal Disorders including Liver    | 62             | 8.19%      |
| Human Musculoskeletal Disorders                     | 52             | 6.87%      |
| Human Immune Disorders                              | 141            | 18.63%     |
| Human Urogenital/Reproductive Disorders             | 3              | 0.4%       |
| Human Sensory Organ Disorders (skin, eyes and ears) | 10             | 1.32%      |
| Other Human Disorders                               | 335            | 44.25%     |
| Total   | 757            | 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           | 2485       |        | 2485       |
| Rats           | 53         |        | 53         |
| Total          | 2538       |        | 2538       |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 2175           | 85.7%      |
| Moderate                   | 44             | 1.73%      |
| Severe                     | 319            | 12.57%     |
| Total                      | 2538           | 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 | 1498           | 59.02%     |
| Genetically altered with a harmful phenotype    | 1040           | 40.98%     |
| Total   | 2538           | 100.00%    |

## Member State: Latvia, 2017

Part 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           | 3332              | 63%        |
| Rats           | 1795              | 33.94%     |
| Pigs           | 22                | 0.42%      |
| Other Mammals  | 140               | 2.65%      |
| Total          | 5289              | 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         | 5127              | 96.94%     |
| Animals born in the EU but not at a registered breeder | 162               | 3.06%      |
| Total  | 5289              | 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

Part 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           | 3332       |        | 3332  |
| Rats           | 1795       |        | 1795  |
| Pigs           | 22         |        | 22    |
| Other Mammals  | 140        |        | 140   |
| Total          | 5289       |        | 5289  |

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

#### categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 1724      | 32.6%      |
| Translational and applied research   | 3543      | 66.99%     |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 22        | 0.42%      |
| skills   |           |            |
| Total  | 5289      | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 4              | 0.23%      |
| Nervous System                              | 1580           | 91.65%     |
| Ethology / Animal Behaviour /Animal Biology | 140            | 8.12%      |
| Total                                       | 1724           | 100.00%    |

#### Translational and applied research related uses

| Translational and applied research          | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer                                | 840            | 23.71%     |
| Human Infectious Disorders                  | 135            | 3.81%      |
| Human Cardiovascular Disorders              | 1406           | 39.68%     |
| Human Nervous and Mental Disorders          | 605            | 17.08%     |
| Human Urogenital/Reproductive Disorders     | 70             | 1.98%      |
| Human Endocrine/Metabolism Disorders        | 0              | 0%         |
| Animal Diseases and Disorders               | 377            | 10.64%     |
| Non-regulatory toxicology and ecotoxicology | 110            | 3.1%       |
| Total                                       | 3543           | 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-<br/>acute toxicity testing methodsNumber of<br/>Percentage<br/>uses

#### 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 | Number of | Percentage |
|--|-----------|------------|
| 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    | 5289           | 100%       |
| Total | 5289           | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 1372           | 25.94%     |
| Mild [up to and including] | 2050           | 38.76%     |
| Moderate                   | 1701           | 32.16%     |
| Severe                     | 166            | 3.14%      |
| Total                      | 5289           | 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                         | 5229           | 98.87%     |
| Genetically altered without a harmful phenotype | 60             | 1.13%      |
| Total   | 5289           | 100.00%    |

## Part 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

# Member State: Lithuania, 2017

Part 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           | 1718              | 62.11%     |
| Rats           | 391               | 14.14%     |
| Guinea-Pigs    | 15                | 0.54%      |
| Rabbits        | 13                | 0.47%      |
| Pigs           | 68                | 2.46%      |
| Sheep          | 15                | 0.54%      |
| Other birds    | 26                | 0.94%      |
| Other Fish     | 520               | 18.8%      |
| Total          | 2766              | 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         | 2683              | 97%        |
| Animals born in the EU but not at a registered breeder | 83                | 3%         |
| Total  | 2766              | 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

# Part 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           | 1718       |        | 1718  |
| Rats           | 391        |        | 391   |
| Guinea-Pigs    | 15         |        | 15    |
| Rabbits        | 13         |        | 13    |
| Pigs           | 68         |        | 68    |
| Sheep          | 15         |        | 15    |
| Other birds    | 26         |        | 26    |
| Other Fish     | 520        |        | 520   |
| Total          | 2766       |        | 2766  |

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

categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 1659      | 59.98%     |
| Translational and applied research   | 501       | 18.11%     |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 606       | 21.91%     |
| skills   |           |            |
| Total  | 2766      | 100.00%    |

#### Basic research related uses

| Basic research                            | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                  | 337            | 20.31%     |
| Cardiovascular Blood and Lymphatic System | 20             | 1.21%      |
| Nervous System                            | 284            | 17.12%     |
| Respiratory System                        | 103            | 6.21%      |
| Musculoskeletal System                    | 10             | 0.6%       |
| Immune System                             | 873            | 52.62%     |
| Multisystemic                             | 32             | 1.93%      |
| Total                                     | 1659           | 100.00%    |

#### Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Infectious Disorders                          | 102            | 20.36%     |
| Human Cardiovascular Disorders                      | 8              | 1.6%       |
| Human Nervous and Mental Disorders                  | 107            | 21.36%     |
| Human Sensory Organ Disorders (skin, eyes and ears) | 17             | 3.39%      |
| Non-regulatory toxicology and ecotoxicology         | 267            | 53.29%     |
| Total   | 501            | 100.00%    |

**Regulatory uses and Routine production** 

Regulatory uses and Routine production Number of uses Percentage

| 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 No data reported   | 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-  | Number of       | Percentage |
| acute toxicity testing methods   | uses            |            |
| No data reported   |                 |            |
| Regulatory uses - Toxicity and other safety testing including pharmacology - Repea   | ted dose toxici | ty         |
| Regulatory uses - Toxicity and other safety testing including pharmacology - Repeated dose   | Number of       | Percentage |
| toxicity   | uses            |            |
| No data reported   |                 |            |
| Regulatory uses - Toxicity and other safety testing including pharmacology - Ecotox  | kicity          |            |
|  |                 | conto co   |
| No data reported   |                 | centage    |
| No data reported   |                 | centage    |
|  |                 | centage    |
| Regulatory uses by type of legislation   |                 | centage    |
| Regulatory uses by type of legislation<br>Type of legislation Number of uses Percentage  |                 | centage    |
| Regulatory uses by type of legislation   |                 | centage    |
| Regulatory uses by type of legislation<br>Type of legislation Number of uses Percentage  |                 | centage    |
| Regulatory uses by type of legislation<br>Type of legislation Number of uses Percentage<br>No data reported  |                 | centage    |
| Regulatory uses by type of legislationType of legislationNumber of usesPercentageNo data reportedRegulatory uses by origin of regulatory requirement   |                 | centage    |
| 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 |                 | centage    |
| 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                          |                 | centage    |

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    | 2766           | 100%       |
| Total | 2766           | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 83             | 3%         |
| Mild [up to and including] | 2186           | 79.03%     |
| Moderate                   | 497            | 17.97%     |
| Total                      | 2766           | 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 | 2766           | 100%       |
| Total                   | 2766           | 100.00%    |

# Part 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

# Member State: Luxembourg, 2017

Part 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           | 5348              | 21.14%     |
| Rats           | 96                | 0.38%      |
| Zebra fish     | 19849             | 78.48%     |
| Total          | 25293             | 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 | 25293             | 100%       |
| Total  | 25293             | 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

# Part 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           | 5348       | 224    | 5572  |
| Rats           | 96         |        | 96    |
| Zebra fish     | 19849      |        | 19849 |
| Total          | 25293      | 224    | 25517 |

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

#### categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 24485     | 95.96%     |
| Translational and applied research   | 888       | 3.48%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 144       | 0.56%      |
| skills   |           |            |
| Total  | 25517     | 100.00%    |

#### Basic research related uses

| Basic research                            | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                  | 1861           | 7.6%       |
| Cardiovascular Blood and Lymphatic System | 374            | 1.53%      |
| Nervous System                            | 20188          | 82.45%     |
| Immune System                             | 2062           | 8.42%      |
| Total                                     | 24485          | 100.00%    |

#### Translational and applied research related uses

| Translational and applied research | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Human Cancer                       | 526            | 59.23%     |
| Human Infectious Disorders         | 326            | 36.71%     |
| Human Immune Disorders             | 36             | 4.05%      |
| Total                              | 888            | 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 usesPercentageNo 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
|   |           |            |

#### 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 | Number of | Percentage |
|--|-----------|------------|
| 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    | 25293          | 99.12%     |
| Yes   | 224            | 0.88%      |
| Total | 25517          | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 519            | 2.03%      |
| Mild [up to and including] | 21614          | 84.7%      |
| Moderate                   | 3213           | 12.59%     |
| Severe                     | 171            | 0.67%      |
| Total                      | 25517          | 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                         | 22113          | 86.66%     |
| Genetically altered without a harmful phenotype | 3336           | 13.07%     |
| Genetically altered with a harmful phenotype    | 68             | 0.27%      |
| Total   | 25517          | 100.00%    |

# Part 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     | 77         |        | 77    |
| Total          | 77         |        | 77    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 77             | 100%       |
| Total                      | 77             | 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 | 77             | 100%       |
| Total   | 77             | 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 | 77             | 100%       |
| Total          | 77             | 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 |
|----------------|------------|--------|------------|
| Zebra fish     | 247        |        | 247        |
| Total          | 247        |        | 247        |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 247            | 100%       |
| Total                      | 247            | 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 | 247            | 100%       |
| Total   | 247            | 100.00%    |

# Member State: Malta, 2017

Part 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     | 250               | 100%       |
| Total          | 250               | 100.00%    |

Place of birth of animals other than non-human primates

| Place of birth                 | Number of animals | Percentage |
|--------------------------------|-------------------|------------|
| Animals born in rest of Europe | 250               | 100%       |
| Total                          | 250               | 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

Part 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     | 250        |        | 250   |
| Total          | 250        |        | 250   |

Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

| Purpose Category                   | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Translational and applied research | 250            | 100%       |
| Total                              | 250            | 100.00%    |

Basic research related uses

Basic research Number of uses Percentage

No data reported

Translational and applied research related uses

| Translational and applied research | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Animal Diseases and Disorders      | 250            | 100%       |
| Total                              | 250            | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
|   | _         | -          |

#### 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 | Number of | Percentage |
|--|-----------|------------|
| 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    | 250            | 100%       |
| Total | 250            | 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] | 250            | 100%       |
| Total                      | 250            | 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 | 250            | 100%       |
| Total                   | 250            | 100.00%    |

# Part 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

# Member State: Netherlands, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 188238            | 41.48%     |
| Rats                             | 89294             | 19.68%     |
| Guinea-Pigs                      | 5702              | 1.26%      |
| Hamsters (Syrian)                | 1025              | 0.23%      |
| Hamsters (Chinese)               | 12                | 0%         |
| Other Rodents                    | 736               | 0.16%      |
| Rabbits                          | 9551              | 2.1%       |
| Cats                             | 174               | 0.04%      |
| Dogs                             | 549               | 0.12%      |
| Ferrets                          | 608               | 0.13%      |
| Other carnivores                 | 270               | 0.06%      |
| Horses, donkeys and cross-breeds | 173               | 0.04%      |
| Pigs                             | 9587              | 2.11%      |
| Goats                            | 176               | 0.04%      |
| Sheep                            | 531               | 0.12%      |
| Cattle                           | 2629              | 0.58%      |
| Marmoset and tamarins            | 27                | 0.01%      |
| Cynomolgus monkey                | 23                | 0.01%      |
| Rhesus monkey                    | 141               | 0.03%      |
| Other Mammals                    | 3305              | 0.73%      |
| Domestic fowl                    | 55152             | 12.15%     |
| Other birds                      | 17946             | 3.95%      |
| Reptiles                         | 294               | 0.06%      |
| Xenopus                          | 278               | 0.06%      |
| Other Amphibians                 | 60                | 0.01%      |
| Zebra fish                       | 51456             | 11.34%     |
| Other Fish                       | 15842             | 3.49%      |
| Total                            | 453779            | 100.00%    |

Numbers of animals used for the first time by species

# 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         | 350508            | 77.27%     |
| Animals born in the EU but not at a registered breeder | 94773             | 20.89%     |
| Animals born in rest of Europe                         | 44                | 0.01%      |
| Animals born in rest of world                          | 8263              | 1.82%      |
| Total  | 453588            | 100.00%    |

# Source of non-human primates

| NHP Source (origin)                            | Number of animals | Percentage |
|--|-------------------|------------|
| Animals born at a registered breeder within EU | 189               | 98.95%     |
| Animals born in Asia                           | 2                 | 1.05%      |
| Total  | 191               | 100.00%    |

Generation of non-human primates

| NHP Generation         | Number of animals | Percentage |
|------------------------|-------------------|------------|
| F2 or greater          | 2                 | 1.05%      |
| Self-sustaining colony | 189               | 98.95%     |
| Total                  | 191               | 100.00%    |

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Mice         188238         5906         194           Rats         89294         1805         91           Guinea-Pigs         5702         114         55           Hamsters (Syrian)         1025         10         1           Hamsters (Chinese)         12         10         1           Other Rodents         736         10         1           Rabbits         9551         213         9           Cats         174         26         1           Dogs         549         360         1 | otal<br>144<br>099<br>816<br>035<br>12<br>736<br>764<br>200 |
|---|---|
| Rats         89294         1805         91           Guinea-Pigs         5702         114         55           Hamsters (Syrian)         1025         10         1           Hamsters (Chinese)         12         10         1           Other Rodents         736         213         9           Cats         174         26         26           Dogs         549         360         1   | 099<br>816<br>035<br>12<br>736<br>764                       |
| Guinea-Pigs         5702         114         5           Hamsters (Syrian)         1025         10         1           Hamsters (Chinese)         12         1         1           Other Rodents         736         1         1           Rabbits         9551         213         9           Cats         174         26         1           Dogs         549         360         1  | 816<br>035<br>12<br>736<br>764                              |
| Hamsters (Syrian)         1025         10         1           Hamsters (Chinese)         12         1           Other Rodents         736         1           Rabbits         9551         213         9           Cats         174         26         1           Dogs         549         360         1   | 035<br>12<br>736<br>764                                     |
| Hamsters (Chinese)         12            Other Rodents         736             Rabbits         9551         213         9           Cats         174         26            Dogs         549         360   | 12<br>736<br>764  |
| Other Rodents         736         736           Rabbits         9551         213         9           Cats         174         26         9           Dogs         549         360         9   | 736<br>764  |
| Rabbits         9551         213         9           Cats         174         26         9           Dogs         549         360         9   | 764   |
| Cats         174         26           Dogs         549         360  | -   |
| Dogs 549 360  | 200   |
|   |   |
| <b>Ferrets</b> 608 72   | 909   |
|   | 680   |
| Other carnivores 270  | 270   |
| Horses, donkeys and cross-breeds 173  | 173   |
| Pigs 9587 151 9   | 738   |
| <b>Goats</b> 176 83   | 259   |
| Sheep 531 27  | 558   |
| Cattle 2629 1204 3  | 833   |
| Marmoset and tamarins 27 14   | 41  |
| Cynomolgus monkey 23 19   | 42  |
| Rhesus monkey14193  | 234   |
| Other Mammals         3305         10         3   | 315   |
| <b>Domestic fowl</b> 55152 219 55   | 371   |
| <b>Other birds</b> 17946 376 18   | 322   |
| Reptiles 294  | 294   |
| Rana 9  | 9   |
| Xenopus 278 160   | 438   |
| Other Amphibians 60   | 60  |
| <b>Zebra fish</b> 51456 220 51  | 676   |
| Other Fish 15842 45 15  | 887   |
| Total 453779 11136 464  | 915   |

#### First use versus reuses

# Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

| Purpose Category   | Number of<br>uses | Percentage |
|--|-------------------|------------|
| Basic Research   | 188633            | 40.57%     |
| Translational and applied research   | 127029            | 27.32%     |
| Regulatory use and Routine production  | 122247            | 26.29%     |
| Protection of the natural environment in the interests of the health or welfare of human   | 873               | 0.19%      |
| beings or animals  |                   |            |
| Preservation of species  | 3698              | 0.8%       |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 22074             | 4.75%      |
| skills   |                   |            |
| Forensic enquiries   | 361               | 0.08%      |
| Total  | 464915            | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 86830          | 46.03%     |
| Cardiovascular Blood and Lymphatic System   | 6673           | 3.54%      |
| Nervous System                              | 17654          | 9.36%      |
| Respiratory System                          | 758            | 0.4%       |
| Gastrointestinal System including Liver     | 2857           | 1.51%      |
| Musculoskeletal System                      | 692            | 0.37%      |
| Immune System                               | 16286          | 8.63%      |
| Urogenital/Reproductive System              | 1129           | 0.6%       |
| Sensory Organs (skin, eyes and ears)        | 1030           | 0.55%      |
| Endocrine System/Metabolism                 | 4351           | 2.31%      |
| Multisystemic                               | 4084           | 2.17%      |
| Ethology / Animal Behaviour /Animal Biology | 20617          | 10.93%     |
| Other basic research                        | 25672          | 13.61%     |
| Total                                       | 188633         | 100.00%    |

# Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 13914          | 10.95%     |
| Human Infectious Disorders                          | 22898          | 18.03%     |
| Human Cardiovascular Disorders                      | 5882           | 4.63%      |
| Human Nervous and Mental Disorders                  | 9358           | 7.37%      |
| Human Respiratory Disorders                         | 2410           | 1.9%       |
| Human Gastrointestinal Disorders including Liver    | 2554           | 2.01%      |
| Human Musculoskeletal Disorders                     | 1587           | 1.25%      |
| Human Immune Disorders                              | 4179           | 3.29%      |
| Human Urogenital/Reproductive Disorders             | 814            | 0.64%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 575            | 0.45%      |
| Human Endocrine/Metabolism Disorders                | 2423           | 1.91%      |
| Other Human Disorders                               | 235            | 0.18%      |
| Animal Diseases and Disorders                       | 31368          | 24.69%     |
| Animal Welfare                                      | 22221          | 17.49%     |
| Diagnosis of diseases                               | 1115           | 0.88%      |
| Plant diseases                                      | 8              | 0.01%      |
| Non-regulatory toxicology and ecotoxicology         | 5488           | 4.32%      |
| Total   | 127029         | 100.00%    |

# Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 50082          | 40.97%     |
| Other efficacy and tolerance testing                     | 3235           | 2.65%      |
| Toxicity and other safety testing including pharmacology | 68753          | 56.24%     |
| Routine production                                       | 177            | 0.14%      |
| Total  | 122247         | 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   | 1948           | 3.89%      |
| Batch potency testing  | 47934          | 95.71%     |
| Other quality controls   | 200            | 0.4%       |
| Total  | 50082          | 100.00%    |

| Regulatory uses - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
|--|----------------|------------|
| Acute and sub-acute  | 1886           | 2.74%      |
| Skin irritation/corrosion  | 47             | 0.07%      |
| Skin sensitisation   | 2378           | 3.46%      |
| Eye irritation/corrosion   | 59             | 0.09%      |
| Repeated dose toxicity   | 8739           | 12.71%     |
| Genotoxicity   | 106            | 0.15%      |
| Reproductive toxicity  | 36568          | 53.19%     |
| Developmental toxicity   | 9944           | 14.46%     |
| Kinetics   | 1635           | 2.38%      |
| Pharmaco-dynamics (incl safety pharmacology)                               | 8              | 0.01%      |
| Phototoxicity  | 4              | 0.01%      |
| Ecotoxicity  | 4101           | 5.96%      |
| Safety testing in food and feed area                                       | 2104           | 3.06%      |
| Target animal safety   | 1174           | 1.71%      |
| Total  | 68753          | 100.00%    |

# Regulatory uses - Toxicity and other safety testing including pharmacology

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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| Non lethal methods  | 1886      | 100%       |
| Total   | 1886      | 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<br>uses | Percentage |
|---|-------------------|------------|
| up to 28 days   | 3875              | 44.34%     |
| 29 - 90 days  | 4131              | 47.27%     |
| > 90 days   | 733               | 8.39%      |
| Total   | 8739              | 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   | 1368           | 33.36%     |
| Chronic toxicity   | 2329           | 56.79%     |
| Bioaccumulation  | 404            | 9.85%      |
| Total  | 4101           | 100.00%    |

#### Regulatory uses by type of legislation

| Type of legislation   | Number of<br>uses | Percentage |
|---|-------------------|------------|
| Legislation on medicinal products for human use   | 30050             | 24.62%     |
| Legislation on medicinal products for veterinary use and their residues                             | 31915             | 26.14%     |
| Industrial chemicals legislation  | 57024             | 46.71%     |
| Plant protection product legislation  | 312               | 0.26%      |
| Biocides legislation  | 92                | 0.08%      |
| Food legislation including food contact material  | 447               | 0.37%      |
| Feed legislation including legislation for the safety of target animals, workers and<br>environment | 2164              | 1.77%      |
| Other legislation   | 66                | 0.05%      |
| Total   | 122070            | 100.00%    |

## Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 119368         | 97.79%     |
| Legislation satisfying national requirements only [within EU] | 8              | 0.01%      |
| Legislation satisfying Non-EU requirements only               | 2694           | 2.21%      |
| Total   | 122070         | 100.00%    |

#### Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 6              | 3.39%      |
| Other product types  | 171            | 96.61%     |
| Total                | 177            | 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    | 453779         | 97.6%      |
| Yes   | 11136          | 2.4%       |
| Total | 464915         | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 31581          | 6.79%      |
| Mild [up to and including] | 298851         | 64.28%     |
| Moderate                   | 120316         | 25.88%     |
| Severe                     | 14167          | 3.05%      |
| Total                      | 464915         | 100.00%    |

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

# Genetic statusNumber of usesPercentageNot genetically altered33591872.25%Genetically altered without a harmful phenotype12128426.09%Genetically altered with a harmful phenotype77131.66%Total464915100.00%

# Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 10790      | 2      | 10792 |
| Rats           | 9          |        | 9     |
| Zebra fish     | 167        |        | 167   |
| Total          | 10966      | 2      | 10968 |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 30             | 0.27%      |
| Mild [up to and including] | 10045          | 91.58%     |
| Moderate                   | 879            | 8.01%      |
| Severe                     | 14             | 0.13%      |
| Total                      | 10968          | 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                         | 8267           | 75.37%     |
| Genetically altered without a harmful phenotype | 2655           | 24.21%     |
| Genetically altered with a harmful phenotype    | 46             | 0.42%      |
| Total   | 10968          | 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                                  | 7630           | 71.9%      |
| Cardiovascular Blood and Lymphatic System | 195            | 1.84%      |
| Nervous System                            | 521            | 4.91%      |
| Gastrointestinal System including Liver   | 346            | 3.26%      |
| Immune System                             | 296            | 2.79%      |
| Urogenital/Reproductive System            | 70             | 0.66%      |
| Multisystemic                             | 31             | 0.29%      |
| Other basic research                      | 1523           | 14.35%     |
| Total                                     | 10612          | 100.00%    |

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

| research p | ourposes |
|------------|----------|
|------------|----------|

| Translational and applied research               | Number of uses | Percentage |
|--|----------------|------------|
| Human Cancer                                     | 6              | 1.69%      |
| Human Infectious Disorders                       | 15             | 4.21%      |
| Human Nervous and Mental Disorders               | 334            | 93.82%     |
| Human Gastrointestinal Disorders including Liver | 1              | 0.28%      |
| Total  | 356            | 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           | 1057       |        | 1057       |
| Rats           | 429        |        | 429        |
| Zebra fish     | 181        |        | 181        |
| Total          | 1667       |        | 1667       |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 1106           | 66.35%     |
| Moderate                   | 544            | 32.63%     |
| Severe                     | 17             | 1.02%      |
| Total                      | 1667           | 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 | 1667           | 100%       |
| Total  | 1667           | 100.00%    |

# Member State: Poland, 2017

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

| Animal species  | Number of animals | Percentage |
|---|-------------------|------------|
| Mice  | 88894             | 57.51%     |
| Rats  | 28865             | 18.67%     |
| Guinea-Pigs   | 5232              | 3.38%      |
| Hamsters (Syrian)                                     | 150               | 0.1%       |
| Mongolian gerbil                                      | 120               | 0.08%      |
| Other Rodents   | 7930              | 5.13%      |
| Rabbits   | 718               | 0.46%      |
| Other carnivores                                      | 130               | 0.08%      |
| Horses, donkeys and cross-breeds                      | 50                | 0.03%      |
| Pigs  | 1513              | 0.98%      |
| Goats   | 17                | 0.01%      |
| Sheep   | 1231              | 0.8%       |
| Cattle  | 403               | 0.26%      |
| Other species of Old World Monkeys (Cercopithecoidea) | 14                | 0.01%      |
| Other species of New World Monkeys (Ceboidea)         | 3                 | 0%         |
| Other Mammals   | 639               | 0.41%      |
| Domestic fowl   | 5067              | 3.28%      |
| Other birds   | 6470              | 4.19%      |
| Reptiles  | 314               | 0.2%       |
| Rana  | 20                | 0.01%      |
| Other Amphibians                                      | 456               | 0.3%       |
| Zebra fish  | 950               | 0.61%      |
| Other Fish  | 5381              | 3.48%      |
| Total   | 154567            | 100.00%    |

Numbers of animals used for the first time by species

# 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         | 135019            | 87.36%     |
| Animals born in the EU but not at a registered breeder | 18496             | 11.97%     |
| Animals born in rest of Europe                         | 361               | 0.23%      |
| Animals born in rest of world                          | 674               | 0.44%      |
| Total  | 154550            | 100.00%    |

# Source of non-human primates

| NHP Source (origin)                            | Number of animals | Percentage |
|--|-------------------|------------|
| Animals born at a registered breeder within EU | 17                | 100%       |
| Total  | 17                | 100.00%    |

## Generation of non-human primates

| NHP Generation | Number of animals | Percentage |
|----------------|-------------------|------------|
| F2 or greater  | 17                | 100%       |
| Total          | 17                | 100.00%    |

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species  | First uses | Reuses | Total  |
|---|------------|--------|--------|
| Mice  | 88894      | 297    | 89191  |
| Rats  | 28865      | 8      | 28873  |
| Guinea-Pigs   | 5232       | 3      | 5235   |
| Hamsters (Syrian)                                     | 150        |        | 150    |
| Mongolian gerbil                                      | 120        |        | 120    |
| Other Rodents   | 7930       | 178    | 8108   |
| Rabbits   | 718        | 102    | 820    |
| Dogs  |            | 10     | 10     |
| Other carnivores                                      | 130        |        | 130    |
| Horses, donkeys and cross-breeds                      | 50         | 23     | 73     |
| Pigs  | 1513       | 4      | 1517   |
| Goats   | 17         | 7      | 24     |
| Sheep   | 1231       | 70     | 1301   |
| Cattle  | 403        | 10     | 413    |
| Other species of Old World Monkeys (Cercopithecoidea) | 14         |        | 14     |
| Other species of New World Monkeys (Ceboidea)         | 3          |        | 3      |
| Other Mammals   | 639        |        | 639    |
| Domestic fowl   | 5067       |        | 5067   |
| Other birds   | 6470       | 96     | 6566   |
| Reptiles  | 314        |        | 314    |
| Rana  | 20         |        | 20     |
| Other Amphibians                                      | 456        |        | 456    |
| Zebra fish  | 950        |        | 950    |
| Other Fish  | 5381       |        | 5381   |
| Total   | 154567     | 808    | 155375 |

First use versus reuses

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

# categories of scientific purposes

| Purpose Category   | Number of<br>uses | Percentage |
|--|-------------------|------------|
| Basic Research   | 113469            | 73.03%     |
| Translational and applied research   | 15947             | 10.26%     |
| Regulatory use and Routine production  | 24762             | 15.94%     |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 43                | 0.03%      |
| Preservation of species  | 25                | 0.02%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills          | 1129              | 0.73%      |
| Total  | 155375            | 100.00%    |

## Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 8173           | 7.2%       |
| Cardiovascular Blood and Lymphatic System   | 6727           | 5.93%      |
| Nervous System                              | 52378          | 46.16%     |
| Respiratory System                          | 784            | 0.69%      |
| Gastrointestinal System including Liver     | 3070           | 2.71%      |
| Musculoskeletal System                      | 673            | 0.59%      |
| Immune System                               | 7755           | 6.83%      |
| Urogenital/Reproductive System              | 2929           | 2.58%      |
| Sensory Organs (skin, eyes and ears)        | 225            | 0.2%       |
| Endocrine System/Metabolism                 | 5992           | 5.28%      |
| Multisystemic                               | 5956           | 5.25%      |
| Ethology / Animal Behaviour /Animal Biology | 10531          | 9.28%      |
| Other basic research                        | 8276           | 7.29%      |
| Total                                       | 113469         | 100.00%    |

# Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 3081           | 19.32%     |
| Human Infectious Disorders                          | 366            | 2.3%       |
| Human Cardiovascular Disorders                      | 815            | 5.11%      |
| Human Nervous and Mental Disorders                  | 1176           | 7.37%      |
| Human Respiratory Disorders                         | 943            | 5.91%      |
| Human Musculoskeletal Disorders                     | 64             | 0.4%       |
| Human Immune Disorders                              | 120            | 0.75%      |
| Human Urogenital/Reproductive Disorders             | 44             | 0.28%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 20             | 0.13%      |
| Human Endocrine/Metabolism Disorders                | 316            | 1.98%      |
| Other Human Disorders                               | 35             | 0.22%      |
| Animal Diseases and Disorders                       | 490            | 3.07%      |
| Animal Welfare                                      | 3852           | 24.16%     |
| Diagnosis of diseases                               | 3088           | 19.36%     |
| Non-regulatory toxicology and ecotoxicology         | 1537           | 9.64%      |
| Total   | 15947          | 100.00%    |

# Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 16493          | 66.61%     |
| Other efficacy and tolerance testing                     | 195            | 0.79%      |
| Toxicity and other safety testing including pharmacology | 7784           | 31.44%     |
| Routine production                                       | 290            | 1.17%      |
| Total  | 24762          | 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   | 3982           | 24.14%     |
| Pyrogenicity testing   | 236            | 1.43%      |
| Batch potency testing  | 11482          | 69.62%     |
| Other quality controls   | 793            | 4.81%      |
| Total  | 16493          | 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  | 1050           | 13.49%     |
| Skin irritation/corrosion  | 139            | 1.79%      |
| Skin sensitisation   | 707            | 9.08%      |
| Eye irritation/corrosion   | 9              | 0.12%      |
| Repeated dose toxicity   | 807            | 10.37%     |
| Reproductive toxicity  | 669            | 8.59%      |
| Developmental toxicity   | 1694           | 21.76%     |
| Kinetics   | 30             | 0.39%      |
| Ecotoxicity  | 2364           | 30.37%     |
| Other toxicity/safety testing  | 315            | 4.05%      |
| Total  | 7784           | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 180       | 17.14%     |
| Non lethal methods  | 870       | 82.86%     |
| Total   | 1050      | 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| up to 28 days  | 387       | 47.96%     |
| 29 - 90 days   | 420       | 52.04%     |
| Total  | 807       | 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   | 2364           | 100%       |
| Total  | 2364           | 100.00%    |

# Regulatory uses by type of legislation

| Type of legislation   | Number of uses | Percentage |
|---|----------------|------------|
| Legislation on medicinal products for human use                         | 16253          | 66.41%     |
| Legislation on medicinal products for veterinary use and their residues | 2251           | 9.2%       |
| Medical devices legislation   | 896            | 3.66%      |
| Industrial chemicals legislation  | 2652           | 10.84%     |
| Plant protection product legislation                                    | 2276           | 9.3%       |
| Biocides legislation  | 24             | 0.1%       |
| Food legislation including food contact material                        | 120            | 0.49%      |
| Total   | 24472          | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 23931          | 97.79%     |
| Legislation satisfying national requirements only [within EU] | 514            | 2.1%       |
| Legislation satisfying Non-EU requirements only               | 27             | 0.11%      |
| Total   | 24472          | 100.00%    |

# Routine production uses by product type

| Product type        | Number of uses | Percentage |
|---------------------|----------------|------------|
| Other product types | 290            | 100%       |
| Total               | 290            | 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    | 154567         | 99.48%     |
| Yes   | 808            | 0.52%      |
| Total | 155375         | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 4757           | 3.06%      |
| Mild [up to and including] | 49725          | 32%        |
| Moderate                   | 49829          | 32.07%     |
| Severe                     | 51064          | 32.87%     |
| Total                      | 155375         | 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                         | 146889         | 94.54%     |
| Genetically altered without a harmful phenotype | 5547           | 3.57%      |
| Genetically altered with a harmful phenotype    | 2939           | 1.89%      |
| Total   | 155375         | 100.00%    |

# Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 188        |        | 188   |
| Rats           | 109        |        | 109   |
| Other Mammals  | 61         |        | 61    |
| Total          | 358        |        | 358   |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 34             | 9.5%       |
| Mild [up to and including] | 34             | 9.5%       |
| Moderate                   | 184            | 51.4%      |
| Severe                     | 106            | 29.61%     |
| Total                      | 358            | 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 | 358            | 100%       |
| Total   | 358            | 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 | 170            | 100%       |
| Total          | 170            | 100.00%    |

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

| Translational and applied research | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Animal Diseases and Disorders      | 188            | 100%       |
| Total                              | 188            | 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           | 501        |        | 501        |
| Total          | 501        |        | 501        |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 501            | 100%       |
| Total                      | 501            | 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 | 501            | 100%       |
| Total  | 501            | 100.00%    |

# Member State: Portugal, 2017

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

| Animal species | Number of animals | Percentage |
|----------------|-------------------|------------|
| Mice           | 35221             | 85.91%     |
| Rats           | 3133              | 7.64%      |
| Other Rodents  | 140               | 0.34%      |
| Rabbits        | 36                | 0.09%      |
| Pigs           | 155               | 0.38%      |
| Sheep          | 12                | 0.03%      |
| Other Mammals  | 32                | 0.08%      |
| Domestic fowl  | 120               | 0.29%      |
| Zebra fish     | 906               | 2.21%      |
| Other Fish     | 793               | 1.93%      |
| Cephalopods    | 450               | 1.1%       |
| Total          | 40998             | 100.00%    |

#### Numbers of animals used for the first time by species

#### 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         | 39214             | 95.65%     |
| Animals born in the EU but not at a registered breeder | 1455              | 3.55%      |
| Animals born in rest of world                          | 329               | 0.8%       |
| Total  | 40998             | 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

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 35221      | 905    | 36126 |
| Rats           | 3133       | 2      | 3135  |
| Other Rodents  | 140        |        | 140   |
| Rabbits        | 36         |        | 36    |
| Pigs           | 155        |        | 155   |
| Sheep          | 12         | 18     | 30    |
| Other Mammals  | 32         |        | 32    |
| Domestic fowl  | 120        |        | 120   |
| Other birds    |            | 56     | 56    |
| Zebra fish     | 906        | 6      | 912   |
| Other Fish     | 793        | 36     | 829   |
| Cephalopods    | 450        |        | 450   |
| Total          | 40998      | 1023   | 42021 |

First use versus reuses

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

# categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 36214     | 86.18%     |
| Translational and applied research   | 5117      | 12.18%     |
| Regulatory use and Routine production  | 298       | 0.71%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 392       | 0.93%      |
| skills   |           |            |
| Total  | 42021     | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 3147           | 8.69%      |
| Cardiovascular Blood and Lymphatic System   | 1202           | 3.32%      |
| Nervous System                              | 4877           | 13.47%     |
| Respiratory System                          | 83             | 0.23%      |
| Gastrointestinal System including Liver     | 683            | 1.89%      |
| Musculoskeletal System                      | 173            | 0.48%      |
| Immune System                               | 20680          | 57.1%      |
| Urogenital/Reproductive System              | 36             | 0.1%       |
| Endocrine System/Metabolism                 | 1437           | 3.97%      |
| Multisystemic                               | 153            | 0.42%      |
| Ethology / Animal Behaviour /Animal Biology | 1277           | 3.53%      |
| Other basic research                        | 2466           | 6.81%      |
| Total                                       | 36214          | 100.00%    |

#### Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 162            | 3.17%      |
| Human Infectious Disorders                          | 403            | 7.88%      |
| Human Cardiovascular Disorders                      | 68             | 1.33%      |
| Human Nervous and Mental Disorders                  | 1973           | 38.56%     |
| Human Gastrointestinal Disorders including Liver    | 102            | 1.99%      |
| Human Musculoskeletal Disorders                     | 127            | 2.48%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 233            | 4.55%      |
| Human Endocrine/Metabolism Disorders                | 36             | 0.7%       |
| Animal Diseases and Disorders                       | 3              | 0.06%      |
| Animal Welfare                                      | 604            | 11.8%      |
| Diagnosis of diseases                               | 914            | 17.86%     |
| Non-regulatory toxicology and ecotoxicology         | 492            | 9.62%      |
| Total   | 5117           | 100.00%    |

#### Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Toxicity and other safety testing including pharmacology | 298            | 100%       |
| 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 |
|--|----------------|------------|
| Ecotoxicity  | 126            | 42.28%     |
| Safety testing in food and feed area                                       | 172            | 57.72%     |
| Total  | 298            | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| No data reported  |           |            |

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 | Number of | Percentage |
|--|-----------|------------|
| 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 |
|--|----------------|------------|
| Chronic toxicity   | 126            | 100%       |
| Total  | 126            | 100.00%    |

#### Regulatory uses by type of legislation

| Type of legislation   | Number of uses | Percentage |
|---|----------------|------------|
| Legislation on medicinal products for veterinary use and their residues | 126            | 42.28%     |
| Food legislation including food contact material                        | 172            | 57.72%     |
| Total   | 298            | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement      | Number of uses | Percentage |
|--|----------------|------------|
| Legislation satisfying EU requirements | 298            | 100%       |
| Total                                  | 298            | 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    | 40998          | 97.57%     |
| Yes   | 1023           | 2.43%      |
| Total | 42021          | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 2017           | 4.8%       |
| Mild [up to and including] | 17515          | 41.68%     |
| Moderate                   | 12114          | 28.83%     |
| Severe                     | 10375          | 24.69%     |
| Total                      | 42021          | 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                         | 27193          | 64.71%     |
| Genetically altered without a harmful phenotype | 13750          | 32.72%     |
| Genetically altered with a harmful phenotype    | 1078           | 2.57%      |
| Total   | 42021          | 100.00%    |

# Part 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           | 495        | 39     | 534   |
| Total          | 495        | 39     | 534   |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 256            | 47.94%     |
| Moderate                   | 237            | 44.38%     |
| Severe                     | 41             | 7.68%      |
| Total                      | 534            | 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                         | 17             | 3.18%      |
| Genetically altered without a harmful phenotype | 502            | 94.01%     |
| Genetically altered with a harmful phenotype    | 15             | 2.81%      |
| Total   | 534            | 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                                  | 83             | 18.49%     |
| Cardiovascular Blood and Lymphatic System | 3              | 0.67%      |
| Nervous System                            | 75             | 16.7%      |
| Immune System                             | 288            | 64.14%     |
| Total                                     | 449            | 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 | 85             | 100%       |
| Total                              | 85             | 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           | 9447       |        | 9447       |
| Zebra fish     | 368        |        | 368        |
| Total          | 9815       |        | 9815       |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 9626           | 98.07%     |
| Moderate                   | 189            | 1.93%      |
| Total                      | 9815           | 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                         | 3347           | 34.1%      |
| Genetically altered without a harmful phenotype | 6214           | 63.31%     |
| Genetically altered with a harmful phenotype    | 254            | 2.59%      |
| Total   | 9815           | 100.00%    |

# Member State: Romania, 2017

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

| Animal species    | Number of animals | Percentage |
|-------------------|-------------------|------------|
| Mice              | 7975              | 55.86%     |
| Rats              | 4367              | 30.59%     |
| Guinea-Pigs       | 792               | 5.55%      |
| Hamsters (Syrian) | 150               | 1.05%      |
| Rabbits           | 318               | 2.23%      |
| Pigs              | 58                | 0.41%      |
| Sheep             | 85                | 0.6%       |
| Domestic fowl     | 280               | 1.96%      |
| Other birds       | 23                | 0.16%      |
| Rana              | 230               | 1.61%      |
| Total             | 14278             | 100.00%    |

## Numbers of animals used for the first time by species

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         | 12356             | 86.54%     |
| Animals born in the EU but not at a registered breeder | 1922              | 13.46%     |
| Total  | 14278             | 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

Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| That use versus reuses           |            |        |       |
|----------------------------------|------------|--------|-------|
| Animal species                   | First uses | Reuses | Total |
| Mice                             | 7975       |        | 7975  |
| Rats                             | 4367       |        | 4367  |
| Guinea-Pigs                      | 792        |        | 792   |
| Hamsters (Syrian)                | 150        |        | 150   |
| Rabbits                          | 318        | 186    | 504   |
| Horses, donkeys and cross-breeds |            | 2      | 2     |
| Pigs                             | 58         |        | 58    |
| Sheep                            | 85         | 124    | 209   |
| Cattle                           |            | 2      | 2     |
| Domestic fowl                    | 280        | 50     | 330   |
| Other birds                      | 23         |        | 23    |
| Rana                             | 230        |        | 230   |
| Total                            | 14278      | 364    | 14642 |

#### First use versus reuses

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

# categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 5381      | 36.75%     |
| Translational and applied research   | 5500      | 37.56%     |
| Regulatory use and Routine production  | 2522      | 17.22%     |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 1239      | 8.46%      |
| skills   |           |            |
| Total  | 14642     | 100.00%    |

#### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 1525           | 28.34%     |
| Cardiovascular Blood and Lymphatic System   | 539            | 10.02%     |
| Nervous System                              | 634            | 11.78%     |
| Gastrointestinal System including Liver     | 165            | 3.07%      |
| Musculoskeletal System                      | 339            | 6.3%       |
| Immune System                               | 1349           | 25.07%     |
| Urogenital/Reproductive System              | 70             | 1.3%       |
| Sensory Organs (skin, eyes and ears)        | 10             | 0.19%      |
| Endocrine System/Metabolism                 | 318            | 5.91%      |
| Multisystemic                               | 342            | 6.36%      |
| Ethology / Animal Behaviour /Animal Biology | 90             | 1.67%      |
| Total                                       | 5381           | 100.00%    |

#### Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Infectious Disorders                          | 114            | 2.07%      |
| Human Cardiovascular Disorders                      | 211            | 3.84%      |
| Human Gastrointestinal Disorders including Liver    | 286            | 5.2%       |
| Human Musculoskeletal Disorders                     | 260            | 4.73%      |
| Human Immune Disorders                              | 275            | 5%         |
| Human Sensory Organ Disorders (skin, eyes and ears) | 121            | 2.2%       |
| Human Endocrine/Metabolism Disorders                | 690            | 12.55%     |
| Animal Diseases and Disorders                       | 74             | 1.35%      |
| Diagnosis of diseases                               | 3040           | 55.27%     |
| Non-regulatory toxicology and ecotoxicology         | 429            | 7.8%       |
| Total   | 5500           | 100.00%    |

## Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 1789           | 70.94%     |
| Toxicity and other safety testing including pharmacology | 106            | 4.2%       |
| Routine production                                       | 627            | 24.86%     |
| Total  | 2522           | 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   | 721            | 40.3%      |
| Pyrogenicity testing   | 234            | 13.08%     |
| Batch potency testing  | 753            | 42.09%     |
| Other quality controls   | 81             | 4.53%      |
| Total  | 1789           | 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  | 20             | 18.87%     |
| Ecotoxicity  | 86             | 81.13%     |
| Total  | 106            | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| Non lethal methods  | 20        | 100%       |
| Total   | 20        | 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 | Number of | Percentage |
|--|-----------|------------|
| 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 |
|--|----------------|------------|
| Chronic toxicity   | 86             | 100%       |
| Total  | 86             | 100.00%    |

## Regulatory uses by type of legislation

| Type of legislation   | Number of uses | Percentage |
|---|----------------|------------|
| Legislation on medicinal products for human use                         | 914            | 48.23%     |
| Legislation on medicinal products for veterinary use and their residues | 875            | 46.17%     |
| Medical devices legislation   | 86             | 4.54%      |
| Food legislation including food contact material                        | 20             | 1.06%      |
| Total   | 1895           | 100.00%    |

## Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement               | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements          | 1513           | 79.84%     |
| Legislation satisfying Non-EU requirements only | 382            | 20.16%     |
| Total   | 1895           | 100.00%    |

## Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 587            | 93.62%     |
| Other product types  | 40             | 6.38%      |
| Total                | 627            | 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    | 14278          | 97.51%     |
| Yes   | 364            | 2.49%      |
| Total | 14642          | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 2110           | 14.41%     |
| Mild [up to and including] | 5061           | 34.56%     |
| Moderate                   | 6094           | 41.62%     |
| Severe                     | 1377           | 9.4%       |
| Total                      | 14642          | 100.00%    |

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

| of animals                                      |                |            |
|---|----------------|------------|
| Genetic status                                  | Number of uses | Percentage |
| Not genetically altered                         | 14289          | 97.59%     |
| Genetically altered without a harmful phenotype | 353            | 2.41%      |
| Total   | 14642          | 100.00%    |

# Part 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

# Member State: Slovakia, 2017

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

| Animal species   | Number of animals | Percentage |
|------------------|-------------------|------------|
| Mice             | 5547              | 37.72%     |
| Rats             | 7619              | 51.81%     |
| Guinea-Pigs      | 1036              | 7.05%      |
| Mongolian gerbil | 9                 | 0.06%      |
| Rabbits          | 195               | 1.33%      |
| Cats             | 11                | 0.07%      |
| Cattle           | 1                 | 0.01%      |
| Domestic fowl    | 228               | 1.55%      |
| Other birds      | 59                | 0.4%       |
| Total            | 14705             | 100.00%    |

# Numbers of animals used for the first time by species

### 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 | 14705             | 100%       |
| Total  | 14705             | 100.00%    |

### Source of non-human primates

NHP Source (origin)Number of animalsPercentageNo data reported

Generation of non-human primates

NHP Generation Number of animals Percentage

No data reported

# Part 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             | 5547       |        | 5547  |

| Animal species   | First uses | neuses | TULAI |
|------------------|------------|--------|-------|
| Mice             | 5547       |        | 5547  |
| Rats             | 7619       |        | 7619  |
| Guinea-Pigs      | 1036       |        | 1036  |
| Mongolian gerbil | 9          |        | 9     |
| Rabbits          | 195        | 31     | 226   |
| Cats             | 11         |        | 11    |
| Sheep            |            | 2      | 2     |
| Cattle           | 1          |        | 1     |
| Domestic fowl    | 228        | 5      | 233   |
| Other birds      | 59         |        | 59    |
| Total            | 14705      | 38     | 14743 |

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

categories of scientific purposes

| Purpose Category  | Number of | Percentage |
|---|-----------|------------|
|   | uses      |            |
| Basic Research  | 10819     | 73.38%     |
| Translational and applied research  | 1046      | 7.09%      |
| Regulatory use and Routine production   | 2822      | 19.14%     |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 56        | 0.38%      |
| Total   | 14743     | 100.00%    |

### Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 316            | 2.92%      |
| Cardiovascular Blood and Lymphatic System   | 932            | 8.61%      |
| Nervous System                              | 4076           | 37.67%     |
| Respiratory System                          | 607            | 5.61%      |
| Gastrointestinal System including Liver     | 180            | 1.66%      |
| Musculoskeletal System                      | 19             | 0.18%      |
| Immune System                               | 424            | 3.92%      |
| Urogenital/Reproductive System              | 1175           | 10.86%     |
| Sensory Organs (skin, eyes and ears)        | 9              | 0.08%      |
| Endocrine System/Metabolism                 | 610            | 5.64%      |
| Multisystemic                               | 782            | 7.23%      |
| Ethology / Animal Behaviour /Animal Biology | 595            | 5.5%       |
| Other basic research                        | 1094           | 10.11%     |
| Total                                       | 10819          | 100.00%    |

## Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cardiovascular Disorders                      | 20             | 1.91%      |
| Human Nervous and Mental Disorders                  | 528            | 50.48%     |
| Human Immune Disorders                              | 21             | 2.01%      |
| Human Urogenital/Reproductive Disorders             | 10             | 0.96%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 27             | 2.58%      |
| Human Endocrine/Metabolism Disorders                | 60             | 5.74%      |
| Animal Diseases and Disorders                       | 374            | 35.76%     |
| Diagnosis of diseases                               | 6              | 0.57%      |
| Total   | 1046           | 100.00%    |

## Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 1014           | 35.93%     |
| Toxicity and other safety testing including pharmacology | 1777           | 62.97%     |
| Routine production                                       | 31             | 1.1%       |
| Total  | 2822           | 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   | 867            | 85.5%      |
| Batch potency testing  | 147            | 14.5%      |
| Total  | 1014           | 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  | 653            | 36.75%     |
| Skin sensitisation   | 542            | 30.5%      |
| Repeated dose toxicity   | 460            | 25.89%     |
| Reproductive toxicity  | 122            | 6.87%      |
| Total  | 1777           | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 603       | 92.34%     |
| Non lethal methods  | 50        | 7.66%      |
| Total   | 653       | 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| up to 28 days  | 280       | 60.87%     |
| 29 - 90 days   | 180       | 39.13%     |
| Total  | 460       | 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<br>uses | Percentage |
|--|-------------------|------------|
| Legislation on medicinal products for human use  | 1269              | 45.47%     |
| Legislation on medicinal products for veterinary use and their residues                          | 133               | 4.77%      |
| Medical devices legislation  | 64                | 2.29%      |
| Industrial chemicals legislation   | 946               | 33.89%     |
| Plant protection product legislation   | 9                 | 0.32%      |
| Food legislation including food contact material   | 190               | 6.81%      |
| Feed legislation including legislation for the safety of target animals, workers and environment | 180               | 6.45%      |
| Total  | 2791              | 100.00%    |

## Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement      | Number of uses | Percentage |
|--|----------------|------------|
| Legislation satisfying EU requirements | 2791           | 100%       |
| Total                                  | 2791           | 100.00%    |

## Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 31             | 100%       |
| Total                | 31             | 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    | 14705          | 99.74%     |
| Yes   | 38             | 0.26%      |
| Total | 14743          | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 1101           | 7.47%      |
| Mild [up to and including] | 4325           | 29.34%     |
| Moderate                   | 8963           | 60.79%     |
| Severe                     | 354            | 2.4%       |
| Total                      | 14743          | 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                         | 13516          | 91.68%     |
| Genetically altered without a harmful phenotype | 242            | 1.64%      |
| Genetically altered with a harmful phenotype    | 985            | 6.68%      |
| Total   | 14743          | 100.00%    |

# Part 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           | 540        |        | 540        |
| Rats           | 320        |        | 320        |
| Total          | 860        |        | 860        |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 860            | 100%       |
| Total                      | 860            | 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                         | 588            | 68.37%     |
| Genetically altered without a harmful phenotype | 18             | 2.09%      |
| Genetically altered with a harmful phenotype    | 254            | 29.53%     |
| Total   | 860            | 100.00%    |

# Member State: Slovenia, 2017

Part 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           | 3998              | 88.57%     |
| Rats           | 226               | 5.01%      |
| Rabbits        | 76                | 1.68%      |
| Pigs           | 80                | 1.77%      |
| Sheep          | 26                | 0.58%      |
| Domestic fowl  | 10                | 0.22%      |
| Other Fish     | 98                | 2.17%      |
| Total          | 4514              | 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 | 4514              | 100%       |
| Total  | 4514              | 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

# Part 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                             | 3998       | 510    | 4508  |
| Rats                             | 226        |        | 226   |
| Rabbits                          | 76         | 59     | 135   |
| Horses, donkeys and cross-breeds |            | 2      | 2     |
| Pigs                             | 80         |        | 80    |
| Sheep                            | 26         | 2      | 28    |
| Domestic fowl                    | 10         |        | 10    |
| Other Fish                       | 98         |        | 98    |
| Total                            | 4514       | 573    | 5087  |

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

# categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 1035      | 20.35%     |
| Translational and applied research   | 1731      | 34.03%     |
| Regulatory use and Routine production  | 2183      | 42.91%     |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 16        | 0.31%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills          | 122       | 2.4%       |
| Total  | 5087      | 100.00%    |

## Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 149            | 14.4%      |
| Nervous System                              | 70             | 6.76%      |
| Gastrointestinal System including Liver     | 150            | 14.49%     |
| Musculoskeletal System                      | 34             | 3.29%      |
| Immune System                               | 102            | 9.86%      |
| Endocrine System/Metabolism                 | 375            | 36.23%     |
| Multisystemic                               | 59             | 5.7%       |
| Ethology / Animal Behaviour /Animal Biology | 48             | 4.64%      |
| Other basic research                        | 48             | 4.64%      |
| Total                                       | 1035           | 100.00%    |

# Translational and applied research related uses

| Translational and applied research   | Number of uses | Percentage |
|--------------------------------------|----------------|------------|
| Human Cancer                         | 1552           | 89.66%     |
| Human Endocrine/Metabolism Disorders | 65             | 3.76%      |
| Diagnosis of diseases                | 114            | 6.59%      |
| Total                                | 1731           | 100.00%    |

#### Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 2101           | 96.24%     |
| Toxicity and other safety testing including pharmacology | 82             | 3.76%      |
| Total  | 2183           | 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   | 272            | 12.95%     |
| Pyrogenicity testing   | 59             | 2.81%      |
| Batch potency testing  | 1770           | 84.25%     |
| Total  | 2101           | 100.00%    |

## Regulatory uses - Toxicity and other safety testing including pharmacology

| Regulatory uses - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
|--|----------------|------------|
| Kinetics   | 82             | 100%       |
| Total  | 82             | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| New data was a stad   |           |            |

#### 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 | Number of | Percentage |
|--|-----------|------------|
| 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 |
|---|----------------|------------|
| Legislation on medicinal products for human use | 2183           | 100%       |
| Total   | 2183           | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement      | Number of uses | Percentage |
|--|----------------|------------|
| Legislation satisfying EU requirements | 2183           | 100%       |
| Total                                  | 2183           | 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    | 4514           | 88.74%     |
| Yes   | 573            | 11.26%     |
| Total | 5087           | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 44             | 0.86%      |
| Mild [up to and including] | 4317           | 84.86%     |
| Moderate                   | 637            | 12.52%     |
| Severe                     | 89             | 1.75%      |
| Total                      | 5087           | 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                         | 4736           | 93.1%      |
| Genetically altered without a harmful phenotype | 288            | 5.66%      |
| Genetically altered with a harmful phenotype    | 63             | 1.24%      |
| Total   | 5087           | 100.00%    |

# Part 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           | 55         |        | 55    |
| Total          | 55         |        | 55    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 55             | 100%       |
| Total                      | 55             | 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 | 55             | 100%       |
| Total                   | 55             | 100.00%    |

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

No data reported

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

| Translational and applied research | Number of uses | Percentage |
|------------------------------------|----------------|------------|
| Other Human Disorders              | 55             | 100%       |
| Total                              | 55             | 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

# Member State: Spain, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 465870            | 65.1%      |
| Rats                             | 55826             | 7.8%       |
| Guinea-Pigs                      | 6411              | 0.9%       |
| Hamsters (Syrian)                | 599               | 0.08%      |
| Other Rodents                    | 141               | 0.02%      |
| Rabbits                          | 22205             | 3.1%       |
| Cats                             | 178               | 0.02%      |
| Dogs                             | 1045              | 0.15%      |
| Ferrets                          | 164               | 0.02%      |
| Other carnivores                 | 25                | 0%         |
| Horses, donkeys and cross-breeds | 46                | 0.01%      |
| Pigs                             | 8655              | 1.21%      |
| Goats                            | 354               | 0.05%      |
| Sheep                            | 1715              | 0.24%      |
| Cattle                           | 1138              | 0.16%      |
| Cynomolgus monkey                | 246               | 0.03%      |
| Other Mammals                    | 99                | 0.01%      |
| Domestic fowl                    | 82047             | 11.46%     |
| Other birds                      | 2385              | 0.33%      |
| Reptiles                         | 1003              | 0.14%      |
| Rana                             | 18                | 0%         |
| Xenopus                          | 1204              | 0.17%      |
| Other Amphibians                 | 1996              | 0.28%      |
| Zebra fish                       | 19941             | 2.79%      |
| Other Fish                       | 42320             | 5.91%      |
| Cephalopods                      | 20                | 0%         |
| Total                            | 715651            | 100.00%    |

Numbers of animals used for the first time by species

## 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         | 668867            | 93.49%     |
| Animals born in the EU but not at a registered breeder | 45911             | 6.42%      |
| Animals born in rest of Europe                         | 31                | 0%         |
| Animals born in rest of world                          | 596               | 0.08%      |
| Total  | 715405            | 100.00%    |

# Source of non-human primates

| NHP Source (origin)    | Number of animals | Percentage |
|------------------------|-------------------|------------|
| Animals born in Asia   | 104               | 42.28%     |
| Animals born in Africa | 142               | 57.72%     |
| Total                  | 246               | 100.00%    |

# Generation of non-human primates

| NHP Generation | Number of animals | Percentage |
|----------------|-------------------|------------|
| F1             | 2                 | 0.81%      |
| F2 or greater  | 244               | 99.19%     |
| Total          | 246               | 100.00%    |

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Animal species                   | First uses | Reuses | Total  |
|----------------------------------|------------|--------|--------|
| Mice                             | 465870     | 1335   | 467205 |
| Rats                             | 55826      | 162    | 55988  |
| Guinea-Pigs                      | 6411       | 336    | 6747   |
| Hamsters (Syrian)                | 599        |        | 599    |
| Other Rodents                    | 141        |        | 141    |
| Rabbits                          | 22205      | 3726   | 25931  |
| Cats                             | 178        | 353    | 531    |
| Dogs                             | 1045       | 431    | 1476   |
| Ferrets                          | 164        |        | 164    |
| Other carnivores                 | 25         |        | 25     |
| Horses, donkeys and cross-breeds | 46         | 15     | 61     |
| Pigs                             | 8655       |        | 8655   |
| Goats                            | 354        | 15     | 369    |
| Sheep                            | 1715       | 238    | 1953   |
| Cattle                           | 1138       | 562    | 1700   |
| Cynomolgus monkey                | 246        | 205    | 451    |
| Other Mammals                    | 99         |        | 99     |
| Domestic fowl                    | 82047      | 60     | 82107  |
| Other birds                      | 2385       | 150    | 2535   |
| Reptiles                         | 1003       |        | 1003   |
| Rana                             | 18         |        | 18     |
| Xenopus                          | 1204       |        | 1204   |
| Other Amphibians                 | 1996       |        | 1996   |
| Zebra fish                       | 19941      | 1434   | 21375  |
| Other Fish                       | 42320      | 1160   | 43480  |
| Cephalopods                      | 20         |        | 20     |
| Total                            | 715651     | 10182  | 725833 |

#### First use versus reuses

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

## categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 310014    | 42.71%     |
| Translational and applied research   | 277423    | 38.22%     |
| Regulatory use and Routine production  | 120192    | 16.56%     |
| Protection of the natural environment in the interests of the health or welfare of human   | 6048      | 0.83%      |
| beings or animals  |           |            |
| Preservation of species  | 371       | 0.05%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 11785     | 1.62%      |
| skills   |           |            |
| Total  | 725833    | 100.00%    |

# Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 26149          | 8.43%      |
| Cardiovascular Blood and Lymphatic System   | 25464          | 8.21%      |
| Nervous System                              | 76225          | 24.59%     |
| Respiratory System                          | 2457           | 0.79%      |
| Gastrointestinal System including Liver     | 8392           | 2.71%      |
| Musculoskeletal System                      | 6847           | 2.21%      |
| Immune System                               | 23703          | 7.65%      |
| Urogenital/Reproductive System              | 6421           | 2.07%      |
| Sensory Organs (skin, eyes and ears)        | 4396           | 1.42%      |
| Endocrine System/Metabolism                 | 22459          | 7.24%      |
| Multisystemic                               | 33719          | 10.88%     |
| Ethology / Animal Behaviour /Animal Biology | 71415          | 23.04%     |
| Other basic research                        | 2367           | 0.76%      |
| Total                                       | 310014         | 100.00%    |

# Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 113728         | 40.99%     |
| Human Infectious Disorders                          | 13579          | 4.89%      |
| Human Cardiovascular Disorders                      | 6440           | 2.32%      |
| Human Nervous and Mental Disorders                  | 20809          | 7.5%       |
| Human Respiratory Disorders                         | 2713           | 0.98%      |
| Human Gastrointestinal Disorders including Liver    | 8755           | 3.16%      |
| Human Musculoskeletal Disorders                     | 2052           | 0.74%      |
| Human Immune Disorders                              | 4675           | 1.69%      |
| Human Urogenital/Reproductive Disorders             | 1160           | 0.42%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 15749          | 5.68%      |
| Human Endocrine/Metabolism Disorders                | 15631          | 5.63%      |
| Other Human Disorders                               | 1651           | 0.6%       |
| Animal Diseases and Disorders                       | 50632          | 18.25%     |
| Animal Welfare                                      | 8413           | 3.03%      |
| Diagnosis of diseases                               | 9346           | 3.37%      |
| Plant diseases                                      | 10             | 0%         |
| Non-regulatory toxicology and ecotoxicology         | 2080           | 0.75%      |
| Total   | 277423         | 100.00%    |

# Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 68653          | 57.12%     |
| Other efficacy and tolerance testing                     | 2121           | 1.76%      |
| Toxicity and other safety testing including pharmacology | 48164          | 40.07%     |
| Routine production                                       | 1254           | 1.04%      |
| Total  | 120192         | 100.00%    |

| Regulatory uses - Quality control (including batch safety and potency testing) | Regulatory use | s - Quality con | trol (including ba | atch safety and r | ootency testing) |
|--|----------------|-----------------|--------------------|-------------------|------------------|
|--|----------------|-----------------|--------------------|-------------------|------------------|

| Regulatory uses - Quality control (including batch safety and potency testing) | Number of uses | Percentage |
|--|----------------|------------|
| Batch safety testing   | 23330          | 33.98%     |
| Pyrogenicity testing   | 9472           | 13.8%      |
| Batch potency testing  | 31416          | 45.76%     |
| Other quality controls   | 4435           | 6.46%      |
| Total  | 68653          | 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  | 11069          | 22.98%     |
| Skin irritation/corrosion  | 43             | 0.09%      |
| Skin sensitisation   | 616            | 1.28%      |
| Eye irritation/corrosion   | 11             | 0.02%      |
| Repeated dose toxicity   | 6225           | 12.92%     |
| Carcinogenicity  | 56             | 0.12%      |
| Genotoxicity   | 22             | 0.05%      |
| Developmental toxicity   | 759            | 1.58%      |
| Neurotoxicity  | 2017           | 4.19%      |
| Kinetics   | 3364           | 6.98%      |
| Pharmaco-dynamics (incl safety pharmacology)                               | 1476           | 3.06%      |
| Ecotoxicity  | 156            | 0.32%      |
| Safety testing in food and feed area                                       | 21778          | 45.22%     |
| Target animal safety   | 486            | 1.01%      |
| Other toxicity/safety testing  | 86             | 0.18%      |
| Total  | 48164          | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 10180     | 91.97%     |
| Non lethal methods  | 889       | 8.03%      |
| Total   | 11069     | 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<br>uses | Percentage |
|---|-------------------|------------|
| up to 28 days   | 1906              | 30.62%     |
| 29 - 90 days  | 3714              | 59.66%     |
| > 90 days   | 605               | 9.72%      |
| Total   | 6225              | 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   | 124            | 79.49%     |
| Reproductive ecotoxicity   | 32             | 20.51%     |
| Total  | 156            | 100.00%    |

## Regulatory uses by type of legislation

| Type of legislation  | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Legislation on medicinal products for human use                                      | 32259     | 27.12%     |
| Legislation on medicinal products for veterinary use and their residues              | 61342     | 51.57%     |
| Medical devices legislation  | 138       | 0.12%      |
| Industrial chemicals legislation   | 3194      | 2.69%      |
| Plant protection product legislation   | 28        | 0.02%      |
| Biocides legislation   | 56        | 0.05%      |
| Food legislation including food contact material                                     | 21850     | 18.37%     |
| Feed legislation including legislation for the safety of target animals, workers and | 68        | 0.06%      |
| environment  |           |            |
| Other legislation  | 3         | 0%         |
| Total  | 118938    | 100.00%    |

## Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 106010         | 89.13%     |
| Legislation satisfying national requirements only [within EU] | 4057           | 3.41%      |
| Legislation satisfying Non-EU requirements only               | 8871           | 7.46%      |
| Total   | 118938         | 100.00%    |

## Routine production uses by product type

| Product type                                | Number of uses | Percentage |
|---|----------------|------------|
| Blood based products                        | 54             | 4.31%      |
| Monoclonal antibody by mouse ascites method | 55             | 4.39%      |
| Other product types                         | 1145           | 91.31%     |
| Total                                       | 1254           | 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    | 715651         | 98.6%      |
| Yes   | 10182          | 1.4%       |
| Total | 725833         | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 40892          | 5.63%      |
| Mild [up to and including] | 355722         | 49.01%     |
| Moderate                   | 266570         | 36.73%     |
| Severe                     | 62649          | 8.63%      |
| Total                      | 725833         | 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                         | 501844         | 69.14%     |
| Genetically altered without a harmful phenotype | 201157         | 27.71%     |
| Genetically altered with a harmful phenotype    | 22832          | 3.15%      |
| Total   | 725833         | 100.00%    |

# Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 17749      | 70     | 17819 |
| Rats           | 48         |        | 48    |
| Pigs           | 1          |        | 1     |
| Zebra fish     | 4886       |        | 4886  |
| Other Fish     | 1187       |        | 1187  |
| Total          | 23871      | 70     | 23941 |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 176            | 0.74%      |
| Mild [up to and including] | 16644          | 69.52%     |
| Moderate                   | 5213           | 21.77%     |
| Severe                     | 1908           | 7.97%      |
| Total                      | 23941          | 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                         | 9606           | 40.12%     |
| Genetically altered without a harmful phenotype | 13230          | 55.26%     |
| Genetically altered with a harmful phenotype    | 1105           | 4.62%      |
| Total   | 23941          | 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                                    | 2268           | 11.63%     |
| Cardiovascular Blood and Lymphatic System   | 800            | 4.1%       |
| Nervous System                              | 2745           | 14.08%     |
| Gastrointestinal System including Liver     | 493            | 2.53%      |
| Musculoskeletal System                      | 150            | 0.77%      |
| Immune System                               | 956            | 4.9%       |
| Urogenital/Reproductive System              | 127            | 0.65%      |
| Sensory Organs (skin, eyes and ears)        | 5887           | 30.2%      |
| Endocrine System/Metabolism                 | 175            | 0.9%       |
| Multisystemic                               | 4093           | 21%        |
| Ethology / Animal Behaviour /Animal Biology | 1800           | 9.23%      |
| Total                                       | 19494          | 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  | 2869           | 64.52%     |
| Human Nervous and Mental Disorders                  | 585            | 13.15%     |
| Human Immune Disorders                              | 418            | 9.4%       |
| Human Sensory Organ Disorders (skin, eyes and ears) | 52             | 1.17%      |
| Human Endocrine/Metabolism Disorders                | 21             | 0.47%      |
| Diagnosis of diseases                               | 502            | 11.29%     |
| Total   | 4447           | 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           | 38443      |        | 38443      |
| Zebra fish     | 14759      |        | 14759      |
| Total          | 53202      |        | 53202      |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 135            | 0.25%      |
| Mild [up to and including] | 42728          | 80.31%     |
| Moderate                   | 8998           | 16.91%     |
| Severe                     | 1341           | 2.52%      |
| Total                      | 53202          | 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                         | 1285           | 2.42%      |
| Genetically altered without a harmful phenotype | 29469          | 55.39%     |
| Genetically altered with a harmful phenotype    | 22448          | 42.19%     |
| Total   | 53202          | 100.00%    |

# Member State: Sweden, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 193965            | 67.99%     |
| Rats                             | 19055             | 6.68%      |
| Guinea-Pigs                      | 409               | 0.14%      |
| Hamsters (Syrian)                | 34                | 0.01%      |
| Other Rodents                    | 5                 | 0%         |
| Rabbits                          | 1573              | 0.55%      |
| Cats                             | 104               | 0.04%      |
| Dogs                             | 279               | 0.1%       |
| Other carnivores                 | 124               | 0.04%      |
| Horses, donkeys and cross-breeds | 17                | 0.01%      |
| Pigs                             | 1220              | 0.43%      |
| Goats                            | 30                | 0.01%      |
| Sheep                            | 35                | 0.01%      |
| Cattle                           | 493               | 0.17%      |
| Cynomolgus monkey                | 2                 | 0%         |
| Rhesus monkey                    | 23                | 0.01%      |
| Other Mammals                    | 192               | 0.07%      |
| Domestic fowl                    | 1452              | 0.51%      |
| Other birds                      | 10657             | 3.74%      |
| Rana                             | 308               | 0.11%      |
| Xenopus                          | 231               | 0.08%      |
| Other Amphibians                 | 2694              | 0.94%      |
| Zebra fish                       | 18461             | 6.47%      |
| Other Fish                       | 33940             | 11.9%      |
| Total                            | 285303            | 100.00%    |

Numbers of animals used for the first time by species

## 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         | 217256            | 76.16%     |
| Animals born in the EU but not at a registered breeder | 64066             | 22.46%     |
| Animals born in rest of Europe                         | 1608              | 0.56%      |
| Animals born in rest of world                          | 2348              | 0.82%      |
| Total  | 285278            | 100.00%    |

## Source of non-human primates

| NHP Source (origin)     | Number of animals | Percentage |
|-------------------------|-------------------|------------|
| Animals born in Asia    | 6                 | 24%        |
| Animals born in America | 19                | 76%        |
| Total                   | 25                | 100.00%    |

## Generation of non-human primates

| NHP Generation | Number of animals | Percentage |
|----------------|-------------------|------------|
| F2 or greater  | 25                | 100%       |
| Total          | 25                | 100.00%    |

# Part 2: Numbers of all uses of animals for research, testing, routine production and educational (including training) purposes

| Thist use versus reuses          |            |        |        |
|----------------------------------|------------|--------|--------|
| Animal species                   | First uses | Reuses | Total  |
| Mice                             | 193965     | 1228   | 195193 |
| Rats                             | 19055      | 246    | 19301  |
| Guinea-Pigs                      | 409        |        | 409    |
| Hamsters (Syrian)                | 34         |        | 34     |
| Other Rodents                    | 5          |        | 5      |
| Rabbits                          | 1573       | 1      | 1574   |
| Cats                             | 104        |        | 104    |
| Dogs                             | 279        | 107    | 386    |
| Other carnivores                 | 124        | 16     | 140    |
| Horses, donkeys and cross-breeds | 17         | 24     | 41     |
| Pigs                             | 1220       | 337    | 1557   |
| Goats                            | 30         |        | 30     |
| Sheep                            | 35         |        | 35     |
| Cattle                           | 493        | 927    | 1420   |
| Cynomolgus monkey                | 2          |        | 2      |
| Rhesus monkey                    | 23         |        | 23     |
| Other Mammals                    | 192        | 135    | 327    |
| Domestic fowl                    | 1452       |        | 1452   |
| Other birds                      | 10657      | 612    | 11269  |
| Rana                             | 308        |        | 308    |
| Xenopus                          | 231        | 30     | 261    |
| Other Amphibians                 | 2694       |        | 2694   |
| Zebra fish                       | 18461      | 880    | 19341  |
| Other Fish                       | 33940      |        | 33940  |
| Total                            | 285303     | 4543   | 289846 |

#### First use versus reuses

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

# categories of scientific purposes

| Purpose Category   | Number of<br>uses | Percentage |
|--|-------------------|------------|
| Basic Research   | 202004            | 69.69%     |
| Translational and applied research   | 52637             | 18.16%     |
| Regulatory use and Routine production  | 2424              | 0.84%      |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 27916             | 9.63%      |
| Preservation of species  | 617               | 0.21%      |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills          | 4248              | 1.47%      |
| Total  | 289846            | 100.00%    |

## Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 20290          | 10.04%     |
| Cardiovascular Blood and Lymphatic System   | 36103          | 17.87%     |
| Nervous System                              | 48921          | 24.22%     |
| Respiratory System                          | 7362           | 3.64%      |
| Gastrointestinal System including Liver     | 1383           | 0.68%      |
| Musculoskeletal System                      | 2641           | 1.31%      |
| Immune System                               | 22592          | 11.18%     |
| Urogenital/Reproductive System              | 1521           | 0.75%      |
| Sensory Organs (skin, eyes and ears)        | 3150           | 1.56%      |
| Endocrine System/Metabolism                 | 25884          | 12.81%     |
| Multisystemic                               | 6172           | 3.06%      |
| Ethology / Animal Behaviour /Animal Biology | 16914          | 8.37%      |
| Other basic research                        | 9071           | 4.49%      |
| Total                                       | 202004         | 100.00%    |

# Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 9717           | 18.46%     |
| Human Infectious Disorders                          | 1328           | 2.52%      |
| Human Cardiovascular Disorders                      | 4936           | 9.38%      |
| Human Nervous and Mental Disorders                  | 9654           | 18.34%     |
| Human Respiratory Disorders                         | 4988           | 9.48%      |
| Human Musculoskeletal Disorders                     | 862            | 1.64%      |
| Human Immune Disorders                              | 9224           | 17.52%     |
| Human Urogenital/Reproductive Disorders             | 255            | 0.48%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 500            | 0.95%      |
| Human Endocrine/Metabolism Disorders                | 5501           | 10.45%     |
| Other Human Disorders                               | 2323           | 4.41%      |
| Animal Diseases and Disorders                       | 704            | 1.34%      |
| Animal Welfare                                      | 105            | 0.2%       |
| Diagnosis of diseases                               | 542            | 1.03%      |
| Non-regulatory toxicology and ecotoxicology         | 1998           | 3.8%       |
| Total   | 52637          | 100.00%    |

# Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 773            | 31.89%     |
| Other efficacy and tolerance testing                     | 235            | 9.69%      |
| Toxicity and other safety testing including pharmacology | 1416           | 58.42%     |
| Total  | 2424           | 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  | 773            | 100%       |
| Total  | 773            | 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   | 113            | 7.98%      |
| Kinetics   | 1303           | 92.02%     |
| Total  | 1416           | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
|   | -         |            |

## 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| up to 28 days  | 113       | 100%       |
| Total  | 113       | 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                         | 1651           | 68.11%     |
| Legislation on medicinal products for veterinary use and their residues | 773            | 31.89%     |
| Total   | 2424           | 100.00%    |

#### Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement      | Number of uses | Percentage |
|--|----------------|------------|
| Legislation satisfying EU requirements | 2424           | 100%       |
| Total                                  | 2424           | 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    | 285303         | 98.43%     |
| Yes   | 4543           | 1.57%      |
| Total | 289846         | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 9102           | 3.14%      |
| Mild [up to and including] | 92527          | 31.92%     |
| Moderate                   | 153733         | 53.04%     |
| Severe                     | 34484          | 11.9%      |

| Severity | Number of uses | Percentage |
|----------|----------------|------------|
| Total    | 289846         | 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                         | 144621         | 49.9%      |
| Genetically altered without a harmful phenotype | 118948         | 41.04%     |
| Genetically altered with a harmful phenotype    | 26277          | 9.07%      |
| Total   | 289846         | 100.00%    |

# Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total |
|----------------|------------|--------|-------|
| Mice           | 22641      | 788    | 23429 |
| Zebra fish     | 8546       | 1271   | 9817  |
| Total          | 31187      | 2059   | 33246 |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 222            | 0.67%      |
| Mild [up to and including] | 15644          | 47.06%     |
| Moderate                   | 10806          | 32.5%      |
| Severe                     | 6574           | 19.77%     |
| Total                      | 33246          | 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                         | 4166           | 12.53%     |
| Genetically altered without a harmful phenotype | 18428          | 55.43%     |
| Genetically altered with a harmful phenotype    | 10652          | 32.04%     |
| Total   | 33246          | 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                                  | 2259           | 7.49%      |
| Cardiovascular Blood and Lymphatic System | 8399           | 27.84%     |
| Nervous System                            | 4504           | 14.93%     |
| Gastrointestinal System including Liver   | 148            | 0.49%      |
| Musculoskeletal System                    | 1579           | 5.23%      |
| Immune System                             | 602            | 2%         |
| Urogenital/Reproductive System            | 5022           | 16.65%     |
| Endocrine System/Metabolism               | 2171           | 7.2%       |
| Multisystemic                             | 4029           | 13.35%     |
| Other basic research                      | 1457           | 4.83%      |
| Total                                     | 30170          | 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                         | 1124           | 36.54%     |
| Human Cardiovascular Disorders       | 1547           | 50.29%     |
| Human Nervous and Mental Disorders   | 83             | 2.7%       |
| Human Respiratory Disorders          | 89             | 2.89%      |
| Human Immune Disorders               | 47             | 1.53%      |
| Human Endocrine/Metabolism Disorders | 186            | 6.05%      |
| Total                                | 3076           | 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           | 1659       |        | 1659       |
| Rats           | 20         |        | 20         |
| Total          | 1679       |        | 1679       |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Mild [up to and including] | 1679           | 100%       |
| Total                      | 1679           | 100.00%    |

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

| uninais   |                |            |
|---|----------------|------------|
| Genetic status                                  | Number of uses | Percentage |
| Not genetically altered                         | 1183           | 70.46%     |
| Genetically altered without a harmful phenotype | 496            | 29.54%     |
| Total   | 1679           | 100.00%    |

# Member State: United Kingdom, 2017

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

| Animal species                   | Number of animals | Percentage |
|----------------------------------|-------------------|------------|
| Mice                             | 1103996           | 60.03%     |
| Rats                             | 231775            | 12.6%      |
| Guinea-Pigs                      | 22560             | 1.23%      |
| Hamsters (Syrian)                | 1126              | 0.06%      |
| Mongolian gerbil                 | 307               | 0.02%      |
| Other Rodents                    | 2325              | 0.13%      |
| Rabbits                          | 9580              | 0.52%      |
| Cats                             | 74                | 0%         |
| Dogs                             | 2518              | 0.14%      |
| Ferrets                          | 405               | 0.02%      |
| Other carnivores                 | 235               | 0.01%      |
| Horses, donkeys and cross-breeds | 288               | 0.02%      |
| Pigs                             | 4476              | 0.24%      |
| Goats                            | 280               | 0.02%      |
| Sheep                            | 5346              | 0.29%      |
| Cattle                           | 8489              | 0.46%      |
| Marmoset and tamarins            | 110               | 0.01%      |
| Cynomolgus monkey                | 2023              | 0.11%      |
| Rhesus monkey                    | 82                | 0%         |
| Other Mammals                    | 792               | 0.04%      |
| Domestic fowl                    | 124629            | 6.78%      |
| Other birds                      | 6258              | 0.34%      |
| Reptiles                         | 92                | 0.01%      |
| Rana                             | 108               | 0.01%      |
| Xenopus                          | 2530              | 0.14%      |
| Other Amphibians                 | 522               | 0.03%      |
| Zebra fish                       | 216671            | 11.78%     |
| Other Fish                       | 91482             | 4.97%      |
| Total                            | 1839079           | 100.00%    |

Numbers of animals used for the first time by species

# 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         | 1710834           | 93.14%     |
| Animals born in the EU but not at a registered breeder | 112655            | 6.13%      |
| Animals born in rest of Europe                         | 3229              | 0.18%      |
| Animals born in rest of world                          | 10146             | 0.55%      |
| Total  | 1836864           | 100.00%    |

# Source of non-human primates

| NHP Source (origin)                            | Number of animals | Percentage |
|--|-------------------|------------|
| Animals born at a registered breeder within EU | 253               | 11.42%     |
| Animals born in Asia                           | 616               | 27.81%     |
| Animals born in Africa                         | 1346              | 60.77%     |
| Total  | 2215              | 100.00%    |

Generation of non-human primates

| NHP Generation         | Number of animals | Percentage |
|------------------------|-------------------|------------|
| F1                     | 1                 | 0.05%      |
| F2 or greater          | 587               | 26.5%      |
| Self-sustaining colony | 1627              | 73.45%     |
| Total                  | 2215              | 100.00%    |

# Part 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                             | 1103996    | 944    | 1104940 |
| Rats                             | 231775     | 3006   | 234781  |
| Guinea-Pigs                      | 22560      |        | 22560   |
| Hamsters (Syrian)                | 1126       |        | 1126    |
| Mongolian gerbil                 | 307        | 4      | 311     |
| Other Rodents                    | 2325       | 2      | 2327    |
| Rabbits                          | 9580       | 864    | 10444   |
| Cats                             | 74         | 214    | 288     |
| Dogs                             | 2518       | 1431   | 3949    |
| Ferrets                          | 405        |        | 405     |
| Other carnivores                 | 235        | 9      | 244     |
| Horses, donkeys and cross-breeds | 288        | 10312  | 10600   |
| Pigs                             | 4476       | 142    | 4618    |
| Goats                            | 280        | 24     | 304     |
| Sheep                            | 5346       | 42583  | 47929   |
| Cattle                           | 8489       | 596    | 9085    |
| Marmoset and tamarins            | 110        | 56     | 166     |
| Cynomolgus monkey                | 2023       | 639    | 2662    |
| Rhesus monkey                    | 82         | 50     | 132     |
| Other Mammals                    | 792        | 12     | 804     |
| Domestic fowl                    | 124629     | 27     | 124656  |
| Other birds                      | 6258       | 471    | 6729    |
| Reptiles                         | 92         |        | 92      |
| Rana                             | 108        |        | 108     |
| Xenopus                          | 2530       | 4923   | 7453    |
| Other Amphibians                 | 522        | 11     | 533     |
| Zebra fish                       | 216671     | 439    | 217110  |
| Other Fish                       | 91482      | 150    | 91632   |
|                                  |            |        |         |

# Uses of animals in research, testing, routine production and education (including training) by main categories of scientific purposes

| Purpose Category   | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Basic Research   | 1058370   | 55.53%     |
| Translational and applied research   | 326965    | 17.15%     |
| Regulatory use and Routine production  | 505504    | 26.52%     |
| Protection of the natural environment in the interests of the health or welfare of human   | 11901     | 0.62%      |
| beings or animals  |           |            |
| Preservation of species  | 1925      | 0.1%       |
| Higher education or training for the acquisition, maintenance or improvement of vocational | 1235      | 0.06%      |
| skills   |           |            |
| Forensic enquiries   | 88        | 0%         |
| Total  | 1905988   | 100.00%    |

## Basic research related uses

| Basic research                              | Number of uses | Percentage |
|---|----------------|------------|
| Oncology                                    | 130655         | 12.34%     |
| Cardiovascular Blood and Lymphatic System   | 67776          | 6.4%       |
| Nervous System                              | 243752         | 23.03%     |
| Respiratory System                          | 10995          | 1.04%      |
| Gastrointestinal System including Liver     | 22962          | 2.17%      |
| Musculoskeletal System                      | 24477          | 2.31%      |
| Immune System                               | 213921         | 20.21%     |
| Urogenital/Reproductive System              | 28064          | 2.65%      |
| Sensory Organs (skin, eyes and ears)        | 17935          | 1.69%      |
| Endocrine System/Metabolism                 | 25990          | 2.46%      |
| Multisystemic                               | 80548          | 7.61%      |
| Ethology / Animal Behaviour /Animal Biology | 64369          | 6.08%      |
| Other basic research                        | 126926         | 11.99%     |
| Total                                       | 1058370        | 100.00%    |

# Translational and applied research related uses

| Translational and applied research                  | Number of uses | Percentage |
|---|----------------|------------|
| Human Cancer  | 86658          | 26.5%      |
| Human Infectious Disorders                          | 69473          | 21.25%     |
| Human Cardiovascular Disorders                      | 4173           | 1.28%      |
| Human Nervous and Mental Disorders                  | 42005          | 12.85%     |
| Human Respiratory Disorders                         | 12633          | 3.86%      |
| Human Gastrointestinal Disorders including Liver    | 3943           | 1.21%      |
| Human Musculoskeletal Disorders                     | 5958           | 1.82%      |
| Human Immune Disorders                              | 6481           | 1.98%      |
| Human Urogenital/Reproductive Disorders             | 3061           | 0.94%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 10774          | 3.3%       |
| Human Endocrine/Metabolism Disorders                | 7815           | 2.39%      |
| Other Human Disorders                               | 10802          | 3.3%       |
| Animal Diseases and Disorders                       | 21921          | 6.7%       |
| Animal Welfare                                      | 2843           | 0.87%      |
| Diagnosis of diseases                               | 3476           | 1.06%      |
| Non-regulatory toxicology and ecotoxicology         | 34949          | 10.69%     |
| Total   | 326965         | 100.00%    |

## Regulatory uses and Routine production

| Regulatory uses and Routine production                   | Number of uses | Percentage |
|--|----------------|------------|
| Quality control (incl batch safety and potency testing)  | 145113         | 28.71%     |
| Other efficacy and tolerance testing                     | 24606          | 4.87%      |
| Toxicity and other safety testing including pharmacology | 196061         | 38.79%     |
| Routine production                                       | 139724         | 27.64%     |
| Total  | 505504         | 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   | 18401          | 12.68%     |
| Pyrogenicity testing   | 1125           | 0.78%      |
| Batch potency testing  | 114151         | 78.66%     |
| Other quality controls   | 11436          | 7.88%      |
| Total  | 145113         | 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  | 16580          | 8.46%      |
| Skin irritation/corrosion  | 112            | 0.06%      |
| Skin sensitisation   | 2942           | 1.5%       |
| Eye irritation/corrosion   | 63             | 0.03%      |
| Repeated dose toxicity   | 40429          | 20.62%     |
| Carcinogenicity  | 8067           | 4.11%      |
| Genotoxicity   | 5314           | 2.71%      |
| Reproductive toxicity  | 61241          | 31.24%     |
| Developmental toxicity   | 34779          | 17.74%     |
| Neurotoxicity  | 314            | 0.16%      |
| Kinetics   | 3124           | 1.59%      |
| Pharmaco-dynamics (incl safety pharmacology)                               | 5309           | 2.71%      |
| Ecotoxicity  | 11444          | 5.84%      |
| Safety testing in food and feed area                                       | 183            | 0.09%      |
| Target animal safety   | 1360           | 0.69%      |
| Other toxicity/safety testing  | 4800           | 2.45%      |
| Total  | 196061         | 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- | Number of | Percentage |
|---|-----------|------------|
| acute toxicity testing methods  | uses      |            |
| LD50, LC50  | 10622     | 64.07%     |
| Other lethal methods  | 98        | 0.59%      |
| Non lethal methods  | 5860      | 35.34%     |
| Total   | 16580     | 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 | Number of | Percentage |
|--|-----------|------------|
| toxicity   | uses      |            |
| up to 28 days  | 21572     | 53.36%     |
| 29 - 90 days   | 11727     | 29.01%     |
| > 90 days  | 7130      | 17.64%     |
| Total  | 40429     | 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   | 3653           | 31.92%     |
| Chronic toxicity   | 6320           | 55.23%     |
| Reproductive ecotoxicity   | 514            | 4.49%      |
| Endocrine activity   | 84             | 0.73%      |
| Bioaccumulation  | 873            | 7.63%      |
| Total  | 11444          | 100.00%    |

# Regulatory uses by type of legislation

| Type of legislation  | Number of | Percentage |
|--|-----------|------------|
|  | uses      |            |
| Legislation on medicinal products for human use                                      | 208034    | 56.87%     |
| Legislation on medicinal products for veterinary use and their residues              | 34282     | 9.37%      |
| Medical devices legislation  | 562       | 0.15%      |
| Industrial chemicals legislation   | 86097     | 23.54%     |
| Plant protection product legislation   | 18417     | 5.03%      |
| Biocides legislation   | 292       | 0.08%      |
| Food legislation including food contact material                                     | 1688      | 0.46%      |
| Feed legislation including legislation for the safety of target animals, workers and | 14831     | 4.05%      |
| environment  |           |            |
| Other legislation  | 1577      | 0.43%      |
| Total  | 365780    | 100.00%    |

# Regulatory uses by origin of regulatory requirement

| Origin of legislative requirement                             | Number of uses | Percentage |
|---|----------------|------------|
| Legislation satisfying EU requirements                        | 338692         | 92.59%     |
| Legislation satisfying national requirements only [within EU] | 1651           | 0.45%      |
| Legislation satisfying Non-EU requirements only               | 25437          | 6.95%      |
| Total   | 365780         | 100.00%    |

## Routine production uses by product type

| Product type         | Number of uses | Percentage |
|----------------------|----------------|------------|
| Blood based products | 55197          | 39.5%      |
| Other product types  | 84527          | 60.5%      |
| Total                | 139724         | 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    | 1839079        | 96.49%     |
| Yes   | 66909          | 3.51%      |
| Total | 1905988        | 100.00%    |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 135307         | 7.1%       |
| Mild [up to and including] | 1171215        | 61.45%     |
| Moderate                   | 504038         | 26.44%     |
| Severe                     | 95428          | 5.01%      |
| Total                      | 1905988        | 100.00%    |

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

| Number of uses | Percentage                  |
|----------------|-----------------------------|
| 1182220        | 62.03%                      |
| 596728         | 31.31%                      |
| 127040         | 6.67%                       |
| 1905988        | 100.00%                     |
|                | 1182220<br>596728<br>127040 |

# Part 3: Creation and maintenance of genetically altered animal lines

| Animal species | First uses | Reuses | Total  |
|----------------|------------|--------|--------|
| Mice           | 213555     | 393    | 213948 |
| Rats           | 131        |        | 131    |
| Pigs           | 124        |        | 124    |
| Sheep          | 17         |        | 17     |
| Domestic fowl  | 647        |        | 647    |
| Xenopus        | 250        |        | 250    |
| Zebra fish     | 49941      | 82     | 50023  |
| Other Fish     | 34         |        | 34     |
| Total          | 264699     | 475    | 265174 |

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

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 201            | 0.08%      |
| Mild [up to and including] | 241543         | 91.09%     |
| Moderate                   | 21638          | 8.16%      |
| Severe                     | 1792           | 0.68%      |
| Total                      | 265174         | 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                         | 56940          | 21.47%     |
| Genetically altered without a harmful phenotype | 191024         | 72.04%     |
| Genetically altered with a harmful phenotype    | 17210          | 6.49%      |
| Total   | 265174         | 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                                    | 45369          | 17.71%     |
| Cardiovascular Blood and Lymphatic System   | 10621          | 4.15%      |
| Nervous System                              | 29420          | 11.48%     |
| Respiratory System                          | 659            | 0.26%      |
| Gastrointestinal System including Liver     | 3235           | 1.26%      |
| Musculoskeletal System                      | 3946           | 1.54%      |
| Immune System                               | 32311          | 12.61%     |
| Urogenital/Reproductive System              | 6774           | 2.64%      |
| Sensory Organs (skin, eyes and ears)        | 5542           | 2.16%      |
| Endocrine System/Metabolism                 | 3421           | 1.34%      |
| Multisystemic                               | 92818          | 36.23%     |
| Ethology / Animal Behaviour /Animal Biology | 2854           | 1.11%      |
| Other basic research                        | 19201          | 7.5%       |
| Total                                       | 256171         | 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  | 4221           | 46.88%     |
| Human Infectious Disorders                          | 730            | 8.11%      |
| Human Cardiovascular Disorders                      | 201            | 2.23%      |
| Human Nervous and Mental Disorders                  | 349            | 3.88%      |
| Human Musculoskeletal Disorders                     | 155            | 1.72%      |
| Human Immune Disorders                              | 873            | 9.7%       |
| Human Urogenital/Reproductive Disorders             | 480            | 5.33%      |
| Human Sensory Organ Disorders (skin, eyes and ears) | 80             | 0.89%      |
| Other Human Disorders                               | 48             | 0.53%      |
| Animal Diseases and Disorders                       | 1586           | 17.62%     |
| Non-regulatory toxicology and ecotoxicology         | 280            | 3.11%      |
| Total   | 9003           | 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           | 346497     | 1      | 346498     |
| Rats           | 2919       |        | 2919       |
| Domestic fowl  | 367        |        | 367        |
| Xenopus        | 195        | 197    | 392        |
| Zebra fish     | 52401      | 612    | 53013      |
| Other Fish     | 524        |        | 524        |
| Total          | 402903     | 810    | 403713     |

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

| Severity                   | Number of uses | Percentage |
|----------------------------|----------------|------------|
| Non-recovery               | 272            | 0.07%      |
| Mild [up to and including] | 328866         | 81.46%     |
| Moderate                   | 33725          | 8.35%      |
| Severe                     | 40850          | 10.12%     |
| Total                      | 403713         | 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                         | 24437          | 6.05%      |
| Genetically altered without a harmful phenotype | 315057         | 78.04%     |
| Genetically altered with a harmful phenotype    | 64219          | 15.91%     |
| Total   | 403713         | 100.00%    |