

**SECTION C: MEMBER STATE DATA BETWEEN 2015 AND 2017**

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# V.1. Introduction

Member States submitted statistical data to the Commission between 2015 and 2017 using the main categorisation of data attributes provided in the Annex II of Commission Implementing Decision 2012/707/EU. The accompanying Member State narratives make reference to the numbers in these submissions.

However, the numbers contained in the Member State submission do not directly correlate with the compiled EU data.

Drawing from the Member State submissions, the EU report is based on a revised, improved, categorisation of data:

* **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)

This has allowed for the presentation of a much clearer and precise picture of the numbers of animals and purposes for which animals are used in the EU.

To provide a possibility to refer back to the Member State data in a similar manner, the part V.3. of this Section C presents recalculation of the Member State data, for the year 2017, divided into the three categories above.

# V.2. Member State narratives and data submissions 2015-2017

Member States annual submissions between years 2015 and 2017 are listed by Member State, first providing the Member State narrative for the respective year followed by the related data tables.

As stated above, these numbers do not directly correlate with numbers in the EU report in Part A but have been left here so that accurate presentation of the Member State submissions is provided, including correspondence with the related annual narratives.

# Austria

## Austria: Narrative 2015

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

Austria already collected statistical data on animals used in 2013 in the new format. Due to changes in the regime for counting the animals (e.g. counting animals at the beginning of a procedure vs. counting them at the end) comparisons with the years before 2013 can only be made with caution. The overall number of animals used in 2015 was 227.317 (2014: 209.183), this constitutes an increase of 8,7%, in comparison to 2013 this is an increase of 9%.

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

Significant increases in animal use were reported for translational research on infectious diseases and regulatory pyrogenicity testing. Significant decrease in animal use was observed for translational research in oncology and regulatory batch potency testing.

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

The percentages of actual severities were

Non-recovery:  4% (2014:   3%)

Mild: 60% (2014: 57%)

Moderate: 24% (2014: 30%)

Severe: 12% (2014: 10%)

These changes could not be considered as significant.

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

The competent authorities promote the 3R principle at all the steps of the authorization processes, so that even with an increase in research activities the overall numbers of animals used have remained fairly constant.

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

Only small, not significant proportions were reported under the category “other”.

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

No such cases were observed or reported.

## Austria: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 187413 | 82.45% |
| Rats | 5162 | 2.27% |
| Guinea-Pigs | 1858 | 0.82% |
| Hamsters (Syrian) | 602 | 0.26% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 99 | 0.04% |
| Rabbits | 15910 | 7% |
| Cats | 34 | 0.01% |
| Dogs | 111 | 0.05% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 94 | 0.04% |
| Pigs | 1762 | 0.78% |
| Goats | 7 | 0% |
| Sheep | 115 | 0.05% |
| Cattle | 632 | 0.28% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 515 | 0.23% |
| Domestic fowl | 1623 | 0.71% |
| Other birds | 465 | 0.2% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus | 121 | 0.05% |
| Other Amphibians | 616 | 0.27% |
| Zebra fish | 9411 | 4.14% |
| Other Fish | 767 | 0.34% |
| Cephalopods |  |  |
| Total | 227317 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 216341 | 96.04% |
| Animals born in the EU but not at a registered breeder | 4188 | 1.86% |
| Animals born in rest of Europe | 61 | 0.03% |
| Animals born in rest of world | 4678 | 2.08% |
| Total | 225268 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 89479 | 39.36% |
| Translational and applied research | 74146 | 32.62% |
| Regulatory use and Routine production | 31789 | 13.98% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 551 | 0.24% |
| Preservation of species | 67 | 0.03% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1925 | 0.85% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 29360 | 12.92% |
| Total | 227317 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 15691 | 17.54% |
| Cardiovascular Blood and Lymphatic System | 10313 | 11.53% |
| Nervous System | 12922 | 14.44% |
| Respiratory System | 739 | 0.83% |
| Gastrointestinal System including Liver | 2525 | 2.82% |
| Musculoskeletal System | 1816 | 2.03% |
| Immune System | 19514 | 21.81% |
| Urogenital/Reproductive System | 553 | 0.62% |
| Sensory Organs (skin, eyes and ears) | 420 | 0.47% |
| Endocrine System/Metabolism | 2055 | 2.3% |
| Multisystemic | 8104 | 9.06% |
| Ethology / Animal Behaviour /Animal Biology | 1343 | 1.5% |
| Other basic research | 13484 | 15.07% |
| Total | 89479 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 13389 | 18.06% |
| Human Infectious Disorders | 42653 | 57.53% |
| Human Cardiovascular Disorders | 7030 | 9.48% |
| Human Nervous and Mental Disorders | 3885 | 5.24% |
| Human Respiratory Disorders | 91 | 0.12% |
| Human Gastrointestinal Disorders including Liver | 471 | 0.64% |
| Human Musculoskeletal Disorders | 595 | 0.8% |
| Human Immune Disorders | 2396 | 3.23% |
| Human Urogenital/Reproductive Disorders | 167 | 0.23% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 262 | 0.35% |
| Human Endocrine/Metabolism Disorders | 263 | 0.35% |
| Other Human Disorders | 20 | 0.03% |
| Animal Diseases and Disorders | 2874 | 3.88% |
| Animal Welfare |  |  |
| Diagnosis of diseases | 15 | 0.02% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 35 | 0.05% |
| Total | 74146 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 31413 | 98.82% |
| Other efficacy and tolerance testing | 44 | 0.14% |
| Toxicity and other safety testing including pharmacology | 151 | 0.48% |
| Routine production | 181 | 0.57% |
| Total | 31789 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 4708 | 14.99% |
| Pyrogenicity testing | 14794 | 47.1% |
| Batch potency testing | 11461 | 36.48% |
| Other quality controls | 450 | 1.43% |
| Total | 31413 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 6 | 3.97% |
| Neurotoxicity | 88 | 58.28% |
| Kinetics | 48 | 31.79% |
| Safety testing in food and feed area | 9 | 5.96% |
| Total | 151 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days | 6 | 100% |
| > 90 days |  |  |
| Total | 6 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 181 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 181 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 31642 | 99.54% |
| Legislation on medicinal products for veterinary use and their residues | 44 | 0.14% |
| Medical devices legislation | 6 | 0.02% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment | 9 | 0.03% |
| Cosmetics legislation |  |  |
| Other legislation | 88 | 0.28% |
| Total | 31789 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 27929 | 87.86% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only | 3860 | 12.14% |
| Total | 31789 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 225268 | 99.1% |
| Yes | 2049 | 0.9% |
| Total | 227317 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 8782 | 3.86% |
| Mild [up to and including] | 136602 | 60.09% |
| Moderate | 54896 | 24.15% |
| Severe | 27037 | 11.89% |
| Total | 227317 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 215627 | 94.86% |
| Yes | 11690 | 5.14% |
| Total | 227317 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 135911 | 59.79% |
| Genetically altered without a harmful phenotype | 73220 | 32.21% |
| Genetically altered with a harmful phenotype | 18186 | 8% |
| Total | 227317 | 100.00% |

## Austria: Narrative 2016

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

In Austria the total number of animals used for scientific purposes in 2016 is 236.459 (2015: 227.317), which is an increase of 4.0% or in absolute numbers 9.142 animals. Due to changes in the regime for counting the animals (e.g. counting animals at the beginning of a procedure vs. counting them at the end) comparisons with the previous years can only be made with certain caveats. However, the overall numbers between 2013 and 2016 remained within the range of the last 10 years.

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

A marked increase is observed in “Basic Research, Immune System” (from 19.514 animals to 29.555 animals). On the other hand, there is a decline in “Maintenance of colonies of established genetically altered animals, not used in other procedures” (from 29.360 animals to 18.905 animals).

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

The proportion of severity "severe" decreased from 12% to 7% compared to the previous year (also in absolute numbers: from 27.037 to 17.272). One possible reason for this could be the case-specific application of humane endpoints.

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

The competent authorities promote the 3R principle at all steps of the authorization processes, in particular by putting emphasis on minimizing pain suffering, distress and lasting harm by adequate humane endpoints. Thus, even with an increase in research activities the numbers of animals used have remained fairly constant, while at the same time the proportion of animals with “severe” suffering declined.

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

“Other rodents” include i.a. the wood mouse (not Mus musculus), the edible dormouse and garden dormouse; “Other mammals” include i.a. llamas, “Other birds” i.a. turkeys, great tits and Eurasian blackcaps; “Other fish” mainly trouts and medaka.

The purpose “Basic Research, Other” includes, in particular, the creation and maintenance of genetically altered animals (as long as their further use in projects is not yet known), as well as the production of antibodies.

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

Procedures involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2) were not performed.

## Austria: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 191896 | 81.15% |
| Rats | 6344 | 2.68% |
| Guinea-Pigs | 1785 | 0.75% |
| Hamsters (Syrian) | 277 | 0.12% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 276 | 0.12% |
| Rabbits | 14684 | 6.21% |
| Cats | 12 | 0.01% |
| Dogs | 177 | 0.07% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 43 | 0.02% |
| Pigs | 4901 | 2.07% |
| Goats | 2 | 0% |
| Sheep | 423 | 0.18% |
| Cattle | 386 | 0.16% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 150 | 0.06% |
| Domestic fowl | 3307 | 1.4% |
| Other birds | 1208 | 0.51% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus | 148 | 0.06% |
| Other Amphibians | 4 | 0% |
| Zebra fish | 7960 | 3.37% |
| Other Fish | 2476 | 1.05% |
| Cephalopods |  |  |
| Total | 236459 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 224314 | 95.23% |
| Animals born in the EU but not at a registered breeder | 7403 | 3.14% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 3843 | 1.63% |
| Total | 235560 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 103605 | 43.82% |
| Translational and applied research | 74336 | 31.44% |
| Regulatory use and Routine production | 36202 | 15.31% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 191 | 0.08% |
| Preservation of species | 563 | 0.24% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 2657 | 1.12% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 18905 | 8% |
| Total | 236459 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 17191 | 16.59% |
| Cardiovascular Blood and Lymphatic System | 11179 | 10.79% |
| Nervous System | 9439 | 9.11% |
| Respiratory System | 399 | 0.39% |
| Gastrointestinal System including Liver | 1761 | 1.7% |
| Musculoskeletal System | 2566 | 2.48% |
| Immune System | 29555 | 28.53% |
| Urogenital/Reproductive System | 469 | 0.45% |
| Sensory Organs (skin, eyes and ears) | 1158 | 1.12% |
| Endocrine System/Metabolism | 2033 | 1.96% |
| Multisystemic | 10967 | 10.59% |
| Ethology / Animal Behaviour /Animal Biology | 2842 | 2.74% |
| Other basic research | 14046 | 13.56% |
| Total | 103605 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 15369 | 20.68% |
| Human Infectious Disorders | 35473 | 47.72% |
| Human Cardiovascular Disorders | 7850 | 10.56% |
| Human Nervous and Mental Disorders | 4748 | 6.39% |
| Human Respiratory Disorders | 64 | 0.09% |
| Human Gastrointestinal Disorders including Liver | 832 | 1.12% |
| Human Musculoskeletal Disorders | 351 | 0.47% |
| Human Immune Disorders | 1437 | 1.93% |
| Human Urogenital/Reproductive Disorders | 8 | 0.01% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 47 | 0.06% |
| Human Endocrine/Metabolism Disorders | 769 | 1.03% |
| Other Human Disorders | 897 | 1.21% |
| Animal Diseases and Disorders | 2637 | 3.55% |
| Animal Welfare | 3848 | 5.18% |
| Diagnosis of diseases | 6 | 0.01% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 74336 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 35884 | 99.12% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 72 | 0.2% |
| Routine production | 246 | 0.68% |
| Total | 36202 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 4228 | 11.78% |
| Pyrogenicity testing | 13157 | 36.67% |
| Batch potency testing | 17604 | 49.06% |
| Other quality controls | 895 | 2.49% |
| Total | 35884 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Neurotoxicity | 22 | 30.56% |
| Target animal safety | 50 | 69.44% |
| Total | 72 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 246 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 246 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 36103 | 99.73% |
| Legislation on medicinal products for veterinary use and their residues | 50 | 0.14% |
| Medical devices legislation | 27 | 0.07% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 22 | 0.06% |
| Total | 36202 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 31134 | 86% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only | 5068 | 14% |
| Total | 36202 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 235560 | 99.62% |
| Yes | 899 | 0.38% |
| Total | 236459 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 5815 | 2.46% |
| Mild [up to and including] | 148333 | 62.73% |
| Moderate | 65039 | 27.51% |
| Severe | 17272 | 7.3% |
| Total | 236459 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 222857 | 94.25% |
| Yes | 13602 | 5.75% |
| Total | 236459 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 138680 | 58.65% |
| Genetically altered without a harmful phenotype | 80249 | 33.94% |
| Genetically altered with a harmful phenotype | 17530 | 7.41% |
| Total | 236459 | 100.00% |

## Austria: Narrative 2017

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

In Austria the total number of animals used for scientific purposes in 2017 is 264.071 (2016: 236.459), which is an increase of 11.7% or in absolute numbers 27.612 animals. Due to changes in the regime for counting the animals (e.g. counting animals at the beginning of a procedure vs. counting them at the end) comparisons with the previous years can only be made with certain caveats.

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

The total number of fish (zebra fish and other fish) used for scientific purposes in 2017 is 20.927 (2016: 10.436). Zebra fish were mainly used for the purpose “Basic Research, Other” in particular cell and developmental biology.

With regard to the categories of purposes, a marked increase is observed in “Basic Research, Oncology” (from 17.191 animals to 25.406 animals used in 2017). For Maintenance of colonies of established genetically altered animals, not used in other procedures” a decrease was reported in 2016, whereas for 2017 an increase is observed in this category (from 18.905 animals to 29.360 animals).

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

No significant changes are observed.

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

The competent authorities promote the 3R principle at all steps of the authorization processes, in particular by putting emphasis on minimizing pain suffering, distress and lasting harm by adequate humane endpoints.

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

“Other rodents” include i.a. the common vole and the wood mouse; “Other mammals” include i.a. the brown hare and wild boar, “Other birds” i.a. reed buntings and Eurasian blackcaps; “Other fish” include i.a. trouts.

The purpose “Basic Research, Other” includes, in particular, the creation and maintenance of genetically altered animals (as long as their further use in projects is not yet known), as well as cell and developmental biology and imaging.

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

Procedures involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2) were not performed.

## Austria: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 212913 | 80.63% |
| Rats | 6038 | 2.29% |
| Guinea-Pigs | 1154 | 0.44% |
| Hamsters (Syrian) | 8 | 0% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 41 | 0.02% |
| Other Rodents | 998 | 0.38% |
| Rabbits | 10388 | 3.93% |
| Cats | 61 | 0.02% |
| Dogs | 203 | 0.08% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 521 | 0.2% |
| Pigs | 2040 | 0.77% |
| Goats | 22 | 0.01% |
| Sheep | 149 | 0.06% |
| Cattle | 908 | 0.34% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 102 | 0.04% |
| Domestic fowl | 3895 | 1.47% |
| Other birds | 1819 | 0.69% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus | 972 | 0.37% |
| Other Amphibians | 912 | 0.35% |
| Zebra fish | 16297 | 6.17% |
| Other Fish | 4630 | 1.75% |
| Cephalopods |  |  |
| Total | 264071 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 247185 | 93.95% |
| Animals born in the EU but not at a registered breeder | 11909 | 4.53% |
| Animals born in rest of Europe | 99 | 0.04% |
| Animals born in rest of world | 3902 | 1.48% |
| Total | 263095 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 127667 | 48.35% |
| Translational and applied research | 77138 | 29.21% |
| Regulatory use and Routine production | 26569 | 10.06% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 198 | 0.07% |
| Preservation of species | 30 | 0.01% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 3108 | 1.18% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 29361 | 11.12% |
| Total | 264071 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 25406 | 19.9% |
| Cardiovascular Blood and Lymphatic System | 10272 | 8.05% |
| Nervous System | 16591 | 13% |
| Respiratory System | 316 | 0.25% |
| Gastrointestinal System including Liver | 2229 | 1.75% |
| Musculoskeletal System | 4947 | 3.87% |
| Immune System | 25283 | 19.8% |
| Urogenital/Reproductive System | 1128 | 0.88% |
| Sensory Organs (skin, eyes and ears) | 1208 | 0.95% |
| Endocrine System/Metabolism | 1694 | 1.33% |
| Multisystemic | 12805 | 10.03% |
| Ethology / Animal Behaviour /Animal Biology | 5799 | 4.54% |
| Other basic research | 19989 | 15.66% |
| Total | 127667 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| 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% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 65 | 0.08% |
| Total | 77138 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 25823 | 97.19% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 740 | 2.79% |
| Routine production | 6 | 0.02% |
| Total | 26569 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Repeated dose toxicity | 43 | 5.81% |
| Neurotoxicity | 32 | 4.32% |
| Target animal safety | 665 | 89.86% |
| Total | 740 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days | 43 | 100% |
| > 90 days |  |  |
| Total | 43 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 6 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 6 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 25870 | 97.37% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation | 2 | 0.01% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation | 665 | 2.5% |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 32 | 0.12% |
| Total | 26569 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 23037 | 86.71% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only | 3532 | 13.29% |
| Total | 26569 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 263095 | 99.63% |
| Yes | 976 | 0.37% |
| Total | 264071 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 5153 | 1.95% |
| Mild [up to and including] | 175022 | 66.28% |
| Moderate | 62516 | 23.67% |
| Severe | 21380 | 8.1% |
| Total | 264071 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 241513 | 91.46% |
| Yes | 22558 | 8.54% |
| Total | 264071 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 145931 | 55.26% |
| Genetically altered without a harmful phenotype | 82509 | 31.25% |
| Genetically altered with a harmful phenotype | 35631 | 13.49% |
| Total | 264071 | 100.00% |

# Belgium

## Belgium: Narrative 2015

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

Compared to 2014 (660.261 animals used), there is a decrease of 14,95 % in the number of animals used for scientific purposes in 2015 (561.551 animals used).

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

The use of animals in the specific areas is similar to the figures of 2014.

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

In 2015 more animals were reported in the ‘severe’ category [2014: severe (14.82%), moderate (28.23%), mild (53.02%) and non-recovery (3.93%); 2015: severe (16.68%), moderate (22.14%), mild (56.69%) and non-recovery (4.49%)]. This trend is mostly due to a better reporting of the actual severities by the users and stricter controls by the ethical committees and the government.

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

* Funding of research projects for the development of alternative toxicity tests
* Collaboration with the university board to promote the development and promotion of alternative methods.
* Collaboration between the different regions and other member states to promote the 3R principle.

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

40.67% of the fishes are reported under the “other” category. They are mostly *Clarias gariepinus* and *Dicentrarchus labrax.* 36.67% of the amphibians reported under the “other” category are *Salamandridae* (in order of importance: *Lissotriton helveticus*, *Ichthyosaura alpestris*, *Salamandra salamandra*) and *Ranidae* (in order of importance: *Lithobates catesbeianus*, *Litoria caerulea*, *Alytes obstetricans*). 18.10% of the birds are reported under the “other” category. They are mostly *Paridae,* *Fringillidae, Passeridae,* *Coturnix, Meleagrididae, Estrildida* and *Laridae*.

19.73% of the regulatory routine production – toxicity and safety testing is reported as “other” toxicity and safety testing. This concerns mostly immunogenicity and psychopharmacology tests.

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

There were no exceeding of the ‘severe’ classification reported in 2015.

## Belgium: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 331692 | 59.07% |
| Rats | 33686 | 6% |
| Guinea-Pigs | 17363 | 3.09% |
| Hamsters (Syrian) | 2246 | 0.4% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 111 | 0.02% |
| Other Rodents | 200 | 0.04% |
| Rabbits | 43304 | 7.71% |
| Cats | 82 | 0.01% |
| Dogs | 1850 | 0.33% |
| Ferrets | 5 | 0% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 115 | 0.02% |
| Pigs | 3391 | 0.6% |
| Goats | 96 | 0.02% |
| Sheep | 417 | 0.07% |
| Cattle | 598 | 0.11% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey | 5 | 0% |
| Rhesus monkey | 41 | 0.01% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 131 | 0.02% |
| Domestic fowl | 18350 | 3.27% |
| Other birds | 4055 | 0.72% |
| Reptiles | 133 | 0.02% |
| Rana |  |  |
| Xenopus | 855 | 0.15% |
| Other Amphibians | 495 | 0.09% |
| Zebra fish | 60711 | 10.81% |
| Other Fish | 41619 | 7.41% |
| Cephalopods |  |  |
| Total | 561551 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 496746 | 91.89% |
| Animals born in the EU but not at a registered breeder | 36621 | 6.77% |
| Animals born in rest of Europe | 2693 | 0.5% |
| Animals born in rest of world | 4501 | 0.83% |
| Total | 540561 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 5 | 50% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 5 | 50% |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 10 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 10 | 100% |
| Self-sustaining colony |  |  |
| Total | 10 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 309245 | 55.07% |
| Translational and applied research | 94736 | 16.87% |
| Regulatory use and Routine production | 146804 | 26.14% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 377 | 0.07% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 8426 | 1.5% |
| Forensic enquiries | 36 | 0.01% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 1927 | 0.34% |
| Total | 561551 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 42541 | 13.76% |
| Cardiovascular Blood and Lymphatic System | 19624 | 6.35% |
| Nervous System | 48985 | 15.84% |
| Respiratory System | 7410 | 2.4% |
| Gastrointestinal System including Liver | 15356 | 4.97% |
| Musculoskeletal System | 18962 | 6.13% |
| Immune System | 59121 | 19.12% |
| Urogenital/Reproductive System | 20248 | 6.55% |
| Sensory Organs (skin, eyes and ears) | 4820 | 1.56% |
| Endocrine System/Metabolism | 30242 | 9.78% |
| Multisystemic | 15254 | 4.93% |
| Ethology / Animal Behaviour /Animal Biology | 17519 | 5.67% |
| Other basic research | 9163 | 2.96% |
| Total | 309245 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 16760 | 17.69% |
| Human Infectious Disorders | 21894 | 23.11% |
| Human Cardiovascular Disorders | 1085 | 1.15% |
| Human Nervous and Mental Disorders | 17936 | 18.93% |
| Human Respiratory Disorders | 4176 | 4.41% |
| Human Gastrointestinal Disorders including Liver | 971 | 1.02% |
| Human Musculoskeletal Disorders | 181 | 0.19% |
| Human Immune Disorders | 2558 | 2.7% |
| Human Urogenital/Reproductive Disorders | 433 | 0.46% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 2880 | 3.04% |
| Human Endocrine/Metabolism Disorders | 1359 | 1.43% |
| Other Human Disorders | 62 | 0.07% |
| Animal Diseases and Disorders | 6235 | 6.58% |
| Animal Welfare | 165 | 0.17% |
| Diagnosis of diseases | 7256 | 7.66% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 10785 | 11.38% |
| Total | 94736 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 89897 | 61.24% |
| Other efficacy and tolerance testing | 7066 | 4.81% |
| Toxicity and other safety testing including pharmacology | 9705 | 6.61% |
| Routine production | 40136 | 27.34% |
| Total | 146804 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 13136 | 14.61% |
| Pyrogenicity testing |  |  |
| Batch potency testing | 74356 | 82.71% |
| Other quality controls | 2405 | 2.68% |
| Total | 89897 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 990 | 10.2% |
| Skin irritation/corrosion | 158 | 1.63% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Phototoxicity |  |  |
| Skin sensitisation |  |  |
| Repeated dose toxicity | 1380 | 14.22% |
| Genotoxicity | 126 | 1.3% |
| Reproductive toxicity | 349 | 3.6% |
| Neurotoxicity | 183 | 1.89% |
| Kinetics | 671 | 6.91% |
| Pharmaco-dynamics (incl safety pharmacology) | 1548 | 15.95% |
| Ecotoxicity | 871 | 8.97% |
| Safety testing in food and feed area | 1506 | 15.52% |
| Target animal safety | 8 | 0.08% |
| Other toxicity/safety testing | 1915 | 19.73% |
| Total | 9705 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 990 | 100% |
| Total | 990 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 1380 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 1380 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 871 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 871 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 39961 | 99.56% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 175 | 0.44% |
| Total | 40136 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 120283 | 81.93% |
| Legislation on medicinal products for veterinary use and their residues | 18724 | 12.75% |
| Medical devices legislation | 552 | 0.38% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation | 136 | 0.09% |
| Biocides legislation |  |  |
| Food legislation including food contact material | 1336 | 0.91% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 332 | 0.23% |
| Cosmetics legislation |  |  |
| Other legislation | 5441 | 3.71% |
| Total | 146804 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 130212 | 88.7% |
| Legislation satisfying national requirements only [within EU] | 871 | 0.59% |
| Legislation satisfying Non-EU requirements only | 15721 | 10.71% |
| Total | 146804 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 540571 | 96.26% |
| Yes | 20980 | 3.74% |
| Total | 561551 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 25221 | 4.49% |
| Mild [up to and including] | 318327 | 56.69% |
| Moderate | 124343 | 22.14% |
| Severe | 93660 | 16.68% |
| Total | 561551 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 539762 | 96.12% |
| Yes | 21789 | 3.88% |
| Total | 561551 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 424438 | 75.58% |
| Genetically altered without a harmful phenotype | 124304 | 22.14% |
| Genetically altered with a harmful phenotype | 12809 | 2.28% |
| Total | 561551 | 100.00% |

## Belgium: Narrative 2016

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

Compared to 2015 (561.551 animals used), there is a decrease of 4.75 % in the number of animals used for scientific purposes in 2016 (534.854 animals used).

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

The use of animals in the specific areas is similar to the figures of 2015.

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

There were no significant changes in actual severities.

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

* Funding of research projects for the development of alternative toxicity tests.
* Collaboration with the university board to promote the development and promotion of alternative methods.
* Collaboration between the different regions and other member states to promote the 3R principle.

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

40.12% of the fishes are reported under the “other” category. They are mostly Cyprinidae, Cichlidae, Salmonidae, Percidae, Soleidae, Pleuronectidae and [Aplocheilidae](https://en.wikipedia.org/wiki/Aplocheilidae).

37,28% of the amphibians reported under the “other” category are mostly Ranidae (Lithobates catesbeianus), Salamandridae (in order of importance: Lissotriton helveticus, Pleurodeles waltl, Ichthyosaura alpestris) and Bombinatoridae (Bombina orientalis).

14.65% of the birds are reported under the “other” category. They are Paridae, Fringillidae, Meleagrididae, Phasianidae, Passeridae, Pycnonotidae, Estrildida, Laridae, Columbidae and Psittacidae.

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

There were no cases in which the ‘severe’ classification was exceeded.

## Belgium: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 336052 | 62.83% |
| Rats | 30337 | 5.67% |
| Guinea-Pigs | 16223 | 3.03% |
| Hamsters (Syrian) | 1880 | 0.35% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 118 | 0.02% |
| Other Rodents | 175 | 0.03% |
| Rabbits | 48036 | 8.98% |
| Cats | 123 | 0.02% |
| Dogs | 1529 | 0.29% |
| Ferrets | 13 | 0% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 231 | 0.04% |
| Pigs | 3630 | 0.68% |
| Goats | 101 | 0.02% |
| Sheep | 581 | 0.11% |
| Cattle | 1279 | 0.24% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey | 40 | 0.01% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 153 | 0.03% |
| Domestic fowl | 26230 | 4.9% |
| Other birds | 4504 | 0.84% |
| Reptiles | 172 | 0.03% |
| Rana |  |  |
| Xenopus | 769 | 0.14% |
| Other Amphibians | 457 | 0.09% |
| Zebra fish | 37256 | 6.97% |
| Other Fish | 24965 | 4.67% |
| Cephalopods |  |  |
| Total | 534854 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 494820 | 93.94% |
| Animals born in the EU but not at a registered breeder | 26817 | 5.09% |
| Animals born in rest of Europe | 48 | 0.01% |
| Animals born in rest of world | 5034 | 0.96% |
| Total | 526719 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 4 | 100% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 4 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 4 | 100% |
| Self-sustaining colony |  |  |
| Total | 4 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 283739 | 53.05% |
| Translational and applied research | 105760 | 19.77% |
| Regulatory use and Routine production | 132925 | 24.85% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 1006 | 0.19% |
| Preservation of species | 6 | 0% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 8819 | 1.65% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 2599 | 0.49% |
| Total | 534854 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 54616 | 19.25% |
| Cardiovascular Blood and Lymphatic System | 14443 | 5.09% |
| Nervous System | 56699 | 19.98% |
| Respiratory System | 6121 | 2.16% |
| Gastrointestinal System including Liver | 19837 | 6.99% |
| Musculoskeletal System | 5877 | 2.07% |
| Immune System | 50140 | 17.67% |
| Urogenital/Reproductive System | 11536 | 4.07% |
| Sensory Organs (skin, eyes and ears) | 3772 | 1.33% |
| Endocrine System/Metabolism | 18300 | 6.45% |
| Multisystemic | 10342 | 3.64% |
| Ethology / Animal Behaviour /Animal Biology | 19464 | 6.86% |
| Other basic research | 12592 | 4.44% |
| Total | 283739 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 18857 | 17.83% |
| Human Infectious Disorders | 18443 | 17.44% |
| Human Cardiovascular Disorders | 920 | 0.87% |
| Human Nervous and Mental Disorders | 22383 | 21.16% |
| Human Respiratory Disorders | 3243 | 3.07% |
| Human Gastrointestinal Disorders including Liver | 1328 | 1.26% |
| Human Musculoskeletal Disorders | 1047 | 0.99% |
| Human Immune Disorders | 2329 | 2.2% |
| Human Urogenital/Reproductive Disorders | 284 | 0.27% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 3290 | 3.11% |
| Human Endocrine/Metabolism Disorders | 2634 | 2.49% |
| Other Human Disorders | 232 | 0.22% |
| Animal Diseases and Disorders | 12467 | 11.79% |
| Animal Welfare | 1514 | 1.43% |
| Diagnosis of diseases | 6481 | 6.13% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 10308 | 9.75% |
| Total | 105760 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 82222 | 61.86% |
| Other efficacy and tolerance testing | 3345 | 2.52% |
| Toxicity and other safety testing including pharmacology | 5467 | 4.11% |
| Routine production | 41891 | 31.51% |
| Total | 132925 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 12844 | 15.62% |
| Pyrogenicity testing |  |  |
| Batch potency testing | 66345 | 80.69% |
| Other quality controls | 3033 | 3.69% |
| Total | 82222 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 392 | 7.17% |
| Carcinogenicity |  |  |
| Eye irritation/corrosion |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Repeated dose toxicity | 964 | 17.63% |
| Genotoxicity | 83 | 1.52% |
| Developmental toxicity | 1697 | 31.04% |
| Neurotoxicity | 30 | 0.55% |
| Kinetics | 465 | 8.51% |
| Ecotoxicity | 358 | 6.55% |
| Safety testing in food and feed area | 1451 | 26.54% |
| Target animal safety | 8 | 0.15% |
| Other toxicity/safety testing | 19 | 0.35% |
| Total | 5467 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 392 | 100% |
| Total | 392 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 864 | 89.63% |
| 29 - 90 days | 92 | 9.54% |
| > 90 days | 8 | 0.83% |
| Total | 964 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 262 | 73.18% |
| Chronic toxicity | 96 | 26.82% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 358 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 41781 | 99.74% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 110 | 0.26% |
| Total | 41891 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 115307 | 86.75% |
| Legislation on medicinal products for veterinary use and their residues | 15187 | 11.43% |
| Medical devices legislation | 1299 | 0.98% |
| Industrial chemicals legislation | 195 | 0.15% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 668 | 0.5% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 159 | 0.12% |
| Cosmetics legislation |  |  |
| Other legislation | 110 | 0.08% |
| Total | 132925 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 118429 | 89.09% |
| Legislation satisfying national requirements only [within EU] | 19 | 0.01% |
| Legislation satisfying Non-EU requirements only | 14477 | 10.89% |
| Total | 132925 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 526723 | 98.48% |
| Yes | 8131 | 1.52% |
| Total | 534854 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 21229 | 3.97% |
| Mild [up to and including] | 297600 | 55.64% |
| Moderate | 119243 | 22.29% |
| Severe | 96782 | 18.1% |
| Total | 534854 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 513065 | 95.93% |
| Yes | 21789 | 4.07% |
| Total | 534854 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 408773 | 76.43% |
| Genetically altered without a harmful phenotype | 108899 | 20.36% |
| Genetically altered with a harmful phenotype | 17182 | 3.21% |
| Total | 534854 | 100.00% |

## Belgium: Narrative 2017

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

Compared to 2016 (534.854 animals used), there is an increase of 1.54% in the number of animals used for scientific purposes in 2017 (543.074 animals used) but still a decrease of 3.29% compared to 2015 (561.551 animals used). The increase in 2017 is the result of an increased use of poultry merely in translational and applied research (animal diseases and disorders) and for forensic enquiries.

|  |  |  |
| --- | --- | --- |
| **Number of use in 2017** | **Number of use in 2016** | **Number of use in 2015** |
| 543074 | 534854 | 561551 |

Since 2015 the numbers of re-used animals continues to decline: 3.74% of all uses in 2015, 1.52% in 2016 and 0.93% in 2017.

|  |  |  |  |
| --- | --- | --- | --- |
| **Re-Use** | **Number of use in 2017** | **Number of use in 2016** | **Number of use in 2015** |
|
|
| **No** | 538043 | 526723 | 540571 |
|
| **Yes** | 5031 | 8131 | 20980 |
|
| **Total uses** | **543074** | **534854** | **561551** |
|

There is a significant increase in the use of birds (108.94% compared with the use of birds in 2015). This is due to an increase in the area of Animal Diseases and Disorders and Regulatory use and Routine production (Legislation on medicinal products for veterinary use and their residues). The fish decreased with 48,73% compared to 2015. No apparent reason was noted.

|  |  |  |  |
| --- | --- | --- | --- |
| **Species** | **Number of use in 2017** | **Number of use in 2016** | **Number of use in 2015** |
|
| Mammals | 442378 | 440501 | 435333 |
|
|
| Birds | 46812 | 30734 | 22405 |
| Fish | 52462 | 62221 | 102330 |
|
| Amphibians | 1241 | 1226 | 1350 |
| Reptiles | 181 | 172 | 133 |
|
| Cephalopods | 0 | 0 | 0 |
|
| **Total uses** | **543074** | **534854** | **561551** |
|

In the mammals the use of rabbits and Artiodactyla increased. The use of rabbits has increased in the Legislation on medicinal products for human use area. This is reflected in an increase of 33.68% compared to 2015. The use of Artiodactyla augmented (61.53% more Artiodactyla used compared to 2015). This is due to an increase in Basic research (this was caused by zootechnics (selection)), Translational and applied research (Animal Diseases and Disorders) and Protection of the natural environment in the interests of the health or welfare of human beings or animals. The use of all other species remained unchanged.

|  |  |  |  |
| --- | --- | --- | --- |
| **Mammals** | **Number of use in 2017** | **Number of use in 2016** | **Number of use in 2015** |
|
|
| Rodents | 374857 | 384785 | 385298 |
|
| Rabbits | 57888 | 48036 | 43304 |
| Carnivores | 1943 | 1665 | 1937 |
|
| Equidae | 234 | 231 | 115 |
| Artiodactyla | 7272 | 5591 | 4502 |
| Non-human primates | 44 | 40 | 46 |
| Other mammals | 140 | 153 | 131 |
| **Total uses** | **442378** | **440501** | **435333** |
|

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

Between 2015 and 2017, basic research diminished with 11,79%. This was in particular due to decreases in the area of Musculoskeletal System, Urogenital/Reproductive System, Multisystemic research, Endocrine System/Metabolism and Respiratory System. However, the research in the domain of the Immune System and Oncology significantly increased between 2015 and 2017.

During the same time period Translational and applied research augmented with 23.77%. We noted a significant increase in Animal Welfare (3,525 animals in 2017 compared to 165 in 2015), Animal Diseases and Disorders, Human Endocrine/Metabolism Disorders, Human Sensory Organ Disorders (skin, eyes and ears), Human Nervous and Mental Disorders and Non-regulatory toxicology and ecotoxicology. A decrease was noted in Diagnosis of diseases and Human Infectious Disorders.

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

Within the actual severities classification we note that the category "severe" decreased from 18.10% in 2016 to 15.61% in 2017.

This is due to a diminution of quality control research (incl. batch safety and potency testing). This percentage is still higher than the European average of 10% but in Belgium a lot of basic research was done with in particular research in the field of Oncology, Immune system and Nervous system. Another important area in the research concerns Translational and applied research with again Human Nervous and Mental Disorders, Human Infectious Disorders and Human Cancer as the most important domains. Since, according to the legislation, tumours leading to metastases, tumours that lead to cachexia, invasive bone tumours, ulcerating tumours, loss of immunity, etc. (research that is often done in Belgium) should be classified as "severe", this can lead to an increase in this category.

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

* Funding of research projects for the development of alternative toxicity tests:
  + Thyroid hormone disruptors: There is a wide-variety of environmental contaminants that have the potential to cause thyroid hormone disruption[[1]](#footnote-1). Exposure to specific environmental toxins, including polychlorinated biphenyls, dioxins, phthalates, polybrominated diphenyl ethers (PBDEs), and other halogenated compounds, has been shown to interfere with the production, transportation, and/or metabolism of thyroid hormones by a variety of mechanisms. Some chemicals, with structural similarity to thyroid hormones, have been shown to bind to thyroid receptors with both agonist and antagonist effects on thyroid hormone signalling. Thyroid hormone disruption can therefore cause severe adverse effects on *e.g*. brain development, growth and metabolism.

Validated and internationally recognised tests methods are essential in assessing the potential of chemicals to interact with the hormonal system and cause adverse effects. Non-animal test methods are needed for efficient testing and screening of substances. In 2014, OECD published a scoping document on *in vitro* and *ex vivo* assays for the identification of modulators of thyroid hormone signalling (OECD, 2014). Several key biological mechanisms of thyroid system disruption were reviewed and the corresponding methods evaluated for their state of readiness as candidates to enter the validation process. Relevant *in vitro* and *ex vivo* methods were identified and recommendations were given for their development/use. Eighteen methods were reported that cover the possible sites of action in the hypothalamic-pituitary-thyroid (HPT) axis. The research is carried out by EU-Netval facilities. By funding this research we enable our EU NETVAL facility to take part of this study.

* + Differentiation of human skin-derived stem cells towards hepatic cells: new source for the "in vitro study" of liver toxicity of drugs. Liver toxicity is one of the most important research elements in drug development. In addition, liver toxicity is the main reason for withdrawing medicines from the market. Presently, pre-clinical drug safety tests are carried out by "in vivo studies", i.e. studies on laboratory animals. In addition to the ethical concerns and the high costs associated with these in vivo studies, it is important to note the relatively low correlation between the results of animals on humans (less than 60% of the results of tests on animals apply to humans). By funding the project, we contribute to research that will lead in the long term to the reduction of the number of laboratory animals that are used in the context of drug development.
* Collaboration with the university board to promote the development and promotion of alternative methods (for example, WALCOPA project in Wallonia).
* Collaboration between the different regions and other member states to promote the 3R principle.
* Establishment of RE-place: The RE-Place project will create a database that brings together all existing expertise on alternative methods for animal testing in the Flemish and Brussels regions. The RE-Place website will be expanded in a next phase into a platform where researchers can find more information about alternative methods for animal testing and share their research methodology with the rest of the research community. By charting and making known generally the available and developing alternative methods for animal testing, not only researchers but also the general public and the political world will be better informed about the expertise in their own region. In the long term, all collected information will be integrated at European level.

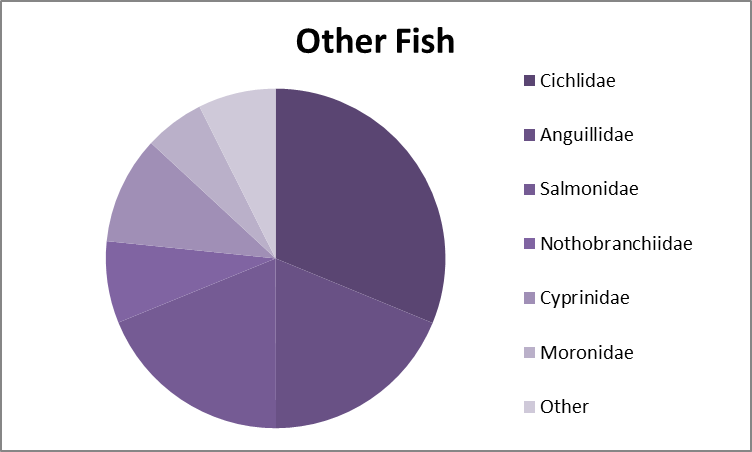
**5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.**

1. Other fish

45.80% of the fishes are reported under the “other” category.

They are mostly Cichlidae (*Oreochromis niloticus*) (31.21% of other fish), Salmonidae (*Salmo salar and Oncorhynchus mykiss*) (18.85% of other fish), Anguillidae (*Anguilla anguilla*) (18.75% of other fish), Cyprinidae (*Cyprinus carpio carpio and Cyprinus carpio*) (10.27% of other fish), Nothobranchiidae (*Nothobranchius furzeri*) (7.79% of other fish) and Moronidae (*Dicentrarchus labrax*) (5.70% of other fish).

|  |  |
| --- | --- |
| **Other Fish** | **Number of uses** |
| *Oreochromis niloticus* | 7499 |
| *Anguilla anguilla* | 4506 |
| *Salmo salar* | 2012 |
| *Oncorhynchus mykiss* | 2522 |
| *Nothobranchius furzeri* | 1871 |
| *Cyprinus carpio carpio* | 1814 |
| *Dicentrarchus labrax* | 1370 |
| *Cyprinus carpio* | 654 |
| *Scortum barcoo* | 648 |
| *Poecilia reticulata* | 300 |
| *Pleuronectes platessa* | 229 |
|
| *Lota lota* | 144 |
| *Gasterosteus aculeatus* | 82 |
| *Clarias gariepinus* | 50 |
| *Kryptolebias marmoratus* | 50 |
| *Limanda limanda* | 48 |
| *Gadus morhua* | 47 |
| *Pseudotropheus saulosi* | 25 |
| *Synodontis grandiops* | 20 |
| *Microsynodontis batesii* | 12 |
|
| *Myloplus schomburgkii* | 8 |
|
| *Catoprion mento* | 7 |
| *Metynnis hypsauchen* | 7 |
| *Pseudotropheus estherae* | 7 |
| *Pygopristis denticulata* | 7 |
| *Serrasalmus spilopleura* | 7 |
| *Ophthalmotilapia ventralis* | 6 |
| *Synodontis nigriventris* | 6 |
| *Maylandia zebra* | 5 |
| *Mochokiella paynei* | 5 |
| *Pygocentrus cariba* | 5 |
| *Pygocentrus nattereri* | 5 |
| *Pygocentrus piraya* | 5 |
| *Botia morleti* | 3 |
| *Myloplus rubripinnis* | 3 |
| *Pantodon buchholzi* | 3 |
| *Piaractus brachypomus* | 3 |
| *Synodontis acanthomias* | 3 |
| *Synodontis brichardi* | 3 |
| *Synodontis contractus* | 3 |
| *Synodontis elongatus* | 3 |
| *Synodontis flavitaeniatus* | 3 |
| *Synodontis lucipinnis* | 3 |
| *Synodontis notatus* | 3 |
| *Botia modesta* | 2 |
| *Serrasalmus manueli* | 2 |
| *Colossoma macropomum* | 1 |
| *Malapterurus electricus* | 1 |
| *Metynnis lippincottianus* | 1 |
| *Ophthalmotilapia nasuta* | 1 |
| *Platydoras hancockii* | 1 |
| *Synodontis eupterus* | 1 |
| *Synodontis schall* | 1 |
| **Total uses:** | **24027** |

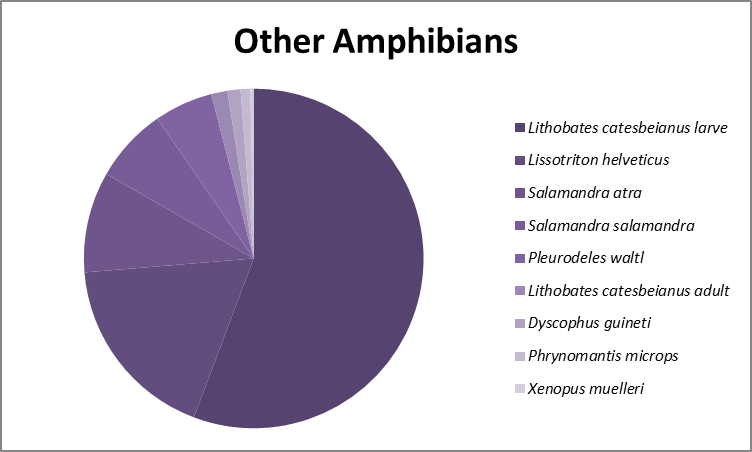


1. Other amphibians

26.03% of the amphibians are reported under the “other” category.

They are mostly Ranidae (*Lithobates catesbeianus larva + adult*) (57.27% of other amphibians) and Salamandridae (in order of importance: *Lissotriton helveticus, Salamandra atra, Salamandra salamandra, Pleurodeles waltl*) (40.24% of other amphibians).

|  |  |
| --- | --- |
| **Other Amphibians** | **Number of uses** |
| *Lithobates catesbeianus larve* | 180 |
| *Lissotriton helveticus* | 58 |
| *Salamandra atra* | 31 |
| *Salamandra salamandra* | 23 |
| *Pleurodeles waltl* | 18 |
| *Lithobates catesbeianus adult* | 5 |
| *Dyscophus guineti* | 4 |
| *Phrynomantis microps* | 3 |
| *Xenopus muelleri* | 1 |
| **Total uses:** | **323** |



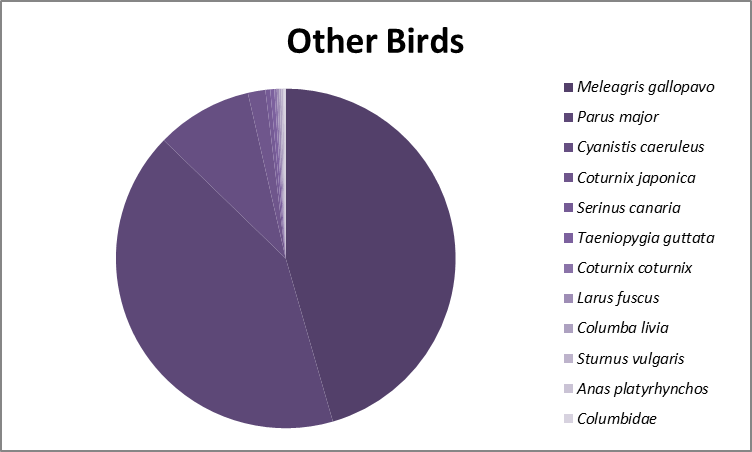
1. Other birds

15.25% of the birds are reported under the “other” category.

They are mostly Paridae (*Parus major and Cyanistis caeruleus*) (50.89% of other birds) and Phasianidae (*Meleagris gallopavo, Coturnix japonica, Coturnix coturnix*) (47.42% of other birds).

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

|  |  |
| --- | --- |
| **Other Birds** | **Number of uses** |
| *Meleagris gallopavo* | 3249 |
| *Parus major* | 2979 |
| *Cyanistis caeruleus* | 654 |
| *Coturnix japonica* | 119 |
| *Serinus canaria* | 33 |
| *Taeniopygia guttata* | 27 |
| *Coturnix coturnix* | 17 |
| *Larus fuscus* | 17 |
| *Columba livia* | 14 |
| *Sturnus vulgaris* | 13 |
| *Anas platyrhynchos* | 8 |
| *Columbidae* | 8 |
| **Total uses:** | **7138** |



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

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

## Belgium: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 334054 | 61.51% |
| Rats | 23826 | 4.39% |
| Guinea-Pigs | 15541 | 2.86% |
| Hamsters (Syrian) | 1147 | 0.21% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 174 | 0.03% |
| Other Rodents | 115 | 0.02% |
| Rabbits | 57888 | 10.66% |
| Cats | 61 | 0.01% |
| Dogs | 1856 | 0.34% |
| Ferrets | 26 | 0% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 234 | 0.04% |
| Pigs | 4970 | 0.92% |
| Goats | 78 | 0.01% |
| Sheep | 666 | 0.12% |
| Cattle | 1558 | 0.29% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey | 44 | 0.01% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 140 | 0.03% |
| Domestic fowl | 39674 | 7.31% |
| Other birds | 7138 | 1.31% |
| Reptiles | 181 | 0.03% |
| Rana |  |  |
| Xenopus | 918 | 0.17% |
| Other Amphibians | 323 | 0.06% |
| Zebra fish | 28435 | 5.24% |
| Other Fish | 24027 | 4.42% |
| Cephalopods |  |  |
| Total | 543074 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 511268 | 95.03% |
| Animals born in the EU but not at a registered breeder | 22269 | 4.14% |
| Animals born in rest of Europe | 903 | 0.17% |
| Animals born in rest of world | 3594 | 0.67% |
| Total | 538034 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 9 | 100% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 9 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 9 | 100% |
| Self-sustaining colony |  |  |
| Total | 9 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 272795 | 50.23% |
| Translational and applied research | 117258 | 21.59% |
| Regulatory use and Routine production | 141853 | 26.12% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 706 | 0.13% |
| Preservation of species | 151 | 0.03% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 8051 | 1.48% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 2260 | 0.42% |
| Total | 543074 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 58087 | 21.29% |
| Cardiovascular Blood and Lymphatic System | 13462 | 4.93% |
| Nervous System | 42974 | 15.75% |
| Respiratory System | 3583 | 1.31% |
| Gastrointestinal System including Liver | 16775 | 6.15% |
| Musculoskeletal System | 4967 | 1.82% |
| Immune System | 70105 | 25.7% |
| Urogenital/Reproductive System | 5852 | 2.15% |
| Sensory Organs (skin, eyes and ears) | 4785 | 1.75% |
| Endocrine System/Metabolism | 14861 | 5.45% |
| Multisystemic | 5600 | 2.05% |
| Ethology / Animal Behaviour /Animal Biology | 14701 | 5.39% |
| Other basic research | 17043 | 6.25% |
| Total | 272795 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 12720 | 10.85% |
| Human Infectious Disorders | 15691 | 13.38% |
| Human Cardiovascular Disorders | 1573 | 1.34% |
| Human Nervous and Mental Disorders | 28936 | 24.68% |
| Human Respiratory Disorders | 5945 | 5.07% |
| Human Gastrointestinal Disorders including Liver | 977 | 0.83% |
| 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 | 4.64% |
| Human Endocrine/Metabolism Disorders | 3722 | 3.17% |
| Other Human Disorders | 40 | 0.03% |
| Animal Diseases and Disorders | 17960 | 15.32% |
| Animal Welfare | 3525 | 3.01% |
| Diagnosis of diseases | 4292 | 3.66% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 13111 | 11.18% |
| Total | 117258 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 8016 | 11.68% |
| Pyrogenicity testing |  |  |
| Batch potency testing | 57716 | 84.12% |
| Other quality controls | 2883 | 4.2% |
| Total | 68615 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 1037 | 25.09% |
| Carcinogenicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 50 | 4.82% |
| Other lethal methods |  |  |
| Non lethal methods | 987 | 95.18% |
| Total | 1037 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of 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 use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 1202 | 84.77% |
| Chronic toxicity | 216 | 15.23% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 1418 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 51804 | 99.81% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 100 | 0.19% |
| Total | 51904 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 113897 | 80.29% |
| Legislation on medicinal products for veterinary use and their residues | 25559 | 18.02% |
| Medical devices legislation | 779 | 0.55% |
| Industrial chemicals legislation | 216 | 0.15% |
| Plant protection product legislation | 52 | 0.04% |
| Biocides legislation |  |  |
| Food legislation including food contact material | 74 | 0.05% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 1276 | 0.9% |
| Total | 141853 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 128208 | 90.38% |
| Legislation satisfying national requirements only [within EU] | 50 | 0.04% |
| Legislation satisfying Non-EU requirements only | 13595 | 9.58% |
| Total | 141853 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 538043 | 99.07% |
| Yes | 5031 | 0.93% |
| Total | 543074 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 26546 | 4.89% |
| Mild [up to and including] | 297189 | 54.72% |
| Moderate | 134577 | 24.78% |
| Severe | 84762 | 15.61% |
| Total | 543074 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 513454 | 94.55% |
| Yes | 29620 | 5.45% |
| Total | 543074 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 402289 | 74.08% |
| Genetically altered without a harmful phenotype | 118326 | 21.79% |
| Genetically altered with a harmful phenotype | 22459 | 4.14% |
| Total | 543074 | 100.00% |

# Bulgaria

## Bulgaria: Narrative 2015 - no narrative submitted

No narrative submitted by the Member State

## Bulgaria : Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 2381 | 25.17% |
| Rats | 1753 | 18.53% |
| Guinea-Pigs | 105 | 1.11% |
| Hamsters (Syrian) | 404 | 4.27% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 365 | 3.86% |
| Cats | 46 | 0.49% |
| Dogs | 10 | 0.11% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 4 | 0.04% |
| Pigs | 50 | 0.53% |
| Goats | 7 | 0.07% |
| Sheep | 320 | 3.38% |
| Cattle | 26 | 0.27% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 1025 | 10.84% |
| Other birds | 24 | 0.25% |
| Reptiles |  |  |
| Rana | 2920 | 30.87% |
| Xenopus |  |  |
| Other Amphibians | 20 | 0.21% |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 9460 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 8850 | 99.55% |
| Animals born in the EU but not at a registered breeder | 40 | 0.45% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 8890 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 4930 | 52.11% |
| Translational and applied research | 322 | 3.4% |
| Regulatory use and Routine production | 1000 | 10.57% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 3208 | 33.91% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 9460 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 1480 | 30.02% |
| Cardiovascular Blood and Lymphatic System | 20 | 0.41% |
| Nervous System | 950 | 19.27% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 242 | 4.91% |
| Musculoskeletal System |  |  |
| Immune System | 1 | 0.02% |
| Urogenital/Reproductive System | 3 | 0.06% |
| Sensory Organs (skin, eyes and ears) | 84 | 1.7% |
| Endocrine System/Metabolism | 284 | 5.76% |
| Multisystemic | 624 | 12.66% |
| Ethology / Animal Behaviour /Animal Biology | 1204 | 24.42% |
| Other basic research | 38 | 0.77% |
| Total | 4930 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders | 100 | 31.06% |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 4 | 1.24% |
| Animal Welfare |  |  |
| Diagnosis of diseases | 218 | 67.7% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 322 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 850 | 85% |
| Other efficacy and tolerance testing |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 150 | 15% |
| Total | 1000 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 700 | 82.35% |
| Pyrogenicity testing | 150 | 17.65% |
| Batch potency testing |  |  |
| Other quality controls |  |  |
| Total | 850 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 50 | 33.33% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Neurotoxicity | 100 | 66.67% |
| Total | 150 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 50 | 100% |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total | 50 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 900 | 90% |
| Legislation on medicinal products for veterinary use and their residues | 100 | 10% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 1000 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 1000 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 1000 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 8890 | 93.97% |
| Yes | 570 | 6.03% |
| Total | 9460 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 815 | 8.62% |
| Mild [up to and including] | 3933 | 41.58% |
| Moderate | 2508 | 26.51% |
| Severe | 2204 | 23.3% |
| Total | 9460 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 9460 | 100% |
| Yes |  |  |
| Total | 9460 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 9460 | 100% |
| Genetically altered without a harmful phenotype |  |  |
| Genetically altered with a harmful phenotype |  |  |
| Total | 9460 | 100.00% |

## Bulgaria: Narrative 2016 - no narrative submitted

No narrative submitted by the Member State

## Bulgaria: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 2015 | 21.19% |
| Rats | 2047 | 21.53% |
| Guinea-Pigs | 1860 | 19.56% |
| Hamsters (Syrian) | 30 | 0.32% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 689 | 7.25% |
| Cats |  |  |
| Dogs | 60 | 0.63% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep | 300 | 3.16% |
| Cattle | 6 | 0.06% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 100 | 1.05% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana | 2400 | 25.24% |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 9507 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 9267 | 100% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 9267 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 6033 | 63.46% |
| Translational and applied research | 691 | 7.27% |
| Regulatory use and Routine production | 180 | 1.89% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 2603 | 27.38% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 9507 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 30 | 0.5% |
| Cardiovascular Blood and Lymphatic System |  |  |
| Nervous System | 1529 | 25.34% |
| Respiratory System | 60 | 0.99% |
| Gastrointestinal System including Liver | 572 | 9.48% |
| Musculoskeletal System | 5 | 0.08% |
| Immune System | 2936 | 48.67% |
| Urogenital/Reproductive System | 40 | 0.66% |
| Sensory Organs (skin, eyes and ears) | 10 | 0.17% |
| Endocrine System/Metabolism | 270 | 4.48% |
| Multisystemic | 563 | 9.33% |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research | 18 | 0.3% |
| Total | 6033 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver | 331 | 47.9% |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders | 30 | 4.34% |
| Other Human Disorders | 74 | 10.71% |
| Animal Diseases and Disorders | 256 | 37.05% |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 691 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 130 | 72.22% |
| Other efficacy and tolerance testing |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 50 | 27.78% |
| Total | 180 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 130 | 100% |
| Total | 130 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 50 | 100% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total | 50 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 50 | 100% |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total | 50 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 180 | 100% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 180 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 180 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 180 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 9267 | 97.48% |
| Yes | 240 | 2.52% |
| Total | 9507 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 1474 | 15.5% |
| Mild [up to and including] | 4016 | 42.24% |
| Moderate | 1762 | 18.53% |
| Severe | 2255 | 23.72% |
| Total | 9507 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 9507 | 100% |
| Yes |  |  |
| Total | 9507 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 9507 | 100% |
| Genetically altered without a harmful phenotype |  |  |
| Genetically altered with a harmful phenotype |  |  |
| Total | 9507 | 100.00% |

## Bulgaria: Narrative 2017 - no narrative submitted

No narrative submitted by the Member State

## Bulgaria: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 989 | 11.39% |
| Rats | 1892 | 21.79% |
| Guinea-Pigs | 1841 | 21.21% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 568 | 6.54% |
| Cats | 30 | 0.35% |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 20 | 0.23% |
| Goats |  |  |
| Sheep | 340 | 3.92% |
| Cattle | 15 | 0.17% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 680 | 7.83% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana | 2306 | 26.56% |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 8681 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| 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% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 8681 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 2246 | 25.87% |
| Translational and applied research | 19 | 0.22% |
| Regulatory use and Routine production | 4126 | 47.53% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 2290 | 26.38% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 8681 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology |  |  |
| Cardiovascular Blood and Lymphatic System |  |  |
| Nervous System | 1651 | 73.51% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 11 | 0.49% |
| Musculoskeletal System | 74 | 3.29% |
| Immune System | 42 | 1.87% |
| Urogenital/Reproductive System | 45 | 2% |
| Sensory Organs (skin, eyes and ears) |  |  |
| 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

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders | 19 | 100% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 19 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 2843 | 68.9% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 238 | 5.77% |
| Routine production | 1045 | 25.33% |
| Total | 4126 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 2843 | 100% |
| Batch potency testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total | 2843 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 38 | 15.97% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Pharmaco-dynamics (incl safety pharmacology) | 150 | 63.03% |
| Ecotoxicity | 50 | 21.01% |
| Total | 238 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 38 | 100% |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total | 38 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity | 50 | 100% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 50 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 1045 | 100% |
| Total | 1045 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 3081 | 74.67% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 1045 | 25.33% |
| Total | 4126 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 4126 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 4126 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 8681 | 100% |
| Yes |  |  |
| Total | 8681 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery |  |  |
| Mild [up to and including] | 4547 | 52.38% |
| Moderate | 3869 | 44.57% |
| Severe | 265 | 3.05% |
| Total | 8681 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 8681 | 100% |
| Yes |  |  |
| Total | 8681 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 8681 | 100% |
| Genetically altered without a harmful phenotype |  |  |
| Genetically altered with a harmful phenotype |  |  |
| Total | 8681 | 100.00% |

# Croatia

## Croatia: Narrative 2015

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

There is an overall decrease in the total number of uses but increase in the use of not genetically altered animals, increase of uses in basic research and decrease in uses for regulatory and routine production. The number of uses for higher education or training for the acquisition, maintenance or improvement of vocational skills is less in number even though it is higher in percentage. There is a significant decrease in testing by legislation and regulatory use and routine production but slightly increase in basic research.

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

There is decrease in 2015 in:

- uses (7,53% (1958)) in 2015 when we compare data from 2015 with the data from 2014:

-Testing by legislation – decrease in total – 45,99% (3899)

- Legislation on medicinal products for human use – 52,73% (1760)

- Food legislation including food contact material – from 32,87 % in 2014 to 8,40% in 2015

- Regulatory use and production – decrease in total 45,99 % (3899):

- Quality control (incl. batch safety and potency testing) – 60,67% (1876)

- Toxicity and other safety testing including pharmacology – 2091 uses less

- Other quality controls uses (they are specified as a use for Registration purpose (use of  
 European viper venom antiserum, Equine on dogs), as a method of validation and use  
 of cock RBCs) in number of uses and also in percentage in 2015 – 33,89% (1993)

There is increase in 2015 in:

- Regulatory use and Routine production:

– Routine production - 68 uses in 2015 (in 2014 such uses were not reported)

* Toxicity and other safety testing including pharmacology:
  + Repeated dose toxicity – 80 uses (in 2014 such uses were not reported)

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Severity of procedures** | **2014** | | **2015** | |
| **number** | **%** | **number** | **%** |
| Non-recovery | 6543 | 25,17 | 3714 | 16,13 |
| Mild (up to and including) | 13 915 | 53,52 | 9 273 | 40,26 |
| Moderate | 4 551 | 17,51 | 7 994 | 34,71 |
| Severe | 989 | 3,80 | 2 051 | 8,91 |
| Total number | 25 998 | 100 | 23 032 | 100 |

In 2015 (when we compare with 2014) there is:

* an increase of Non-recovery procedures in Basic research but in total it is decrease of Non-recovery procedures (in 2014 it was reported 2659 uses in Basic research, 3445 in Regulatory use and Routine production, 359 in education and 60 in Translation and applied research and in 2015 it was reported 3236 uses in Basic research, nothing in Regulatory use and Routine production, 361 in education and 117 in Translation and applied research)
* an decrease of mild procedures in total
* an increase of moderate procedures in Basic research mainly and in total and
* an increase of severe procedures in Regulatory use and Routine production (in 2014 it was reported 903 uses in Basic research, nothing in Regulatory use and Routine production, 78 in Translation and applied research and 8 in education and in 2015 it was reported 908 uses in Basic research, 1078 in Regulatory use and Routine production and 67 in Translation and applied research)

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

* 22 October 2015, 2nd Workshop of the Croatian Society for Laboratory Animal Science, international participation, Implementation of 3R principles, Zagreb, Croatia - for users, breeders, suppliers
* 10th October 2015, 2nd Symposium of Croatian Society for the Science of Laboratory Animals 'Experimental Animals in Scientific Research", Zagreb, Croatia - for users, breeders, suppliers
* 25th March 2015, Scientific Forum, Application and evaluation of projects and experiments using animal models for scientific purposes, Zagreb - for users, breeders, suppliers

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

See point 2.

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

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

## Croatia: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 16197 | 70.32% |
| Rats | 5374 | 23.33% |
| Guinea-Pigs | 264 | 1.15% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 472 | 2.05% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 26 | 0.11% |
| Pigs | 1 | 0% |
| Goats |  |  |
| Sheep | 44 | 0.19% |
| Cattle | 28 | 0.12% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 626 | 2.72% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 23032 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 22347 | 97.65% |
| Animals born in the EU but not at a registered breeder | 538 | 2.35% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 22885 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 18073 | 78.47% |
| Translational and applied research | 421 | 1.83% |
| Regulatory use and Routine production | 3321 | 14.42% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1217 | 5.28% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 23032 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 447 | 2.47% |
| Cardiovascular Blood and Lymphatic System | 412 | 2.28% |
| Nervous System | 1619 | 8.96% |
| Respiratory System | 4426 | 24.49% |
| Gastrointestinal System including Liver | 565 | 3.13% |
| Musculoskeletal System | 217 | 1.2% |
| Immune System | 4177 | 23.11% |
| Urogenital/Reproductive System | 424 | 2.35% |
| Sensory Organs (skin, eyes and ears) | 431 | 2.38% |
| Endocrine System/Metabolism | 873 | 4.83% |
| Multisystemic | 2223 | 12.3% |
| Ethology / Animal Behaviour /Animal Biology | 28 | 0.15% |
| Other basic research | 2231 | 12.34% |
| Total | 18073 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders | 92 | 21.85% |
| Human Nervous and Mental Disorders | 108 | 25.65% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 185 | 43.94% |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 1 | 0.24% |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases | 35 | 8.31% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 421 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 2894 | 87.14% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 359 | 10.81% |
| Routine production | 68 | 2.05% |
| Total | 3321 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 569 | 19.66% |
| Pyrogenicity testing | 63 | 2.18% |
| Batch potency testing | 1236 | 42.71% |
| Other quality controls | 1026 | 35.45% |
| Total | 2894 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 80 | 22.28% |
| Safety testing in food and feed area | 279 | 77.72% |
| Total | 359 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 80 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 80 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 68 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 68 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 1964 | 59.14% |
| Legislation on medicinal products for veterinary use and their residues | 1078 | 32.46% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 279 | 8.4% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 3321 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 3321 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 3321 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 22885 | 99.36% |
| Yes | 147 | 0.64% |
| Total | 23032 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 3714 | 16.13% |
| Mild [up to and including] | 9273 | 40.26% |
| Moderate | 7994 | 34.71% |
| Severe | 2051 | 8.91% |
| Total | 23032 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 23032 | 100% |
| Yes |  |  |
| Total | 23032 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 21756 | 94.46% |
| Genetically altered without a harmful phenotype | 1143 | 4.96% |
| Genetically altered with a harmful phenotype | 133 | 0.58% |
| Total | 23032 | 100.00% |

## Croatia: Narrative 2016

This report shows statistical data on the number of animals used for scientific purposes during the year 2016. Report was prepared in accordance with the provisions of Article 54 of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes and Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

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

Data for 2016, in comparison with data from 2014 and 2015:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Purpose** | **2016** | | **2015** | | **2014** | |
| **number** | **%** | **number** | **%** | **number** | **%** |
| Total number of animals used for scientific purposes | 21,901 | 100 | 23,032 | 100 | 25,998 | 100 |
| Basic research | 19,183 | 87.59 | 18,073 | 78.47 | 15,024 | 57.79 |
| Testing by legislation | 988 | 4.51 | 3,321 | 14.42 | 7,220 | 27.77 |
| Number of genetically altered animals with a harmful phenotype | 129 | 0.59 | 133 | 0.58 | 3,930 | 15.12 |

Compared to the data for 2014 and 2015, the data for 2016 shows:

* an overall decrease in the total number of animals used for scientific purposes
* an increase in number of animals used for basic research and
* a decrease in number of genetically altered animals with a harmful phenotype used for scientific purposes.

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

When data from 2016 are compared with data from 2015 and 2014, the following is apparent:

* a significant decrease in number of animals used for regulatory use and routine production
* a significant decrease in number of animals used for testing by legislation
* a decrease in number of animals used in non-recovery and mild procedures and significant decrease in number of animals used in severe procedures while the number of animals used in moderate procedures is significantly higher.
* a significant decrease in number of animals used for regulatory use and routine production (Quality control including batch safety and potency testing).

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

**Compared to the data for 2014 and 2015, the data for 2016 shows:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Severity of procedures** | **2016** | | **2015** | | **2014** | |
| **number** | **%** | **number** | **%** | **number** | **%** |
| Non-recovery | 3,220 | 14.70 | 3,714 | 16.13 | 6,543 | 25.17 |
| Mild (up to and including) | 6,875 | 31.31 | 9,273 | 40.26 | 13,915 | 53.52 |
| Moderate | 11,394 | 52.03 | 7,994 | 34.71 | 4,551 | 17.51 |
| Severe | 430 | 1.96 | 2,051 | 8.91 | 989 | 3.80 |
| Total number | 21,901 | 100 | 23,032 | 100 | 25,998 | 100 |

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

* 26 – 29th October 2016, Implementation of legislation on the protection of animals used for scientific purposes, Croatian Veterinary Days 2016, Croatia, Scientific – Proffesional conference with International participation – for veterinary inspectors
* 24th October 2016, Workshop “Best practice and alternatives to animal experiments in education and training”, Co-organisers Ministry of Agriculture, Animal Friends Croatia and InterNICHE, Zagreb – for users, breeders, suppliers
* 4th October 2016, Training “Implementation of legislation on the protection of animals in experiments”, Medicin School of the University of Rijeka, Croatia - for users, breeders, suppliers
* 3 May 2016, Presentation on education and training in implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes, Zagreb - for users, breeders, suppliers
* [Workshop “Animal Experiment Design”](http://www.crolasa.com/en/dizajn2017/) organised by *Croatian Laboratory Animal Science Association (CroLASA)*.

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

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

## Croatia: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 14976 | 68.38% |
| Rats | 5762 | 26.31% |
| Guinea-Pigs | 71 | 0.32% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 704 | 3.21% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 27 | 0.12% |
| Pigs | 2 | 0.01% |
| Goats |  |  |
| Sheep | 49 | 0.22% |
| Cattle | 50 | 0.23% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 260 | 1.19% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 21901 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 21701 | 99.59% |
| Animals born in the EU but not at a registered breeder | 89 | 0.41% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 21790 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 19183 | 87.59% |
| Translational and applied research | 456 | 2.08% |
| Regulatory use and Routine production | 988 | 4.51% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1203 | 5.49% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 71 | 0.32% |
| Total | 21901 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 708 | 3.69% |
| Cardiovascular Blood and Lymphatic System | 510 | 2.66% |
| Nervous System | 1613 | 8.41% |
| Respiratory System | 4564 | 23.79% |
| Gastrointestinal System including Liver | 663 | 3.46% |
| Musculoskeletal System | 122 | 0.64% |
| Immune System | 3861 | 20.13% |
| Urogenital/Reproductive System | 146 | 0.76% |
| Sensory Organs (skin, eyes and ears) | 1652 | 8.61% |
| Endocrine System/Metabolism | 397 | 2.07% |
| Multisystemic | 2673 | 13.93% |
| Ethology / Animal Behaviour /Animal Biology | 88 | 0.46% |
| Other basic research | 2186 | 11.4% |
| Total | 19183 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 70 | 15.35% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders | 119 | 26.1% |
| Human Nervous and Mental Disorders | 60 | 13.16% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 37 | 8.11% |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders | 120 | 26.32% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 50 | 10.96% |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 456 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 831 | 84.11% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 98 | 9.92% |
| Routine production | 59 | 5.97% |
| Total | 988 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 210 | 25.27% |
| Pyrogenicity testing | 67 | 8.06% |
| Batch potency testing | 194 | 23.35% |
| Other quality controls | 360 | 43.32% |
| Total | 831 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 88 | 89.8% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 4 | 4.08% |
| Kinetics | 6 | 6.12% |
| Total | 98 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 88 | 100% |
| Total | 88 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 4 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 4 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 59 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 59 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 618 | 62.55% |
| Legislation on medicinal products for veterinary use and their residues | 364 | 36.84% |
| Medical devices legislation | 6 | 0.61% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 988 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 988 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 988 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 21790 | 99.49% |
| Yes | 111 | 0.51% |
| Total | 21901 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 3220 | 14.7% |
| Mild [up to and including] | 6857 | 31.31% |
| Moderate | 11394 | 52.03% |
| Severe | 430 | 1.96% |
| Total | 21901 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 21901 | 100% |
| Yes |  |  |
| Total | 21901 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 19422 | 88.68% |
| Genetically altered without a harmful phenotype | 2350 | 10.73% |
| Genetically altered with a harmful phenotype | 129 | 0.59% |
| Total | 21901 | 100.00% |

## Croatia: Narrative 2017

This report shows statistical data on the number of animals used for scientific purposes during the year 2017. Report was prepared in accordance with the provisions of Article 54 of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes and Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

1. **General information on any changes in trends observed since the previous reporting periods.**
2. Animal Species used for scientific procedures

Data for 2017, 2016, 2015 and 2014:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Animal Species** | **2017** | | **2016** | | **2015** | | **2014** | |
| **number** | **%** | **number** | **%** | **number** | **%** | **number** | **%** |
| Mice | 19,806 | 69.41 | 14,976 | 68.38 | 16,197 | 70.32 | 19,427 | 74.72 |
| Rats | 7,700 | 26.99 | 5,762 | 26.31 | 5,374 | 23.33 | 4,962 | 19.09 |
| Guinea Pigs | 21 | 0.07 | 71 | 0.32 | 264 | 1.15 | 488 | 1.88 |
| Rabbits | 426 | 1,49 | 704 | 3.21 | 472 | 2.05 | 331 | 1.27 |
| Horses, donkeys and cross-breeds | 25 | 0.09 | 27 | 0.12 | 26 | 0.11 | 0 | 0 |
| Pigs | 2 | 0.01 | 2 | 0.01 | 1 | 0.00 | 0 | 0 |
| Sheep | 39 | 0.14 | 49 | 0.22 | 44 | 0.19 | 18 | 0.07 |
| Cattle | 30 | 0.11 | 50 | 0.23 | 28 | 0.12 | 0 | 0 |
| Domestic fowl | 255 | 0.89 | 260 | 1.19 | 626 | 2.72 | 772 | 2.97 |
| Zebra fish | 230 | 0.81 | 0 | 0 | 0 | 0 | 0 | 0 |
| SUMMARY | 28,534 | 100 | 21,901 | 100 | 23,032 | 100 | 25,998 | 100 |

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

* an overall decrease in the total number of animals used for scientific purposes and most in mice and rats
* Zebra fish as new animal model has been reported

1. Information on any changes in trends in Purpose

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Purpose** | **2017** | | **2016** | | **2015** | | **2014** | |
| **number** | **%** | **number** | **%** | **number** | **%** | **number** | **%** |
| Total number of animals used for scientific purposes | 28,534 | 100 | 21,901 | 100 | 23,032 | 100 | 25,998 | 100 |
| Basic research | 22,067 | 77.36 | 19,183 | 87.59 | 18,073 | 78.47 | 15,024 | 57.79 |
| Translational and applied research | 2,761 | 9,68 | 456 | 2,08 | 421 | 1.83 | 671 | 2.58 |
| Regulatory use and routine production | 2,182 | 7.65 | 988 | 4.51 | 3,321 | 14.42 | 7,220 | 27.77 |
| Higher education or training for acquisition, maintenance or improvement of vocational skills | 1,428 | 5,01 | 1,203 | 5,49 | 1,217 | 5.28 | 0 | 0 |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 96 | 0,34 | 71 | 0,32 | 0 | 0 | 0 | 0 |

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

* an increase in the total number of animals used for basic and translational/applied research and regulatory use and routine production
* in 2017 and 2016 the data for maintenance of colonies of established genetically altered animals, not used in other procedures have been reported.

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

When data from 2017 are compared with the data from 2016, 2015 and 2014, the following is apparent:

* a significant increase in the total number of animals used for translational/applied research and regulatory use and routine production
* an overall decrease in the total number of rabbits and domestic fowl used for scientific purposes
* increase of number of animals not used for creation of new GL
* for the first time use of animals for use for creation of new GL reported
* increase of number of not genetically altered animals and genetically altered animals without a harmful phenotype
* decrease of number of animals genetically altered with a harmful phenotype
* no animals in pyrogenicity testing are reported

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

Compared to the data for 2014, 2015 and 2016, the data for 2017 shows:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Severity of procedures** | **2017** | | **2016** | | **2015** | | **2014** | |
| **number** | **%** | **number** | **%** | **number** | **%** | **number** | **%** |
| Non-recovery | 3,005 | 10.53 | 3,220 | 14.70 | 3,714 | 16.13 | 6,543 | 25.17 |
| Mild (up to and including) | 8,338 | 29.22 | 6,875 | 31.31 | 9,273 | 40.26 | 13,915 | 53.52 |
| Moderate | 11,593 | 40.63 | 11,394 | 52.03 | 7,994 | 34.71 | 4,551 | 17.51 |
| Severe | 5,598 | 19.62 | 430 | 1.96 | 2,051 | 8.91 | 989 | 3.80 |
| Total number | 28,534 | 100 | 21,901 | 100 | 23,032 | 100 | 25,998 | 100 |

* an increase in number of animals used in mild and severe procedures but in percentage there is a decrease in all categories except in “severe” where the significant increase is reported

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

* 2nd [Workshop “Animal Experiment Design”](http://www.crolasa.com/en/dizajn2017/) organised by *Croatian Laboratory Animal Science Association (CroLASA), 19-20 October 2017*
* Workshop "How to submit an experiment on animals for approval", 2017

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

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

## Croatia: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 19806 | 69.41% |
| Rats | 7700 | 26.99% |
| Guinea-Pigs | 21 | 0.07% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 426 | 1.49% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 25 | 0.09% |
| Pigs | 2 | 0.01% |
| Goats |  |  |
| Sheep | 39 | 0.14% |
| Cattle | 30 | 0.11% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 255 | 0.89% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 230 | 0.81% |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 28534 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 28292 | 99.51% |
| Animals born in the EU but not at a registered breeder | 60 | 0.21% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 79 | 0.28% |
| Total | 28431 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 22067 | 77.34% |
| Translational and applied research | 2761 | 9.68% |
| Regulatory use and Routine production | 2182 | 7.65% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1428 | 5% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 96 | 0.34% |
| Total | 28534 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| 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

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 230 | 8.33% |
| Human Infectious Disorders | 1394 | 50.49% |
| Human Cardiovascular Disorders | 510 | 18.47% |
| Human Nervous and Mental Disorders | 214 | 7.75% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 28 | 1.01% |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders | 60 | 2.17% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 30 | 1.09% |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 295 | 10.68% |
| Total | 2761 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 1585 | 72.64% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 556 | 25.48% |
| Routine production | 41 | 1.88% |
| Total | 2182 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 262 | 16.53% |
| Pyrogenicity testing |  |  |
| Batch potency testing | 128 | 8.08% |
| Other quality controls | 1195 | 75.39% |
| Total | 1585 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 556 | 100% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total | 556 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 556 | 100% |
| Total | 556 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 41 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 41 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 1799 | 82.45% |
| Legislation on medicinal products for veterinary use and their residues | 383 | 17.55% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 2182 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 2182 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 2182 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 28431 | 99.64% |
| Yes | 103 | 0.36% |
| Total | 28534 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 3005 | 10.53% |
| Mild [up to and including] | 8338 | 29.22% |
| Moderate | 11593 | 40.63% |
| Severe | 5598 | 19.62% |
| Total | 28534 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 28304 | 99.19% |
| Yes | 230 | 0.81% |
| Total | 28534 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 26027 | 91.21% |
| Genetically altered without a harmful phenotype | 2452 | 8.59% |
| Genetically altered with a harmful phenotype | 55 | 0.19% |
| Total | 28534 | 100.00% |

# Cyprus

## Cyprus: Narrative 2015

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

-

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

There was a significant increase in the use of animals in 2015 (almost doubled) due to the improvement of the economic situation in Cyprus that resulted in increased funds for research.

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

-

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

-

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

-

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

-

## Cyprus: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1141 | 100% |
| Rats |  |  |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 1141 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 1141 | 100% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 1141 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 685 | 60.04% |
| Translational and applied research | 456 | 39.96% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills |  |  |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 1141 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 126 | 18.39% |
| Cardiovascular Blood and Lymphatic System |  |  |
| Nervous System | 476 | 69.49% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System | 83 | 12.12% |
| Immune System |  |  |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 685 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 215 | 47.15% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders | 241 | 52.85% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 456 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 1141 | 100% |
| Yes |  |  |
| Total | 1141 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 110 | 9.64% |
| Mild [up to and including] | 700 | 61.35% |
| Moderate | 331 | 29.01% |
| Severe |  |  |
| Total | 1141 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 1141 | 100% |
| Yes |  |  |
| Total | 1141 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 607 | 53.2% |
| Genetically altered without a harmful phenotype | 434 | 38.04% |
| Genetically altered with a harmful phenotype | 100 | 8.76% |
| Total | 1141 | 100.00% |

## Cyprus: Narrative 2016

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

-

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

There was a slight expected increase in the number of animal use in 2016 due to the further improvement of the economic situation in Cyprus.

-

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

-

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

-

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

-

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

-

## Cyprus: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1448 | 100% |
| Rats |  |  |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 1448 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 1448 | 100% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 1448 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 927 | 64.02% |
| Translational and applied research | 521 | 35.98% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills |  |  |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 1448 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 108 | 11.65% |
| Cardiovascular Blood and Lymphatic System |  |  |
| Nervous System | 350 | 37.76% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System | 250 | 26.97% |
| Immune System |  |  |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) | 180 | 19.42% |
| Endocrine System/Metabolism | 39 | 4.21% |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 927 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 404 | 77.54% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders | 117 | 22.46% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 521 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 1448 | 100% |
| Yes |  |  |
| Total | 1448 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery |  |  |
| Mild [up to and including] | 1244 | 85.91% |
| Moderate | 204 | 14.09% |
| Severe |  |  |
| Total | 1448 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 1448 | 100% |
| Yes |  |  |
| Total | 1448 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 789 | 54.49% |
| Genetically altered without a harmful phenotype | 659 | 45.51% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 1448 | 100.00% |

## Cyprus: Narrative 2017

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

-

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

In general there were no significant changes in the numbers of animals used since the previous reporting periods*.*

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

-

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

-

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

-

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

-

## Cyprus: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1209 | 100% |
| Rats |  |  |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 1209 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 1209 | 100% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 1209 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 839 | 69.4% |
| Translational and applied research | 370 | 30.6% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills |  |  |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 1209 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 129 | 15.38% |
| Cardiovascular Blood and Lymphatic System | 17 | 2.03% |
| Nervous System | 368 | 43.86% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System | 275 | 32.78% |
| Immune System |  |  |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) | 50 | 5.96% |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 839 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 370 | 100% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 370 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 1209 | 100% |
| Yes |  |  |
| Total | 1209 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery |  |  |
| Mild [up to and including] | 1197 | 99.01% |
| Moderate | 12 | 0.99% |
| Severe |  |  |
| Total | 1209 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 1209 | 100% |
| Yes |  |  |
| Total | 1209 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 623 | 51.53% |
| Genetically altered without a harmful phenotype | 586 | 48.47% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 1209 | 100.00% |

# Czechia

## Czechia: Narrative 2015

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

The statistical data has been collected since 1993 in the Czech Republic. In 2015 statistical data there are no changes in trends observed since the previous reporting periods.

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

There is no significant increase or decrease in use animals in any of the specific areas.

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

There are no changes in actual severity.

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

There are no impacts of principle of 3Rs on 2015 statistical data. We are expecting this impact in subsequent years.

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

Categories “other” has been used where is appropriate. When “other” has been used, “specify other” has been always fulfilled.

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

Classification “severe” is not exceeded in 2015 statistical data.

## Czechia: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 73415 | 31.94% |
| Rats | 24200 | 10.53% |
| Guinea-Pigs | 1008 | 0.44% |
| Hamsters (Syrian) | 48 | 0.02% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 18 | 0.01% |
| Other Rodents | 988 | 0.43% |
| Rabbits | 4840 | 2.11% |
| Cats | 341 | 0.15% |
| Dogs | 1135 | 0.49% |
| Ferrets | 154 | 0.07% |
| Other carnivores | 10 | 0% |
| Horses, donkeys and cross-breeds | 113 | 0.05% |
| Pigs | 2118 | 0.92% |
| Goats | 318 | 0.14% |
| Sheep | 1468 | 0.64% |
| Cattle | 1941 | 0.84% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey | 6 | 0% |
| Rhesus monkey | 51 | 0.02% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 36 | 0.02% |
| Domestic fowl | 22962 | 9.99% |
| Other birds | 3003 | 1.31% |
| Reptiles | 453 | 0.2% |
| Rana | 100 | 0.04% |
| Xenopus | 135 | 0.06% |
| Other Amphibians | 675 | 0.29% |
| Zebra fish | 2729 | 1.19% |
| Other Fish | 87604 | 38.11% |
| Cephalopods |  |  |
| Total | 229869 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 197689 | 87.69% |
| Animals born in the EU but not at a registered breeder | 27419 | 12.16% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 334 | 0.15% |
| Total | 225442 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 85456 | 37.18% |
| Translational and applied research | 26835 | 11.67% |
| Regulatory use and Routine production | 61272 | 26.66% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 40441 | 17.59% |
| Preservation of species | 176 | 0.08% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 15673 | 6.82% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 16 | 0.01% |
| Total | 229869 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 12911 | 15.11% |
| Cardiovascular Blood and Lymphatic System | 7180 | 8.4% |
| Nervous System | 13447 | 15.74% |
| Respiratory System | 314 | 0.37% |
| Gastrointestinal System including Liver | 1862 | 2.18% |
| Musculoskeletal System | 509 | 0.6% |
| Immune System | 11136 | 13.03% |
| Urogenital/Reproductive System | 8142 | 9.53% |
| Sensory Organs (skin, eyes and ears) | 549 | 0.64% |
| Endocrine System/Metabolism | 3889 | 4.55% |
| Multisystemic | 5835 | 6.83% |
| Ethology / Animal Behaviour /Animal Biology | 8909 | 10.43% |
| Other basic research | 10773 | 12.61% |
| Total | 85456 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 1631 | 6.08% |
| Human Infectious Disorders | 541 | 2.02% |
| Human Cardiovascular Disorders | 426 | 1.59% |
| Human Nervous and Mental Disorders | 803 | 2.99% |
| Human Respiratory Disorders | 12 | 0.04% |
| Human Gastrointestinal Disorders including Liver | 45 | 0.17% |
| Human Musculoskeletal Disorders | 79 | 0.29% |
| Human Immune Disorders | 219 | 0.82% |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 30 | 0.11% |
| Human Endocrine/Metabolism Disorders | 1183 | 4.41% |
| Other Human Disorders | 60 | 0.22% |
| Animal Diseases and Disorders | 7189 | 26.79% |
| Animal Welfare | 7541 | 28.1% |
| Diagnosis of diseases | 6913 | 25.76% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 163 | 0.61% |
| Total | 26835 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 11354 | 18.53% |
| Other efficacy and tolerance testing | 219 | 0.36% |
| Toxicity and other safety testing including pharmacology | 29613 | 48.33% |
| Routine production | 20086 | 32.78% |
| Total | 61272 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 1742 | 15.34% |
| Pyrogenicity testing | 72 | 0.63% |
| Batch potency testing | 9354 | 82.39% |
| Other quality controls | 186 | 1.64% |
| Total | 11354 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 3091 | 10.44% |
| Skin irritation/corrosion | 12 | 0.04% |
| Skin sensitisation | 568 | 1.92% |
| Eye irritation/corrosion | 9 | 0.03% |
| Repeated dose toxicity | 1532 | 5.17% |
| Carcinogenicity |  |  |
| Neurotoxicity |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Target animal safety |  |  |
| Genotoxicity | 109 | 0.37% |
| Reproductive toxicity | 1256 | 4.24% |
| Developmental toxicity | 658 | 2.22% |
| Kinetics | 554 | 1.87% |
| Ecotoxicity | 21394 | 72.25% |
| Safety testing in food and feed area | 72 | 0.24% |
| Other toxicity/safety testing | 358 | 1.21% |
| Total | 29613 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 1650 | 53.38% |
| Other lethal methods | 1435 | 46.43% |
| Non lethal methods | 6 | 0.19% |
| Total | 3091 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 782 | 51.04% |
| 29 - 90 days | 540 | 35.25% |
| > 90 days | 210 | 13.71% |
| Total | 1532 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 19257 | 90.01% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity | 2137 | 9.99% |
| Total | 21394 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 899 | 4.48% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 19187 | 95.52% |
| Total | 20086 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 3476 | 5.67% |
| Legislation on medicinal products for veterinary use and their residues | 29178 | 47.62% |
| Medical devices legislation | 1320 | 2.15% |
| Industrial chemicals legislation | 2685 | 4.38% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 817 | 1.33% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 12 | 0.02% |
| Cosmetics legislation |  |  |
| Other legislation | 23784 | 38.82% |
| Total | 61272 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 49869 | 81.39% |
| Legislation satisfying national requirements only [within EU] | 11403 | 18.61% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 61272 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 225442 | 98.07% |
| Yes | 4427 | 1.93% |
| Total | 229869 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 21573 | 9.38% |
| Mild [up to and including] | 124277 | 54.06% |
| Moderate | 60578 | 26.35% |
| Severe | 23441 | 10.2% |
| Total | 229869 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 221507 | 96.36% |
| Yes | 8362 | 3.64% |
| Total | 229869 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 204049 | 88.77% |
| Genetically altered without a harmful phenotype | 24009 | 10.44% |
| Genetically altered with a harmful phenotype | 1811 | 0.79% |
| Total | 229869 | 100.00% |

## Czechia: Narrative 2016

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

The statistical data has been collected since 1993 in the Czech Republic. In 2016 statistical data there are no changes in trends observed since the previous reporting periods.

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

There is no significant increase or decrease in use animals in any of the specific areas.

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

There are no changes in actual severity.

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

There are no impacts of principle of 3Rs on 2016 statistical data. We are expecting this impact in subsequent years.

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

Categories “other” has been used where is appropriate. When “other” has been used, “specify other” has been always fulfilled.

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

Classification “severe” is not exceeded in 2016 statistical data.

## Czechia: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 78249 | 32.92% |
| Rats | 30323 | 12.76% |
| Guinea-Pigs | 1202 | 0.51% |
| Hamsters (Syrian) | 82 | 0.03% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 30 | 0.01% |
| Other Rodents | 1122 | 0.47% |
| Rabbits | 6834 | 2.88% |
| Cats | 240 | 0.1% |
| Dogs | 797 | 0.34% |
| Ferrets | 42 | 0.02% |
| Other carnivores | 53 | 0.02% |
| Horses, donkeys and cross-breeds | 155 | 0.07% |
| Pigs | 2173 | 0.91% |
| Goats | 48 | 0.02% |
| Sheep | 1032 | 0.43% |
| Cattle | 2978 | 1.25% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey | 9 | 0% |
| Rhesus monkey | 26 | 0.01% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 37 | 0.02% |
| Domestic fowl | 27261 | 11.47% |
| Other birds | 3124 | 1.31% |
| Reptiles | 915 | 0.39% |
| Rana |  |  |
| Xenopus | 58 | 0.02% |
| Other Amphibians | 819 | 0.34% |
| Zebra fish | 4495 | 1.89% |
| Other Fish | 75558 | 31.79% |
| Cephalopods |  |  |
| Total | 237662 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 212176 | 90.81% |
| Animals born in the EU but not at a registered breeder | 21429 | 9.17% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 51 | 0.02% |
| Total | 233656 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 87751 | 36.92% |
| Translational and applied research | 25941 | 10.92% |
| Regulatory use and Routine production | 74739 | 31.45% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 32752 | 13.78% |
| Preservation of species | 228 | 0.1% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 16143 | 6.79% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 108 | 0.05% |
| Total | 237662 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 11267 | 12.84% |
| Cardiovascular Blood and Lymphatic System | 12055 | 13.74% |
| Nervous System | 12066 | 13.75% |
| Respiratory System | 1511 | 1.72% |
| Gastrointestinal System including Liver | 2348 | 2.68% |
| Musculoskeletal System | 46 | 0.05% |
| Immune System | 7811 | 8.9% |
| Urogenital/Reproductive System | 9041 | 10.3% |
| Sensory Organs (skin, eyes and ears) | 750 | 0.85% |
| Endocrine System/Metabolism | 4128 | 4.7% |
| Multisystemic | 4223 | 4.81% |
| Ethology / Animal Behaviour /Animal Biology | 7278 | 8.29% |
| Other basic research | 15227 | 17.35% |
| Total | 87751 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 3288 | 12.67% |
| Human Infectious Disorders | 905 | 3.49% |
| Human Cardiovascular Disorders | 969 | 3.74% |
| Human Nervous and Mental Disorders | 674 | 2.6% |
| Human Respiratory Disorders | 12 | 0.05% |
| Human Gastrointestinal Disorders including Liver | 137 | 0.53% |
| Human Musculoskeletal Disorders | 93 | 0.36% |
| Human Immune Disorders | 368 | 1.42% |
| Human Urogenital/Reproductive Disorders | 551 | 2.12% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 39 | 0.15% |
| Human Endocrine/Metabolism Disorders | 1191 | 4.59% |
| Other Human Disorders | 107 | 0.41% |
| Animal Diseases and Disorders | 5469 | 21.08% |
| Animal Welfare | 3611 | 13.92% |
| Diagnosis of diseases | 8227 | 31.71% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 300 | 1.16% |
| Total | 25941 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 17569 | 23.51% |
| Other efficacy and tolerance testing | 316 | 0.42% |
| Toxicity and other safety testing including pharmacology | 36408 | 48.71% |
| Routine production | 20446 | 27.36% |
| Total | 74739 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 1574 | 8.96% |
| Pyrogenicity testing | 51 | 0.29% |
| Batch potency testing | 15636 | 89% |
| Other quality controls | 308 | 1.75% |
| Total | 17569 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 14946 | 41.05% |
| Carcinogenicity |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation | 570 | 1.57% |
| Eye irritation/corrosion | 3 | 0.01% |
| Repeated dose toxicity | 958 | 2.63% |
| Reproductive toxicity | 5497 | 15.1% |
| Developmental toxicity | 127 | 0.35% |
| Kinetics | 511 | 1.4% |
| Ecotoxicity | 13552 | 37.22% |
| Safety testing in food and feed area | 40 | 0.11% |
| Target animal safety | 12 | 0.03% |
| Other toxicity/safety testing | 192 | 0.53% |
| Total | 36408 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 12250 | 81.96% |
| Other lethal methods | 2668 | 17.85% |
| Non lethal methods | 28 | 0.19% |
| Total | 14946 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 538 | 56.16% |
| 29 - 90 days | 420 | 43.84% |
| > 90 days |  |  |
| Total | 958 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 12132 | 89.52% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity | 1420 | 10.48% |
| Total | 13552 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 838 | 4.1% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 19608 | 95.9% |
| Total | 20446 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 3069 | 4.11% |
| Legislation on medicinal products for veterinary use and their residues | 35721 | 47.79% |
| Medical devices legislation | 1110 | 1.49% |
| Industrial chemicals legislation | 6746 | 9.03% |
| Plant protection product legislation |  |  |
| Biocides legislation | 5 | 0.01% |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 28088 | 37.58% |
| Total | 74739 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 51716 | 69.2% |
| Legislation satisfying national requirements only [within EU] | 23023 | 30.8% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 74739 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 233656 | 98.31% |
| Yes | 4006 | 1.69% |
| Total | 237662 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 23268 | 9.79% |
| Mild [up to and including] | 87633 | 36.87% |
| Moderate | 77641 | 32.67% |
| Severe | 49120 | 20.67% |
| Total | 237662 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 224531 | 94.47% |
| Yes | 13131 | 5.53% |
| Total | 237662 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 205032 | 86.27% |
| Genetically altered without a harmful phenotype | 30738 | 12.93% |
| Genetically altered with a harmful phenotype | 1892 | 0.8% |
| Total | 237662 | 100.00% |

## Czechia: Narrative 2017

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

The statistical data has been collected since 1993 in the Czech Republic. In the last three years appears trend increasing number of animal used for preservation of species, in year 2017 is the number of these animals more significant than 2 years ago. In 2017 statistical data there are no other changes in trends observed since the previous reporting periods.

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

There is no significant increase or decrease in use animals in any of the specific areas.

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

There are no changes in trends in actual severity.

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

There are no impacts of principle of 3Rs on 2017 statistical data. We are expecting this impact in subsequent years.

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

Categories “other” has been used where is appropriate. When “other” has been used, “specify other” has been always fulfilled.

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

Classification “severe” is not exceeded in 2017 statistical data.

## Czechia: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 82219 | 34.02% |
| Rats | 26967 | 11.16% |
| Guinea-Pigs | 1383 | 0.57% |
| Hamsters (Syrian) | 15 | 0.01% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 46 | 0.02% |
| Other Rodents | 635 | 0.26% |
| Rabbits | 2133 | 0.88% |
| Cats | 132 | 0.05% |
| Dogs | 637 | 0.26% |
| Ferrets | 1 | 0% |
| Other carnivores | 1 | 0% |
| Horses, donkeys and cross-breeds | 105 | 0.04% |
| Pigs | 2447 | 1.01% |
| Goats | 97 | 0.04% |
| Sheep | 918 | 0.38% |
| Cattle | 2734 | 1.13% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 21217 | 8.78% |
| Other birds | 4260 | 1.76% |
| Reptiles | 558 | 0.23% |
| Rana |  |  |
| Xenopus | 50 | 0.02% |
| Other Amphibians | 531 | 0.22% |
| Zebra fish | 19765 | 8.18% |
| Other Fish | 74861 | 30.97% |
| Cephalopods |  |  |
| Total | 241712 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 213502 | 95.63% |
| Animals born in the EU but not at a registered breeder | 9222 | 4.13% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 539 | 0.24% |
| Total | 223263 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 100107 | 41.42% |
| Translational and applied research | 27657 | 11.44% |
| Regulatory use and Routine production | 54133 | 22.4% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 47646 | 19.71% |
| Preservation of species | 6437 | 2.66% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 5732 | 2.37% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 241712 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 8918 | 8.91% |
| Cardiovascular Blood and Lymphatic System | 22979 | 22.95% |
| Nervous System | 9106 | 9.1% |
| Respiratory System | 503 | 0.5% |
| Gastrointestinal System including Liver | 1727 | 1.73% |
| Musculoskeletal System | 484 | 0.48% |
| Immune System | 13127 | 13.11% |
| Urogenital/Reproductive System | 12105 | 12.09% |
| Sensory Organs (skin, eyes and ears) | 525 | 0.52% |
| Endocrine System/Metabolism | 3777 | 3.77% |
| Multisystemic | 6311 | 6.3% |
| Ethology / Animal Behaviour /Animal Biology | 7542 | 7.53% |
| Other basic research | 13003 | 12.99% |
| Total | 100107 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 3761 | 13.6% |
| Human Infectious Disorders | 1309 | 4.73% |
| Human Cardiovascular Disorders | 1308 | 4.73% |
| Human Nervous and Mental Disorders | 2009 | 7.26% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver | 861 | 3.11% |
| 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 | 0.4% |
| Human Endocrine/Metabolism Disorders | 2066 | 7.47% |
| Other Human Disorders | 379 | 1.37% |
| Animal Diseases and Disorders | 3643 | 13.17% |
| Animal Welfare | 3914 | 14.15% |
| Diagnosis of diseases | 7373 | 26.66% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 9 | 0.03% |
| Total | 27657 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 4646 | 18.37% |
| Carcinogenicity |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Phototoxicity |  |  |
| Skin irritation/corrosion |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 994 | 21.39% |
| Other lethal methods | 3652 | 78.61% |
| Non lethal methods |  |  |
| Total | 4646 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of 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 use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 12714 | 88.45% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity | 1660 | 11.55% |
| Total | 14374 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | 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 to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 2682 | 4.95% |
| Legislation on medicinal products for veterinary use and their residues | 27478 | 50.76% |
| Medical devices legislation | 1411 | 2.61% |
| Industrial chemicals legislation | 4345 | 8.03% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 170 | 0.31% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 525 | 0.97% |
| Cosmetics legislation |  |  |
| Other legislation | 17522 | 32.37% |
| Total | 54133 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 44484 | 82.18% |
| Legislation satisfying national requirements only [within EU] | 9649 | 17.82% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 54133 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 223263 | 92.37% |
| Yes | 18449 | 7.63% |
| Total | 241712 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 19114 | 7.91% |
| Mild [up to and including] | 110130 | 45.56% |
| Moderate | 96317 | 39.85% |
| Severe | 16151 | 6.68% |
| Total | 241712 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 216026 | 89.37% |
| Yes | 25686 | 10.63% |
| Total | 241712 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 199255 | 82.43% |
| Genetically altered without a harmful phenotype | 39574 | 16.37% |
| Genetically altered with a harmful phenotype | 2883 | 1.19% |
| Total | 241712 | 100.00% |

# Denmark

## Denmark: Narrative 2015

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

Although the number of animals reported in Denmark has been declining for many years, and the total number for 2014 , reported only about 200.000 animals, the number reported for 2015 has increased to about 242.000 animals. This number is almost identical to the number of animals reported for 2013. However, the number for 2014 cannot be compared to previous years, as the reporting format has been changed. These data for 2015 suggest that the number of animals used for research has stabilized around 240.000 animals.

The number of pigs has increased significantly in 2015. The increase is primarily caused by an increase in research using pigs as animal models for human diseases. Also the number of cats has increased significantly in 2015. This is caused by clinical studies in treatment of type-2 diabetes in cats. The number of fish has also increased significantly in 2015. This is primarily caused by an increase in research in aqua cultures. Furthermore in a small country with a small scientific community, the change of focus in one or a few research groups can have a significant impact on the statistics for the whole country.

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

No major significant changes are visible in the statistics from 2015

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

In general only few experiments with severe strain are licensed. This is reflected in that the actual reported severity is 0.89%. This is a decrease compared to 1.5% reported for 2014.

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

Denmark has established a 3R-center operating from 2014. The centre is funding 3R-research, collection and dissemination information on the 3R´s and establishing initiatives to analyze and implement 3R-strategies. Read more here: <http://en.3rcenter.dk/>

Furthermore the Danish National Committee strongly supports and collaborates with the animal welfare bodies, i.e. yearly meeting for all bodies, hands on exchange of best practice between institutions and companies and best practice guideline. Visit the website: [Danish National Committee](http://3rcenter.dk/om-3r-centeret/udvalget-for-forsoegsdyr-og-alternativer/)

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

As Denmark has a relatively large production of trout, the species is commonly used in research. Hence it would be a good idea with a specific category for trout. Furthermore Denmark also has a large mink industry, and this species too is often used in research. A specific category for mink will also be appreciated.

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

The classification “severe” has not been exceeded in 2015 in Denmark.

## Denmark: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 155141 | 63.64% |
| Rats | 48614 | 19.94% |
| Guinea-Pigs | 2643 | 1.08% |
| Hamsters (Syrian) | 172 | 0.07% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 86 | 0.04% |
| Rabbits | 1665 | 0.68% |
| Cats | 59 | 0.02% |
| Dogs | 157 | 0.06% |
| Ferrets |  |  |
| Other carnivores | 886 | 0.36% |
| Horses, donkeys and cross-breeds | 115 | 0.05% |
| Pigs | 10576 | 4.34% |
| Goats | 11 | 0% |
| Sheep | 47 | 0.02% |
| Cattle | 534 | 0.22% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 38 | 0.02% |
| Domestic fowl | 2407 | 0.99% |
| Other birds | 438 | 0.18% |
| Reptiles | 265 | 0.11% |
| Rana |  |  |
| Xenopus | 64 | 0.03% |
| Other Amphibians | 26 | 0.01% |
| Zebra fish | 2530 | 1.04% |
| Other Fish | 17318 | 7.1% |
| Cephalopods |  |  |
| Total | 243792 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 205674 | 85.32% |
| Animals born in the EU but not at a registered breeder | 27687 | 11.49% |
| Animals born in rest of Europe | 1311 | 0.54% |
| Animals born in rest of world | 6397 | 2.65% |
| Total | 241069 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 88453 | 36.28% |
| Translational and applied research | 123439 | 50.63% |
| Regulatory use and Routine production | 22956 | 9.42% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 2660 | 1.09% |
| Preservation of species | 258 | 0.11% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 6023 | 2.47% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 3 | 0% |
| Total | 243792 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 5382 | 6.08% |
| Cardiovascular Blood and Lymphatic System | 4860 | 5.49% |
| Nervous System | 15725 | 17.78% |
| Respiratory System | 1262 | 1.43% |
| Gastrointestinal System including Liver | 2539 | 2.87% |
| Musculoskeletal System | 2682 | 3.03% |
| Immune System | 29246 | 33.06% |
| Urogenital/Reproductive System | 2623 | 2.97% |
| Sensory Organs (skin, eyes and ears) | 1503 | 1.7% |
| Endocrine System/Metabolism | 12561 | 14.2% |
| Multisystemic | 883 | 1% |
| Ethology / Animal Behaviour /Animal Biology | 4924 | 5.57% |
| Other basic research | 4263 | 4.82% |
| Total | 88453 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 9115 | 7.38% |
| Human Infectious Disorders | 4683 | 3.79% |
| Human Cardiovascular Disorders | 1404 | 1.14% |
| Human Nervous and Mental Disorders | 35568 | 28.81% |
| Human Respiratory Disorders | 75 | 0.06% |
| Human Gastrointestinal Disorders including Liver | 258 | 0.21% |
| Human Musculoskeletal Disorders | 400 | 0.32% |
| Human Immune Disorders | 10037 | 8.13% |
| Human Urogenital/Reproductive Disorders | 66 | 0.05% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 852 | 0.69% |
| Human Endocrine/Metabolism Disorders | 39839 | 32.27% |
| Other Human Disorders | 9137 | 7.4% |
| Animal Diseases and Disorders | 7934 | 6.43% |
| Animal Welfare | 3248 | 2.63% |
| Diagnosis of diseases | 682 | 0.55% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 141 | 0.11% |
| Total | 123439 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 14819 | 64.55% |
| Other efficacy and tolerance testing | 95 | 0.41% |
| Toxicity and other safety testing including pharmacology | 8021 | 34.94% |
| Routine production | 21 | 0.09% |
| Total | 22956 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 3687 | 24.88% |
| Pyrogenicity testing |  |  |
| Batch potency testing | 11105 | 74.94% |
| Other quality controls | 27 | 0.18% |
| Total | 14819 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 786 | 9.8% |
| Skin irritation/corrosion | 12 | 0.15% |
| Skin sensitisation | 138 | 1.72% |
| Eye irritation/corrosion | 6 | 0.07% |
| Repeated dose toxicity | 1755 | 21.88% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Kinetics | 2095 | 26.12% |
| Pharmaco-dynamics (incl safety pharmacology) | 9 | 0.11% |
| Ecotoxicity | 3080 | 38.4% |
| Target animal safety | 120 | 1.5% |
| Other toxicity/safety testing | 20 | 0.25% |
| Total | 8021 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 80 | 10.18% |
| Other lethal methods |  |  |
| Non lethal methods | 706 | 89.82% |
| Total | 786 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 1136 | 64.73% |
| 29 - 90 days | 488 | 27.81% |
| > 90 days | 131 | 7.46% |
| Total | 1755 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity | 3080 | 100% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 3080 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 21 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 21 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 19630 | 85.51% |
| Legislation on medicinal products for veterinary use and their residues | 142 | 0.62% |
| Medical devices legislation | 24 | 0.1% |
| Industrial chemicals legislation | 1360 | 5.92% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 1800 | 7.84% |
| Total | 22956 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 21134 | 92.06% |
| Legislation satisfying national requirements only [within EU] | 1822 | 7.94% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 22956 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 241069 | 98.88% |
| Yes | 2723 | 1.12% |
| Total | 243792 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 21199 | 8.7% |
| Mild [up to and including] | 136701 | 56.07% |
| Moderate | 83727 | 34.34% |
| Severe | 2165 | 0.89% |
| Total | 243792 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 238948 | 98.01% |
| Yes | 4844 | 1.99% |
| Total | 243792 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 204237 | 83.78% |
| Genetically altered without a harmful phenotype | 26191 | 10.74% |
| Genetically altered with a harmful phenotype | 13364 | 5.48% |
| Total | 243792 | 100.00% |

## Denmark: Narrative 2016

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

The overall number at animals used for scientific purposes in Denmark in 2016 is 253.546. In 2015 the same number was 244.411animals. This strengthens a trend, that the number of animals used in Denmark has been relatively stable over the last years.

As usually, mice, rats and fish covers more than 90 % of the animals, but the number of fish has increased a lot, going from 19.848 to 51.659. See 2. for further specification. At the same time, the number of mice and rats has decreased by 10 %.

The percentage of animals used for basic research has increased from 36 % to 41 %. This is due to the fact, that increased number of fish primarily has been used in basic research.

Animals used for regulatory purposes and for routine production have decreased from 9 % to less than   
6 %.

Finally the number of animals experiencing severe suffering has doubled in 2016, still being on a relative low level of 1.78 %.

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

The clearest trend in 2016 was the large increase in the use of fish for research. But almost the whole increase was due to introduction of a new species and a new field of research in the statistics. There is a very strong research community in Denmark concerning breeding eel for human consumption.

Until now it has not been possible to breed eel, which could survive beyond the larvae stadium. However due to scientific breakthroughs, it has recently changed, and the bread eel larvae now develop into fish covered by the directive. This covers a number of 23.935 animals, accounting for almost the whole increase in the use of fish. Procedures also covered by the directive are then performed on the animals, making them part of the statistic.

As this is a very important and economical interesting area, the numbers of eel in research are suspected to rise in the coming years. As this area is considered to be basic research, the increase in eel will affect the ratio.

In regard to the decrease in the numbers of rats and mice, the overall assessment is, that a stronger competition on research grands and stronger financially focus on the universities have made an impact on the number of research project using animals.

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

The number of animals experiencing severe severity has doubled in 2016 from 0,89 % to 1,75 %. The main reason is that two large research groups have had specific new focus on models with the highest severity. As Denmark generally has few animals experiencing severe severity, a new focus from just one or two research groups will affect the numbers dramatically. However the level of severe severity in Denmark is still relatively low.

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

Also in 2016, the Danish 3R-center has worked hard to promote the 3R´s, including funding research. Further information can be found on [www.3rcenter.dk](http://www.3rcenter.dk).

The national committee has also supported the animal welfare bodies, which are working more and more effectively. Yearly meetings, platforms for charring best practise, dissemination of 3R-tools and guidelines are some of the tolls used in 2016. Further information can be found on: <https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The_National_Committee_for_the_Protection_of_Animals_used_for_Scientific_Purposes/Pages/default.aspx>

The Danish Animal Experiments Inspectorate hosts 3 annual mini-symposium for both scientific staff and for animal caretakers, discussing best practise and new models, as well as dissemination information on the legislation and correct statistical reporting.

It is difficult to investigate whether these efforts has a directly impact on the use of animals for research. However the decrease in the numbers of traditional animals as mice and rats will be followed to see, if some of this decrease has been influenced by the 3R initiatives.

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

The use of “other” categories has been used on an acceptable level in 2016.

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

No cases of animal experiencing the severe clarification exceeded was recorded in 2016 in Denmark.

## Denmark: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 169970 | 58.77% |
| Rats | 47575 | 16.45% |
| Guinea-Pigs | 3362 | 1.16% |
| Hamsters (Syrian) | 152 | 0.05% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 4 | 0% |
| Rabbits | 2370 | 0.82% |
| Cats | 18 | 0.01% |
| Dogs | 266 | 0.09% |
| Ferrets | 2 | 0% |
| Other carnivores | 627 | 0.22% |
| Horses, donkeys and cross-breeds | 328 | 0.11% |
| Pigs | 8066 | 2.79% |
| Goats | 6 | 0% |
| Sheep | 37 | 0.01% |
| Cattle | 2077 | 0.72% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 55 | 0.02% |
| Domestic fowl | 1732 | 0.6% |
| Other birds | 373 | 0.13% |
| Reptiles | 220 | 0.08% |
| Rana |  |  |
| Xenopus | 56 | 0.02% |
| Other Amphibians | 30 | 0.01% |
| Zebra fish | 3308 | 1.14% |
| Other Fish | 48591 | 16.8% |
| Cephalopods |  |  |
| Total | 289225 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 236103 | 83.01% |
| Animals born in the EU but not at a registered breeder | 40201 | 14.13% |
| Animals born in rest of Europe | 684 | 0.24% |
| Animals born in rest of world | 7456 | 2.62% |
| Total | 284444 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 104787 | 36.23% |
| Translational and applied research | 153016 | 52.91% |
| Regulatory use and Routine production | 21532 | 7.44% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 2792 | 0.97% |
| Preservation of species | 1491 | 0.52% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 5547 | 1.92% |
| Forensic enquiries | 60 | 0.02% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 289225 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 6312 | 6.02% |
| Cardiovascular Blood and Lymphatic System | 4789 | 4.57% |
| Nervous System | 17706 | 16.9% |
| Respiratory System | 1601 | 1.53% |
| Gastrointestinal System including Liver | 4618 | 4.41% |
| Musculoskeletal System | 2723 | 2.6% |
| Immune System | 19079 | 18.21% |
| Urogenital/Reproductive System | 1538 | 1.47% |
| Sensory Organs (skin, eyes and ears) | 876 | 0.84% |
| Endocrine System/Metabolism | 13964 | 13.33% |
| Multisystemic | 949 | 0.91% |
| Ethology / Animal Behaviour /Animal Biology | 25748 | 24.57% |
| Other basic research | 4884 | 4.66% |
| Total | 104787 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 27113 | 17.72% |
| Human Infectious Disorders | 6632 | 4.33% |
| Human Cardiovascular Disorders | 1786 | 1.17% |
| Human Nervous and Mental Disorders | 34826 | 22.76% |
| Human Respiratory Disorders | 137 | 0.09% |
| Human Gastrointestinal Disorders including Liver | 139 | 0.09% |
| Human Musculoskeletal Disorders | 401 | 0.26% |
| Human Immune Disorders | 7015 | 4.58% |
| Human Urogenital/Reproductive Disorders | 641 | 0.42% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 455 | 0.3% |
| Human Endocrine/Metabolism Disorders | 40930 | 26.75% |
| Other Human Disorders | 9135 | 5.97% |
| Animal Diseases and Disorders | 19732 | 12.9% |
| Animal Welfare | 2524 | 1.65% |
| Diagnosis of diseases | 884 | 0.58% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 666 | 0.44% |
| Total | 153016 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 8833 | 41.02% |
| Other efficacy and tolerance testing | 113 | 0.52% |
| Toxicity and other safety testing including pharmacology | 12586 | 58.45% |
| Routine production |  |  |
| Total | 21532 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 3295 | 37.3% |
| Pyrogenicity testing |  |  |
| Batch potency testing | 5486 | 62.11% |
| Other quality controls | 52 | 0.59% |
| Total | 8833 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 5366 | 42.63% |
| Skin irritation/corrosion | 35 | 0.28% |
| Skin sensitisation | 80 | 0.64% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 1701 | 13.52% |
| Kinetics | 267 | 2.12% |
| Pharmaco-dynamics (incl safety pharmacology) | 609 | 4.84% |
| Ecotoxicity | 4528 | 35.98% |
| Total | 12586 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 5366 | 100% |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total | 5366 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 862 | 50.68% |
| 29 - 90 days | 229 | 13.46% |
| > 90 days | 610 | 35.86% |
| Total | 1701 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity | 3030 | 66.92% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity | 1440 | 31.8% |
| Bioaccumulation | 58 | 1.28% |
| Other ecotoxicity |  |  |
| Total | 4528 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 17000 | 78.95% |
| Legislation on medicinal products for veterinary use and their residues | 4 | 0.02% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation | 2458 | 11.42% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 2070 | 9.61% |
| Total | 21532 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 19398 | 90.09% |
| Legislation satisfying national requirements only [within EU] | 2134 | 9.91% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 21532 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 284444 | 98.35% |
| Yes | 4781 | 1.65% |
| Total | 289225 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 22852 | 7.9% |
| Mild [up to and including] | 181393 | 62.72% |
| Moderate | 80451 | 27.82% |
| Severe | 4529 | 1.57% |
| Total | 289225 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 287229 | 99.31% |
| Yes | 1996 | 0.69% |
| Total | 289225 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 247082 | 85.43% |
| Genetically altered without a harmful phenotype | 28548 | 9.87% |
| Genetically altered with a harmful phenotype | 13595 | 4.7% |
| Total | 289225 | 100.00% |

## Denmark: Narrative 2017

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

The overall number of animals used for scientific purposes in Denmark in 2017 is 236,100. This is a significant decrease since 2016, where the number was 273,224 animals. But the total decrease is covered by the large drop in the number of fish – from 51,899 in 2016 to 17,125 in 2017. Taking this in account, the number of animals used in Denmark has been relatively stable over the last years

As usually, mice, rats and fish covers more than 90 % of the animals. The number of mice and rats has remained stable for several years (202,035 in 2015, 201,973 in 2016 and 201,621 in 2017).

The percentage of animals used for basic research is fallen from 38 % to 35 % reflecting the drop in fish (eel) used for this purpose.

Animals used for regulatory purposes and for routine production continues to be 8 %, confirming the relatively low number of animals used for that purpose in Denmark.

Finally the number of animals experiencing severe suffering has fallen in 2017 to a level of 0.74 %. This is confirming the trend that the percentage of severe suffering is varying around 1 %.

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

The clearest trend in 2017 was the large decrease in the use of fish for research. But as the large increase in 2016 was due to introduction of a new field of research in eel in the statistics, the large decrease is due to a change in research focus concerning the same animals.

Even though the total number of mice and rats is relatively stable, the number of mice has increased from 153,748 to 163,666 and the number of rats has decreased from 45,951 to 37,955. Some establishments traditionally using rats have been restructuring their laboratories in 2017, probably explaining the decrease in numbers. There is no obvious reason for the rice in the use of mice, but in a small country a strengthened focuses from a few research groups can have a large impact on the statistics. A rising use of GA animals could affect the number of mice, but the use of GA animals has not changed significantly from 2016 to 2017.

Finally the use of 3,680 cattle in 2017 is remarkable, as the number in 2016 was as low as 419 animals. However this is due to a few large “on farm” studies on cattle. The number probably will return to a much lower level in 2018.

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

The number of animals experiencing severe severity has fallen from 1,68 % in 2016 to 0,74 % in 2017. As Denmark generally has few animals experiencing severe severity, a changed focus from just one or two research groups will affect the numbers dramatically. The level of severe severity in Denmark is consistently relatively low.

There has been an increase in the percentage of moderate severity from 29 % to 36 % and a corresponding drop in the percentage of mild severity from 61 % to 53 %. There is no apparent explanation for this change, but the numbers will be followed closely to identify any lasting change.

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

Also in 2017, the Danish 3R-center has worked hard to promote the 3R´s, including funding research. Further information can be found on [www.3rcenter.dk](http://www.3rcenter.dk).

The national committee has also supported the animal welfare bodies, which are working more and more effectively. Yearly meetings, platforms for charring best practise, dissemination of 3R-tools and guidelines are some of the tolls used in 2017. Further information can be found on: <https://www.foedevarestyrelsen.dk/english/Animal/AnimalWelfare/The_National_Committee_for_the_Protection_of_Animals_used_for_Scientific_Purposes/Pages/default.aspx>

The Danish Animal Experiments Inspectorate hosts 3 annual mini-symposiums for both scientific staff and for animal caretakers, discussing best practise and new models, as well as dissemination information on the legislation and correct statistical reporting.

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

In two cases the use of “other” is relatively high in Denmark – in other carnivores and other fish. The carnivores represent a strong focus on research in mink for farming and concerning fish, Denmark has a large focus on research on rainbow trout for farming, as well as a continuing focus on eel research.

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

No cases of animal experiencing the severe clarification exceeded were recorded in 2017 in Denmark.

## Denmark: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 164137 | 68.98% |
| Rats | 38498 | 16.18% |
| Guinea-Pigs | 2947 | 1.24% |
| Hamsters (Syrian) | 282 | 0.12% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 3 | 0% |
| Rabbits | 2443 | 1.03% |
| Cats |  |  |
| Dogs | 214 | 0.09% |
| Ferrets | 4 | 0% |
| Other carnivores | 1035 | 0.43% |
| Horses, donkeys and cross-breeds | 119 | 0.05% |
| Pigs | 5803 | 2.44% |
| Goats | 1 | 0% |
| Sheep | 66 | 0.03% |
| Cattle | 3677 | 1.55% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 28 | 0.01% |
| Domestic fowl | 466 | 0.2% |
| Other birds | 408 | 0.17% |
| Reptiles | 289 | 0.12% |
| Rana | 4 | 0% |
| Xenopus | 285 | 0.12% |
| Other Amphibians | 47 | 0.02% |
| Zebra fish | 1587 | 0.67% |
| Other Fish | 15606 | 6.56% |
| Cephalopods |  |  |
| Total | 237949 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 205163 | 87.11% |
| Animals born in the EU but not at a registered breeder | 24582 | 10.44% |
| Animals born in rest of Europe | 552 | 0.23% |
| Animals born in rest of world | 5215 | 2.21% |
| Total | 235512 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 82918 | 34.85% |
| Translational and applied research | 122146 | 51.33% |
| Regulatory use and Routine production | 19865 | 8.35% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 2875 | 1.21% |
| Preservation of species | 5637 | 2.37% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 4463 | 1.88% |
| Forensic enquiries | 16 | 0.01% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 29 | 0.01% |
| Total | 237949 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 6727 | 8.11% |
| Cardiovascular Blood and Lymphatic System | 4270 | 5.15% |
| Nervous System | 18241 | 22% |
| Respiratory System | 2444 | 2.95% |
| Gastrointestinal System including Liver | 2478 | 2.99% |
| Musculoskeletal System | 3280 | 3.96% |
| Immune System | 22727 | 27.41% |
| Urogenital/Reproductive System | 2220 | 2.68% |
| Sensory Organs (skin, eyes and ears) | 77 | 0.09% |
| Endocrine System/Metabolism | 12632 | 15.23% |
| Multisystemic | 485 | 0.58% |
| Ethology / Animal Behaviour /Animal Biology | 2454 | 2.96% |
| Other basic research | 4883 | 5.89% |
| Total | 82918 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 18429 | 15.09% |
| Human Infectious Disorders | 7665 | 6.28% |
| Human Cardiovascular Disorders | 2016 | 1.65% |
| Human Nervous and Mental Disorders | 31509 | 25.8% |
| Human Respiratory Disorders | 176 | 0.14% |
| Human Gastrointestinal Disorders including Liver | 762 | 0.62% |
| Human Musculoskeletal Disorders | 378 | 0.31% |
| Human Immune Disorders | 4959 | 4.06% |
| Human Urogenital/Reproductive Disorders | 647 | 0.53% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 336 | 0.28% |
| Human Endocrine/Metabolism Disorders | 37015 | 30.3% |
| Other Human Disorders | 9168 | 7.51% |
| Animal Diseases and Disorders | 5708 | 4.67% |
| Animal Welfare | 1568 | 1.28% |
| Diagnosis of diseases | 1023 | 0.84% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 787 | 0.64% |
| Total | 122146 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 2504 | 30.77% |
| Pyrogenicity testing |  |  |
| Batch potency testing | 5601 | 68.82% |
| Other quality controls | 34 | 0.42% |
| Total | 8139 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Phototoxicity |  |  |
| Safety testing in food and feed area |  |  |
| Target animal safety |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 3968 | 100% |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total | 3968 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 1382 | 62.68% |
| 29 - 90 days | 586 | 26.58% |
| > 90 days | 237 | 10.75% |
| Total | 2205 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 120 | 5.71% |
| Chronic toxicity | 1800 | 85.71% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation | 180 | 8.57% |
| Other ecotoxicity |  |  |
| Total | 2100 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 288 | 38.71% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 456 | 61.29% |
| Total | 744 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 16634 | 83.74% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation | 2987 | 15.04% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 244 | 1.23% |
| Total | 19865 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 19765 | 99.5% |
| Legislation satisfying national requirements only [within EU] | 100 | 0.5% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 19865 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 235512 | 98.98% |
| Yes | 2437 | 1.02% |
| Total | 237949 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 22871 | 9.61% |
| Mild [up to and including] | 127013 | 53.38% |
| Moderate | 86303 | 36.27% |
| Severe | 1762 | 0.74% |
| Total | 237949 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 234261 | 98.45% |
| Yes | 3688 | 1.55% |
| Total | 237949 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 198043 | 83.23% |
| Genetically altered without a harmful phenotype | 27907 | 11.73% |
| Genetically altered with a harmful phenotype | 11999 | 5.04% |
| Total | 237949 | 100.00% |

# Estonia

## Estonia: Narrative 2015

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

No significant trends are observed in 2015 compared to 2014. The number of companies dealing with experimental animals is the same. No new authorisations were given to small companies which do not have separate AWB at the place. Experiments done in such small companies are with small number of animals. All new licences were given to companies with own animal welfare body at establishment, therefore the quality of animal experiments has increased.

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

In 2014 Estonia reported that 50.55% of the animals used were used for basic research purpose. In 2015 the percentage for basic research was 83.53. In 2014 47.70% of animals were used for translational and applied research, in 2015 this percentage was 14.28. In 2014 8.28% of animals were used for legislation satisfying EU requirements, in 2015 this percentage was 38.53. In 2014 24.05% of animals were used for human cancer research, in 2015 this percentage was 85.38. These were the biggest changes in the number of animals used in certain categories. Main reason for such changes is finance. Human cancer, legislation satisfying EU requirements and translational and applied research projects got grants in 2015.

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

In 2014 13.16% of animals were classified as non-recovery, in 2015 this percentage was 7.01. In 2014 1.87% of animals were classified as severe, in 2015 this percentage was 8.02. As Estonia only gave 26 licences in 2015 these changes are not significant. The usage of animals mostly depends on finance (what grants are received). All projects are evaluated by PAC members.

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

We have continued the process of carefully evaluating each application. The members of PAC include and expert of anaesthesia, expert of statistics, expert of pharmacology etc. Such experts make sure that optimal number of animals is used in each project and no projects are duplicated.

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

All fish classified as other fish were roaches. All birds classified as other birds were common gulls.

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

PAC has not given licences exceeding severe classification.

## Estonia: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 2965 | 76.99% |
| Rats | 123 | 3.19% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 6 | 0.16% |
| Goats |  |  |
| Sheep |  |  |
| Cattle | 283 | 7.35% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds | 294 | 7.63% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish | 180 | 4.67% |
| Cephalopods |  |  |
| Total | 3851 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 2920 | 78.2% |
| Animals born in the EU but not at a registered breeder | 736 | 19.71% |
| Animals born in rest of Europe | 78 | 2.09% |
| Animals born in rest of world |  |  |
| Total | 3734 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 3190 | 82.84% |
| Translational and applied research | 570 | 14.8% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 83 | 2.16% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 8 | 0.21% |
| Total | 3851 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 1338 | 41.94% |
| Cardiovascular Blood and Lymphatic System | 12 | 0.38% |
| Nervous System | 274 | 8.59% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 78 | 2.45% |
| Musculoskeletal System |  |  |
| Immune System | 435 | 13.64% |
| Urogenital/Reproductive System | 60 | 1.88% |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism | 213 | 6.68% |
| Multisystemic | 50 | 1.57% |
| Ethology / Animal Behaviour /Animal Biology | 215 | 6.74% |
| Other basic research | 515 | 16.14% |
| Total | 3190 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 483 | 84.74% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders | 87 | 15.26% |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 570 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 3734 | 96.96% |
| Yes | 117 | 3.04% |
| Total | 3851 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 284 | 7.37% |
| Mild [up to and including] | 1552 | 40.3% |
| Moderate | 1681 | 43.65% |
| Severe | 334 | 8.67% |
| Total | 3851 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 3851 | 100% |
| Yes |  |  |
| Total | 3851 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 3397 | 88.21% |
| Genetically altered without a harmful phenotype | 454 | 11.79% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 3851 | 100.00% |

## Estonia: Narrative 2016

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

No significant trends are observed in 2016 compared to 2015. One new authorisation was given to a company dealing with experimental animals, however they did not apply for a licence in 2016. All new licences were given to companies with own animal welfare body at establishment, therefore the quality of animal experiments has increased.

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

In 2015 2376 mice, 51 rats, 6 pigs, 566 cattle, 294 other birds, 180 other fish were used for basic research. In 2016 3079 mice, 90 rats, 252 other birds and 32 other fish were used for basic research. In 2015 550 mice and 45 rats were used for translational and applied research, in 2016 31 mice and no rats were used for that purpose. In 2015 56 mice and 27 rats were used for higher education purposes, however no animals were used for that purpose in 2016. In 2015 16 mice were used for the purpose of maintaining colonies, in 2016 the number of mice used for that purpose was 242. It can be said that the main difference between the years was that the number of animal used for maintaining colonies significantly increased and compared to 2015, in 2016 no animals were used for higher education purpose. Also, no cattle or other animal species were used in 2016 compared to 2015.

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

In 2015 44.04% of animals used were classified as mild, in 2016 this percentage was 37.44. In 2015, 40.94% of animals used were classified as moderate, in 2016 this percentage was 48.85. In 2015, 8.02% of animals were severely used, in 2016 this percentage was 10.82. In 2015, 7.01% of animals were classified as non- recovery. In 2016 this percentage was 2.90. There are no major changes in actual severities when comparing the two years.

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

We have continued the process of carefully evaluating each application. The members of PAC include and expert of anaesthesia, expert of statistics, expert of pharmacology etc. Such experts make sure that optimal number of animals is used in each project and no projects are duplicated.

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

All birds classified as other birds were great tits (*Parus major*). All fish classified as other fish were round gobies (*Neogobius melanostomus*).

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

PAC has not given licences exceeding severe classification.

## Estonia: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 3193 | 89.51% |
| Rats | 90 | 2.52% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds | 252 | 7.06% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish | 32 | 0.9% |
| Cephalopods |  |  |
| Total | 3567 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 3176 | 91.79% |
| Animals born in the EU but not at a registered breeder | 284 | 8.21% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 3460 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 3294 | 92.35% |
| Translational and applied research | 31 | 0.87% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills |  |  |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 242 | 6.78% |
| Total | 3567 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 1638 | 49.73% |
| Cardiovascular Blood and Lymphatic System | 12 | 0.36% |
| Nervous System | 546 | 16.58% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 140 | 4.25% |
| Musculoskeletal System | 75 | 2.28% |
| Immune System | 20 | 0.61% |
| Urogenital/Reproductive System | 30 | 0.91% |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism | 549 | 16.67% |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology | 284 | 8.62% |
| Other basic research |  |  |
| Total | 3294 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders | 31 | 100% |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 31 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 3460 | 97% |
| Yes | 107 | 3% |
| Total | 3567 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 108 | 3.03% |
| Mild [up to and including] | 1395 | 39.11% |
| Moderate | 1724 | 48.33% |
| Severe | 340 | 9.53% |
| Total | 3567 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 3351 | 93.94% |
| Yes | 216 | 6.06% |
| Total | 3567 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 2668 | 74.8% |
| Genetically altered without a harmful phenotype | 899 | 25.2% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 3567 | 100.00% |

## Estonia: Narrative 2017

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

Compared to 2016 some changes in trends were observed. Number of animals used dropped another 12% (decrease in 2015 vs 2016 was 10%). This year there we none in re-use (in 2016 3% from all uses). Creation of new GL dropped again, from 6,06% to 2,8% (none in 2015). Like in 2015 and 2016 no harmful GA lines were used in 2017. The GA animals used are thoroughly researched and known to have no harmful qualities. About 2/3 of the animals used are not genetically altered. This number has dropped from last year where about ¾ were not altered since more projects use GA animals. Insignificant changes in severities - non-recovery and mild have mildly increased, moderate and severe decreased. Changes in species – less mice, more rats were used; quantity of birds decreased as well; no fish were used but in 2017 again 16 cattle and 4 pigs were used (no projects in 2016). More animals came from an EU registered breeder (94,28% vs 91,79%).

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

Number of uses in translational and applied research rose from 0,87% to 6,68%. Human respiratory disorders were investigated with 210 uses. There were no projects of higher education or training for the acquisition, maintenance or improvement of vocational skills in 2016 but now in 2017 it took 1,21% of all uses. There were no competence courses in laboratory animal science in Estonia that year. Maintenance of colonies rose from 6,78% to 12,52% since laboratories are using more GA lines. No regulatory use in 2016 but 112 in 2017 – legislation on medicinal products for human use (from that 38 uses for carcinogenicity and 74 for genotoxicity). Oncology still is the most important research area, where 41% of the work is done. More uses than last year had cardiovascular, sensory, multisystemic, immune and nervous system.

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

In 2016 39% of animals used were classified as mild, in 2017 this percentage was 44. In 2016, 48% of animals used were classified as moderate, in 2017 this percentage was 43. In 2016, 9,5% of animals were severely used, in 2017 this percentage was 8,7. In 2016, 3% of animals were classified as non- recovery. In 2017 this percentage was 4. There are no major changes in actual severities when comparing the two years. The proportion of moderate is higher than the average EU and might come from the facts that the committee is strict and that more harsh projects are done.

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

We have continued the process of carefully evaluating each application. The members of PAC include and expert of anaesthesia, expert of statistics, expert of pharmacology etc. Such experts make sure that optimal number of animals is used in each project and no projects are duplicated.

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

From the birds that were classified as other birds 115 were common gulls and 65 were great tits. Proportion of birds 5,72% of all animals.

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

PAC has not given licences exceeding severe classification.

## Estonia: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 2578 | 81.95% |
| Rats | 368 | 11.7% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 4 | 0.13% |
| Goats |  |  |
| Sheep |  |  |
| Cattle | 16 | 0.51% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds | 180 | 5.72% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 3146 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 2966 | 94.28% |
| Animals born in the EU but not at a registered breeder | 180 | 5.72% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 3146 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 2392 | 76.03% |
| Translational and applied research | 210 | 6.68% |
| Regulatory use and Routine production | 112 | 3.56% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 38 | 1.21% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 394 | 12.52% |
| Total | 3146 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 985 | 41.18% |
| Cardiovascular Blood and Lymphatic System | 93 | 3.89% |
| Nervous System | 495 | 20.69% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 32 | 1.34% |
| Musculoskeletal System | 88 | 3.68% |
| Immune System | 99 | 4.14% |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) | 32 | 1.34% |
| Endocrine System/Metabolism | 219 | 9.16% |
| Multisystemic | 153 | 6.4% |
| Ethology / Animal Behaviour /Animal Biology | 180 | 7.53% |
| Other basic research | 16 | 0.67% |
| Total | 2392 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders | 210 | 100% |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 210 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 112 | 100% |
| Total | 112 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 38 | 33.93% |
| Carcinogenicity | 74 | 66.07% |
| Total | 112 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 38 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 38 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 112 | 100% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 112 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 112 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 112 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 3146 | 100% |
| Yes |  |  |
| Total | 3146 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 132 | 4.2% |
| Mild [up to and including] | 1385 | 44.02% |
| Moderate | 1354 | 43.04% |
| Severe | 275 | 8.74% |
| Total | 3146 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 3058 | 97.2% |
| Yes | 88 | 2.8% |
| Total | 3146 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1956 | 62.17% |
| Genetically altered without a harmful phenotype | 1190 | 37.83% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 3146 | 100.00% |

# Finland

## Finland: Narrative 2015

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

In 2015, a total of 96 817 procedures in animals were done in Finland, which was 33 % less than 2014 (145 542 procedures in 2014). The greatest reductions were in the procedures with fish (other than zebra fish 38 483). The change was due to the ending of one project with large fish use. The use of mice in procedures decreased also (10 941). This may however be explained with the more precise reporting. The reductions in use of both species were mainly in basic research. The use of rats increased by 1679 rats in translational and applied research.

28 % of animals used were genetically altered (mice, rats and zebra fish). 7 % of them had a harmful phenotype.

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

The number of procedures done in basic research were 62 223 procedures - main areas being nervous system, immune system, multisystemic and ethology/animal behavior/animal biology. For the translational and applied research (25 634 procedures) the main category of purposes were human nervous and mental disorders (15 878 procedures).

Dogs reported as used in procedures (2619) included 2326 pet dogs which gave a blood sample for a study of disease genes and 196 pet dogs which participated in patient studies for better treatment methods. Dogs bred and used in laboratories were used in 97 procedures including 71 re-use. Cats reported as used in procedures (100) were all pet cats with blood sampling for a study of disease genes.

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

Actual severities of procedures: 60 % of the procedures were classified as non-recovery or mild, 34 % moderate and 6 % severe. By species, the severe procedures involved 2934 mice (5199 mice in 2014) and 2679 rats (1960 rats in 2014). Most of the severe procedures (4008) were done in category of human nervous and mental disorders.

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

Funding of Finnish Centre for Alternative Methods (FICAM) for development of alternative methods and training courses.

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

-

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

The severe classification was not exceeded in any procedures.

## Finland: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 50047 | 51.69% |
| Rats | 15976 | 16.5% |
| Guinea-Pigs | 50 | 0.05% |
| Hamsters (Syrian) | 197 | 0.2% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 213 | 0.22% |
| Cats | 100 | 0.1% |
| Dogs | 2619 | 2.71% |
| Ferrets |  |  |
| Other carnivores | 270 | 0.28% |
| Horses, donkeys and cross-breeds | 48 | 0.05% |
| Pigs | 479 | 0.49% |
| Goats |  |  |
| Sheep | 1128 | 1.17% |
| Cattle | 87 | 0.09% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 2880 | 2.97% |
| Domestic fowl | 3646 | 3.77% |
| Other birds | 717 | 0.74% |
| Reptiles |  |  |
| Rana | 10 | 0.01% |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 10821 | 11.18% |
| Other Fish | 7529 | 7.78% |
| Cephalopods |  |  |
| Total | 96817 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 76799 | 79.95% |
| Animals born in the EU but not at a registered breeder | 18207 | 18.95% |
| Animals born in rest of Europe | 7 | 0.01% |
| Animals born in rest of world | 1042 | 1.08% |
| Total | 96055 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 62223 | 64.27% |
| Translational and applied research | 25634 | 26.48% |
| Regulatory use and Routine production | 5364 | 5.54% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 1455 | 1.5% |
| Preservation of species | 41 | 0.04% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1170 | 1.21% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 930 | 0.96% |
| Total | 96817 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 7529 | 12.1% |
| Cardiovascular Blood and Lymphatic System | 5253 | 8.44% |
| Nervous System | 14531 | 23.35% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 558 | 0.9% |
| Musculoskeletal System | 701 | 1.13% |
| Immune System | 10115 | 16.26% |
| Urogenital/Reproductive System | 500 | 0.8% |
| Sensory Organs (skin, eyes and ears) | 1223 | 1.97% |
| Endocrine System/Metabolism | 4000 | 6.43% |
| Multisystemic | 8112 | 13.04% |
| Ethology / Animal Behaviour /Animal Biology | 9425 | 15.15% |
| Other basic research | 276 | 0.44% |
| Total | 62223 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 2375 | 9.27% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders | 604 | 2.36% |
| Human Nervous and Mental Disorders | 15878 | 61.94% |
| Human Respiratory Disorders | 62 | 0.24% |
| Human Gastrointestinal Disorders including Liver | 24 | 0.09% |
| Human Musculoskeletal Disorders | 16 | 0.06% |
| Human Immune Disorders | 24 | 0.09% |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 1237 | 4.83% |
| Human Endocrine/Metabolism Disorders | 85 | 0.33% |
| Other Human Disorders | 23 | 0.09% |
| Animal Diseases and Disorders | 4593 | 17.92% |
| Animal Welfare | 444 | 1.73% |
| Diagnosis of diseases | 127 | 0.5% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 142 | 0.55% |
| Total | 25634 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 1576 | 29.38% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 2538 | 47.32% |
| Routine production | 1250 | 23.3% |
| Total | 5364 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 1576 | 100% |
| Total | 1576 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 50 | 1.97% |
| Skin irritation/corrosion | 10 | 0.39% |
| Skin sensitisation | 40 | 1.58% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 94 | 3.7% |
| Kinetics | 590 | 23.25% |
| Pharmaco-dynamics (incl safety pharmacology) | 1754 | 69.11% |
| Total | 2538 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 50 | 100% |
| Total | 50 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 94 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 94 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 1250 | 100% |
| Total | 1250 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 3708 | 69.13% |
| Legislation on medicinal products for veterinary use and their residues | 1656 | 30.87% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 5364 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 5364 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 5364 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 96055 | 99.21% |
| Yes | 762 | 0.79% |
| Total | 96817 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 4977 | 5.14% |
| Mild [up to and including] | 53408 | 55.16% |
| Moderate | 32819 | 33.9% |
| Severe | 5613 | 5.8% |
| Total | 96817 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 87608 | 90.49% |
| Yes | 9209 | 9.51% |
| Total | 96817 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 69334 | 71.61% |
| Genetically altered without a harmful phenotype | 22004 | 22.73% |
| Genetically altered with a harmful phenotype | 5479 | 5.66% |
| Total | 96817 | 100.00% |

## Finland: Narrative 2016

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

In 2016, a total of 105 615 procedures in animals were done in Finland, which was 9 % more than in 2015 (96 817 procedures). The greatest increases were in the procedures with mice (7 792 animals more), other rodents (1364 more) and domestic fowls (4 765 more).

45 % of mice used were genetically altered and 13 % (7328 mice) had a harmful phenotype. With rats, 3 % were genetically altered, one rat with harmful phenotype. With zebrafish, the numbers were 58 % and 16 % (1206 zebra fish), respectively.

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

The number of procedures done in basic research were 55 744 procedures, main areas being Nervous system (14 320 procedures), Immune system, Multisystemic and Ethology/Animal behavior/Animal biology (8 795, 10 539 and 7 376, respectively). For the translational and applied research (40 591 procedures) the main categories of purposes were Human nervous and mental disorders (20 831 procedures) and Animal diseases and disorders (9 869 procedures). In regulatory use and routine production, 2 645 domestic fowls were used for quality control, 1 457 animals (sheep, pigs, domestic fowls and horses) for routine products and 2 916 animals (mice, rats, dogs, pigs) in toxicity and other safety testing.

The increased use of mice in procedures (16 %) took place in the translational and applied research in studies for Human nervous and mental disorders. Other rodents (bank voles: 1314 animals) were used in the basic research (Ethology/Animal behavior/Animal biology). The procedures in domestic fowls increased in the translational and applied research (Animal diseases and disorders) and in the regulatory use and routine production (Quality control).

Procedures reported as done in dogs (3961) included 3582 procedures in pet dogs which gave a blood sample for a study of disease genes. 244 procedures were done in pet dogs which participated in patient studies for better treatment methods. Dogs bred and used in laboratories were used in 135 procedures including 116 re-use. Cats reported as used in procedures (259) were all pet cats with blood sampling for a study of disease genes.

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

61,5 % of the procedures were classified as non-recovery or mild, 30 % moderate and 8,5 % severe. By species, the severe procedures involved 6 862 mice (2934 in 2015) and 2161 rats (2 679 in 2015). The severe procedures in mice and rats were done mainly in the purpose of Human nervous and mental disorders both in basic and translational research. The significant increase or severe procedures with mice was due to single projects with high animal numbers.

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

Funding of Finnish Centre for Alternative Methods (FICAM) for development of alternative methods and training courses.

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

-

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

The severe classification was not exceeded in any procedures.

## Finland: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 57839 | 54.76% |
| Rats | 15297 | 14.48% |
| Guinea-Pigs | 10 | 0.01% |
| Hamsters (Syrian) | 273 | 0.26% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 1364 | 1.29% |
| Rabbits | 237 | 0.22% |
| Cats | 259 | 0.25% |
| Dogs | 3961 | 3.75% |
| Ferrets |  |  |
| Other carnivores | 18 | 0.02% |
| Horses, donkeys and cross-breeds | 76 | 0.07% |
| Pigs | 611 | 0.58% |
| Goats |  |  |
| Sheep | 1350 | 1.28% |
| Cattle | 541 | 0.51% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 103 | 0.1% |
| Domestic fowl | 8411 | 7.96% |
| Other birds | 501 | 0.47% |
| Reptiles |  |  |
| Rana | 2 | 0% |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 7483 | 7.09% |
| Other Fish | 7279 | 6.89% |
| Cephalopods |  |  |
| Total | 105615 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 84134 | 80.23% |
| Animals born in the EU but not at a registered breeder | 15053 | 14.35% |
| Animals born in rest of Europe | 981 | 0.94% |
| Animals born in rest of world | 4702 | 4.48% |
| Total | 104870 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 55744 | 52.78% |
| Translational and applied research | 40591 | 38.43% |
| Regulatory use and Routine production | 7026 | 6.65% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species | 35 | 0.03% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1753 | 1.66% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 466 | 0.44% |
| Total | 105615 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 4212 | 7.56% |
| Cardiovascular Blood and Lymphatic System | 5187 | 9.31% |
| Nervous System | 14320 | 25.69% |
| Respiratory System | 258 | 0.46% |
| Gastrointestinal System including Liver | 501 | 0.9% |
| Musculoskeletal System | 562 | 1.01% |
| Immune System | 8795 | 15.78% |
| Urogenital/Reproductive System | 524 | 0.94% |
| Sensory Organs (skin, eyes and ears) | 310 | 0.56% |
| Endocrine System/Metabolism | 2614 | 4.69% |
| Multisystemic | 10539 | 18.91% |
| Ethology / Animal Behaviour /Animal Biology | 7376 | 13.23% |
| Other basic research | 546 | 0.98% |
| Total | 55744 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 3325 | 8.19% |
| Human Infectious Disorders | 995 | 2.45% |
| Human Cardiovascular Disorders | 676 | 1.67% |
| Human Nervous and Mental Disorders | 20831 | 51.32% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver | 74 | 0.18% |
| Human Musculoskeletal Disorders | 1204 | 2.97% |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 2169 | 5.34% |
| Human Endocrine/Metabolism Disorders | 386 | 0.95% |
| Other Human Disorders | 586 | 1.44% |
| Animal Diseases and Disorders | 9869 | 24.31% |
| Animal Welfare | 199 | 0.49% |
| Diagnosis of diseases | 89 | 0.22% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 188 | 0.46% |
| Total | 40591 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 2645 | 37.65% |
| Other efficacy and tolerance testing | 8 | 0.11% |
| Toxicity and other safety testing including pharmacology | 2916 | 41.5% |
| Routine production | 1457 | 20.74% |
| Total | 7026 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 2645 | 100% |
| Total | 2645 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 49 | 1.68% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 196 | 6.72% |
| Kinetics | 850 | 29.15% |
| Pharmaco-dynamics (incl safety pharmacology) | 1821 | 62.45% |
| Total | 2916 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 9 | 18.37% |
| Other lethal methods |  |  |
| Non lethal methods | 40 | 81.63% |
| Total | 49 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 100 | 51.02% |
| 29 - 90 days |  |  |
| > 90 days | 96 | 48.98% |
| Total | 196 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 317 | 21.76% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 1140 | 78.24% |
| Total | 1457 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 4332 | 61.66% |
| Legislation on medicinal products for veterinary use and their residues | 2694 | 38.34% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 7026 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 6709 | 95.49% |
| Legislation satisfying national requirements only [within EU] | 317 | 4.51% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 7026 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 104870 | 99.29% |
| Yes | 745 | 0.71% |
| Total | 105615 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 9198 | 8.71% |
| Mild [up to and including] | 55602 | 52.65% |
| Moderate | 31797 | 30.11% |
| Severe | 9018 | 8.54% |
| Total | 105615 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 101359 | 95.97% |
| Yes | 4256 | 4.03% |
| Total | 105615 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 74960 | 70.97% |
| Genetically altered without a harmful phenotype | 22120 | 20.94% |
| Genetically altered with a harmful phenotype | 8535 | 8.08% |
| Total | 105615 | 100.00% |

## Finland: Narrative 2017

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

In 2017, a total of 102 575 procedures in animals were done in Finland, which was 3 % less than in 2016 (105 615 procedures). The greatest decreases were in the procedures with mice (4 838 animals less) mainly in basic research and rats (1 825 less) in translational and applied research. The number of procedures with other fish increased (4 450 more).

48 % of mice used were genetically altered and 17 % (8817 mice) had a harmful phenotype. With rats, 4 % were genetically altered, all without a harmful phenotype. With zebrafish, 51 % of the used fish were genetically altered, all without a harmful phenotype.

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

The number of procedures done in basic research were 59 278 procedures, main areas being Nervous system (11 905 procedures, decreased) and Immune system (11 024 procedures, increased). Other areas of basic research were Multisystemic (7 587, decreased), Ethology/Animal Behavior/Animal Biology (7 546, no change), Oncology (6 791, increased) and Cardiovascular Blood and Lymphatic Systems (5 145, no change).

For the translational and applied research (33 521 procedures) the main categories of purposes were Human nervous and mental disorders (19 703 procedures, decreased), Human Cancer (5 016, increased) and Animal diseases and disorders (4 384 procedures, decreased).

In Regulatory use and Routine production, 3 395 domestic fowls were used for Quality control and 1 476 animals (sheep, pigs, domestic fowls and horses) for Routine products. For Toxicity and other safety testing, 2 868 animals (mice, rats, dogs, pigs, rabbits) were used mainly for Kinetics and Pharmaco-dynamics.

Procedures reported as done in dogs (3 061) included 2 840 procedures in pet dogs which gave a blood sample for a study of disease genes. 195 procedures were done in pet dogs which participated in patient studies for better treatment methods. Dogs bred and used in laboratories were used in 26 procedures including 26 re-use. Cats reported as used in procedures (311) were all pet cats with blood sampling for a study of disease genes.

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

Actual severities of procedures: 8,9 % of the procedures were classified as non-recovery, 48,5 % mild, 34,1 % moderate and 8,5 % severe. By species, the severe procedures involved 7 125 mice (6 862 in 2016) and 1 568 rats (2 161 in 2016). There were changes in the numbers of procedures with mild or moderate severity without clear reasons for them. As in previous years, the severe procedures were done mainly in the purpose of Human nervous and mental disorders in translational research (6 722 procedures).

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

Funding of Finnish Centre for Alternative Methods (FICAM) for development of alternative methods and training courses.

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

-

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

The severe classification was not exceeded in any procedures.

## Finland: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 53001 | 51.67% |
| Rats | 13472 | 13.13% |
| Guinea-Pigs | 9 | 0.01% |
| Hamsters (Syrian) | 149 | 0.15% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 690 | 0.67% |
| Rabbits | 227 | 0.22% |
| Cats | 311 | 0.3% |
| Dogs | 3061 | 2.98% |
| Ferrets |  |  |
| Other carnivores | 107 | 0.1% |
| Horses, donkeys and cross-breeds | 77 | 0.08% |
| Pigs | 632 | 0.62% |
| Goats |  |  |
| Sheep | 1319 | 1.29% |
| Cattle | 216 | 0.21% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 1533 | 1.49% |
| Domestic fowl | 8485 | 8.27% |
| Other birds | 404 | 0.39% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 7153 | 6.97% |
| Other Fish | 11729 | 11.43% |
| Cephalopods |  |  |
| Total | 102575 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 76287 | 74.48% |
| Animals born in the EU but not at a registered breeder | 23562 | 23% |
| Animals born in rest of Europe | 5 | 0% |
| Animals born in rest of world | 2572 | 2.51% |
| Total | 102426 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 59278 | 57.79% |
| Translational and applied research | 33521 | 32.68% |
| Regulatory use and Routine production | 7895 | 7.7% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species | 60 | 0.06% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1606 | 1.57% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 215 | 0.21% |
| Total | 102575 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 6791 | 11.46% |
| Cardiovascular Blood and Lymphatic System | 5145 | 8.68% |
| Nervous System | 11905 | 20.08% |
| Respiratory System | 80 | 0.13% |
| Gastrointestinal System including Liver | 545 | 0.92% |
| Musculoskeletal System | 337 | 0.57% |
| Immune System | 11024 | 18.6% |
| Urogenital/Reproductive System | 181 | 0.31% |
| Sensory Organs (skin, eyes and ears) | 268 | 0.45% |
| Endocrine System/Metabolism | 1387 | 2.34% |
| Multisystemic | 7587 | 12.8% |
| Ethology / Animal Behaviour /Animal Biology | 7546 | 12.73% |
| Other basic research | 6482 | 10.93% |
| Total | 59278 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 5016 | 14.96% |
| Human Infectious Disorders | 860 | 2.57% |
| Human Cardiovascular Disorders | 662 | 1.97% |
| Human Nervous and Mental Disorders | 19703 | 58.78% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver | 117 | 0.35% |
| Human Musculoskeletal Disorders | 605 | 1.8% |
| Human Immune Disorders | 71 | 0.21% |
| Human Urogenital/Reproductive Disorders | 8 | 0.02% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 477 | 1.42% |
| Human Endocrine/Metabolism Disorders | 442 | 1.32% |
| Other Human Disorders | 759 | 2.26% |
| Animal Diseases and Disorders | 4384 | 13.08% |
| Animal Welfare | 226 | 0.67% |
| Diagnosis of diseases | 123 | 0.37% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 68 | 0.2% |
| Total | 33521 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 3395 | 100% |
| Total | 3395 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 134 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 134 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 296 | 20.05% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 1180 | 79.95% |
| Total | 1476 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 4468 | 56.59% |
| Legislation on medicinal products for veterinary use and their residues | 3395 | 43% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment | 32 | 0.41% |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 7895 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 7599 | 96.25% |
| Legislation satisfying national requirements only [within EU] | 296 | 3.75% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 7895 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 102426 | 99.85% |
| Yes | 149 | 0.15% |
| Total | 102575 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 9082 | 8.85% |
| Mild [up to and including] | 49770 | 48.52% |
| Moderate | 34984 | 34.11% |
| Severe | 8739 | 8.52% |
| Total | 102575 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 97716 | 95.26% |
| Yes | 4859 | 4.74% |
| Total | 102575 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 73080 | 71.25% |
| Genetically altered without a harmful phenotype | 20678 | 20.16% |
| Genetically altered with a harmful phenotype | 8817 | 8.6% |
| Total | 102575 | 100.00% |

# France

## France: Narrative 2015

**1. General information on any changes in trends observed since the previous reporting period (2014).**

The transposition of Directive 2010/63/EU into French law has given rise to significant changes.

Indeed, the format prescribed by the European Union for the retrospective survey for 2015 under Directive 2010/63/EU, which was transposed into French law on 7 February 2013, is different from that used for the previous surveys under Directive 86/609/EU. Any comparison with the 2014 survey would therefore be inappropriate, particularly for the period 2013-2017, which was marked by transitional regulatory measures.

The scope of the survey has changed considerably:

* only animals for which the experimental procedures ended in 2015 are recorded;
* captive-bred animals present in user establishments are excluded;
* animals involved in procedures below the stress threshold, including genetically modified animal lines that do not exhibit a harmful phenotype, are excluded;
* animals humanely killed according to regulatory methods for the removal of organs or tissue (used for alternative methods) are excluded.

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

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2014). Consequently, any comparative analysis that reached a conclusion regarding an increase or decrease in the number of animals used for scientific purposes would be inappropriate.

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

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2014). Consequently, any comparative analysis of the changes in trends in actual severities would be inappropriate.

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

The principles of replacement, refinement and reduction have been part of the French policy on the use of animals for scientific purposes since the ten founding measures were introduced in 1992 by the Minister for Research, Hubert Curien. Teaching these principles is an essential part of training staff, whether they are responsible for caring for the animals or for carrying out and designing scientific projects. The work of the National Commission for Animal Testing and the National Ethical Reflection Committee on Animal Testing, which meet several times a year, is crucial in this respect. The transposition of Directive 2010/63/EU, which requires prior authorisation for any project using animals for scientific purposes, and the choice of the French authorities to draw on the expertise of nearly 130 ethical committees spread throughout France, has also encouraged researchers to think more about these three principles and helped increase the sharing of best practice.

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

Grouping species of the same taxon in the ‘other’ category, as proposed by the European Commission, does not always seem to be the most appropriate method and could be improved, in particular in the case of fish and birds.

For example, although zebra-fish account for just 0.6% of animals used (11,665 animals), ‘other fish’ account for 29.6% (524,024 animals). The latter category includes farmed fish such as trout, eel, seabass and salmon, the reproduction, physiology and diet of which are the subject of numerous studies, particularly by the National Institute for Agricultural Research (INRA).

Large numbers of birds are also categorised as ‘other’ (44,248 animals), while ‘domestic fowl’ account for 48,528.

Finally, with respect to the distribution of animals involved in procedures laid down in the rules, almost half are entered in the ‘other’ category, which suggests that the proposed headings are not the most appropriate, or have been misunderstood by users. Particular attention will be given to how this section is completed in the next survey.

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

Procedures are classified into four categories: non-recovery, mild, moderate and severe (including intense/severe procedures). No instances of the ‘severe’ classification being exceeded have been identified.

## France: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1007245 | 52.97% |
| Rats | 157183 | 8.27% |
| Guinea-Pigs | 44414 | 2.34% |
| Hamsters (Syrian) | 10986 | 0.58% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 1417 | 0.07% |
| Other Rodents | 755 | 0.04% |
| Rabbits | 108110 | 5.69% |
| Cats | 336 | 0.02% |
| Dogs | 3143 | 0.17% |
| Ferrets | 155 | 0.01% |
| Other carnivores | 30 | 0% |
| Horses, donkeys and cross-breeds | 629 | 0.03% |
| Pigs | 12203 | 0.64% |
| Goats | 436 | 0.02% |
| Sheep | 3446 | 0.18% |
| Cattle | 2203 | 0.12% |
| Prosimians | 157 | 0.01% |
| Marmoset and tamarins | 97 | 0.01% |
| Cynomolgus monkey | 2756 | 0.14% |
| Rhesus monkey | 64 | 0% |
| Vervets (Chlorocebus spp.) | 56 | 0% |
| Baboons | 18 | 0% |
| Squirrel monkey | 13 | 0% |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 1772 | 0.09% |
| Domestic fowl | 66734 | 3.51% |
| Other birds | 46433 | 2.44% |
| Reptiles | 1051 | 0.06% |
| Rana | 306 | 0.02% |
| Xenopus | 1644 | 0.09% |
| Other Amphibians | 3167 | 0.17% |
| Zebra fish | 11399 | 0.6% |
| Other Fish | 413183 | 21.73% |
| Cephalopods | 1 | 0% |
| Total | 1901542 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 1550643 | 82.26% |
| Animals born in the EU but not at a registered breeder | 258592 | 13.72% |
| Animals born in rest of Europe | 66947 | 3.55% |
| Animals born in rest of world | 8893 | 0.47% |
| Total | 1885075 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 128 | 6.92% |
| Animals born in rest of Europe | 14 | 0.76% |
| Animals born in Asia | 42 | 2.27% |
| Animals born in America | 55 | 2.97% |
| Animals born in Africa | 1521 | 82.17% |
| Animals born elsewhere | 91 | 4.92% |
| Total | 1851 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 | 1 | 0.05% |
| F1 | 1202 | 64.94% |
| F2 or greater | 433 | 23.39% |
| Self-sustaining colony | 215 | 11.62% |
| Total | 1851 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 792453 | 41.67% |
| Translational and applied research | 432557 | 22.75% |
| Regulatory use and Routine production | 572144 | 30.09% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 1122 | 0.06% |
| Preservation of species | 3380 | 0.18% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 28062 | 1.48% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 71824 | 3.78% |
| Total | 1901542 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 63910 | 8.06% |
| Cardiovascular Blood and Lymphatic System | 40007 | 5.05% |
| Nervous System | 92332 | 11.65% |
| Respiratory System | 11520 | 1.45% |
| Gastrointestinal System including Liver | 63028 | 7.95% |
| Musculoskeletal System | 9931 | 1.25% |
| Immune System | 68167 | 8.6% |
| Urogenital/Reproductive System | 26770 | 3.38% |
| Sensory Organs (skin, eyes and ears) | 12399 | 1.56% |
| Endocrine System/Metabolism | 26196 | 3.31% |
| Multisystemic | 29703 | 3.75% |
| Ethology / Animal Behaviour /Animal Biology | 345624 | 43.61% |
| Other basic research | 2866 | 0.36% |
| Total | 792453 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 126277 | 29.19% |
| Human Infectious Disorders | 65335 | 15.1% |
| Human Cardiovascular Disorders | 9735 | 2.25% |
| Human Nervous and Mental Disorders | 61259 | 14.16% |
| Human Respiratory Disorders | 3043 | 0.7% |
| Human Gastrointestinal Disorders including Liver | 7405 | 1.71% |
| Human Musculoskeletal Disorders | 12075 | 2.79% |
| Human Immune Disorders | 11943 | 2.76% |
| Human Urogenital/Reproductive Disorders | 2756 | 0.64% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 9717 | 2.25% |
| Human Endocrine/Metabolism Disorders | 22966 | 5.31% |
| Other Human Disorders | 1387 | 0.32% |
| Animal Diseases and Disorders | 45194 | 10.45% |
| Animal Welfare | 2656 | 0.61% |
| Diagnosis of diseases | 31652 | 7.32% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 19157 | 4.43% |
| Total | 432557 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 276166 | 48.27% |
| Other efficacy and tolerance testing | 39738 | 6.95% |
| Toxicity and other safety testing including pharmacology | 102867 | 17.98% |
| Routine production | 153373 | 26.81% |
| Total | 572144 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 62846 | 22.76% |
| Pyrogenicity testing | 5981 | 2.17% |
| Batch potency testing | 207339 | 75.08% |
| Other quality controls |  |  |
| Total | 276166 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 7869 | 7.65% |
| Skin irritation/corrosion | 1750 | 1.7% |
| Skin sensitisation | 11491 | 11.17% |
| Eye irritation/corrosion | 548 | 0.53% |
| Repeated dose toxicity | 22904 | 22.27% |
| Carcinogenicity | 1054 | 1.02% |
| Genotoxicity | 854 | 0.83% |
| Reproductive toxicity | 13109 | 12.74% |
| Developmental toxicity | 8293 | 8.06% |
| Neurotoxicity | 202 | 0.2% |
| Kinetics | 8841 | 8.59% |
| Pharmaco-dynamics (incl safety pharmacology) | 9119 | 8.86% |
| Phototoxicity | 420 | 0.41% |
| Ecotoxicity | 13360 | 12.99% |
| Safety testing in food and feed area | 733 | 0.71% |
| Target animal safety | 273 | 0.27% |
| Other toxicity/safety testing | 2047 | 1.99% |
| Total | 102867 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 2713 | 34.48% |
| Other lethal methods | 1373 | 17.45% |
| Non lethal methods | 3783 | 48.07% |
| Total | 7869 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 13008 | 56.79% |
| 29 - 90 days | 4542 | 19.83% |
| > 90 days | 5354 | 23.38% |
| Total | 22904 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 9383 | 70.23% |
| Chronic toxicity | 3977 | 29.77% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 13360 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 91483 | 59.65% |
| Monoclonal antibody by mouse ascites method | 24200 | 15.78% |
| Other product types | 37690 | 24.57% |
| Total | 153373 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 368792 | 64.46% |
| Legislation on medicinal products for veterinary use and their residues | 115003 | 20.1% |
| Medical devices legislation | 40847 | 7.14% |
| Industrial chemicals legislation | 7479 | 1.31% |
| Plant protection product legislation | 7026 | 1.23% |
| Biocides legislation | 394 | 0.07% |
| Food legislation including food contact material | 1033 | 0.18% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 27971 | 4.89% |
| Cosmetics legislation |  |  |
| Other legislation | 3599 | 0.63% |
| Total | 572144 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 565901 | 98.91% |
| Legislation satisfying national requirements only [within EU] | 1871 | 0.33% |
| Legislation satisfying Non-EU requirements only | 4372 | 0.76% |
| Total | 572144 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 1886926 | 99.23% |
| Yes | 14616 | 0.77% |
| Total | 1901542 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 81482 | 4.29% |
| Mild [up to and including] | 845322 | 44.45% |
| Moderate | 782033 | 41.13% |
| Severe | 192705 | 10.13% |
| Total | 1901542 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 1873951 | 98.55% |
| Yes | 27591 | 1.45% |
| Total | 1901542 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1487378 | 78.22% |
| Genetically altered without a harmful phenotype | 324456 | 17.06% |
| Genetically altered with a harmful phenotype | 89708 | 4.72% |
| Total | 1901542 | 100.00% |

## France: Narrative 2016

**1. General information on any changes in trends observed since the previous reporting period (2015).**

The transposition of Directive 2010/63/EU into French law has given rise to significant changes.

Indeed, the format prescribed by the European Union for the retrospective survey for 2016 under Directive 2010/63/EU, which was transposed into French law on 7 February 2013, is different from that used for the previous surveys under Directive 86/609/EU. Any comparison with the 2015 survey would therefore be inappropriate, particularly for the period 2013-2017, which was marked by transitional regulatory measures.

The scope of the survey has changed considerably:

* only animals for which the experimental procedures ended in 2016 are recorded;
* captive-bred animals present in user establishments are excluded;
* animals involved in procedures below the stress threshold, including genetically modified animal lines that do not exhibit a harmful phenotype, are excluded;
* animals humanely killed according to regulatory methods for the removal of organs or tissue (used for alternative methods) are excluded.

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

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2015). Consequently, any comparative analysis that reached a conclusion regarding an increase or decrease in the number of animals used for scientific purposes would be inappropriate.

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

As the conditions of the statistical survey have changed, its results are not directly comparable with the figures previously published (for 2015). Consequently, any comparative analysis of the changes in trends in actual severities would be inappropriate.

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

The principles of replacement, refinement and reduction have been part of the French policy on the use of animals for scientific purposes since the ten founding measures were introduced in 1992 by the Minister for Research, Hubert Curien. Teaching these principles is an essential part of training staff, whether they are responsible for caring for the animals or for carrying out and designing scientific projects. The work of the National Commission for Animal Testing and the National Ethical Reflection Committee on Animal Testing, which meet several times a year, is crucial in this respect. The transposition of Directive 2010/63/EU, which requires prior authorisation for any project using animals for scientific purposes, and the choice of the French authorities to draw on the expertise of nearly 130 ethical committees spread throughout France, has also encouraged researchers to think more about these three principles and helped increase the sharing of best practice.

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

Grouping species of the same taxon in the ‘other’ category, as proposed by the European Commission, does not always seem to be the most appropriate method and could be improved, in particular in the case of fish and birds.

For example, although zebra-fish account for just 0.5 % of animals used (11,399 animals), ‘other fish’ account for 21.7 % (413,183 animals). The latter category includes farmed fish such as trout, eel, seabass and salmon, the reproduction, physiology and diet of which are the subject of numerous studies, particularly by the National Institute for Agricultural Research (INRA).

Large numbers of birds are also categorised as ‘other’ (46,433 animals), while ‘domestic fowl’ account for 66,734.

Finally, with respect to the distribution of animals involved in procedures imposed by the rules, particular attention was given to completing this section, which had been misunderstood by users in the previous survey. Only 1% of animals were entered in the ‘other’ category in this survey.

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

Procedures are classified into four categories: non-recovery, mild, moderate and severe (including intense/severe procedures). No instances of the ‘severe’ classification being exceeded have been identified.

## France: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1144745 | 59.67% |
| Rats | 172209 | 8.98% |
| Guinea-Pigs | 44705 | 2.33% |
| Hamsters (Syrian) | 10481 | 0.55% |
| Hamsters (Chinese) | 287 | 0.01% |
| Mongolian gerbil | 817 | 0.04% |
| Other Rodents | 651 | 0.03% |
| Rabbits | 117531 | 6.13% |
| Cats | 1067 | 0.06% |
| Dogs | 4204 | 0.22% |
| Ferrets | 160 | 0.01% |
| Other carnivores | 23 | 0% |
| Horses, donkeys and cross-breeds | 540 | 0.03% |
| Pigs | 11707 | 0.61% |
| Goats | 1025 | 0.05% |
| Sheep | 5763 | 0.3% |
| Cattle | 2492 | 0.13% |
| Prosimians | 1 | 0% |
| Marmoset and tamarins | 41 | 0% |
| Cynomolgus monkey | 3170 | 0.17% |
| Rhesus monkey | 173 | 0.01% |
| Vervets (Chlorocebus spp.) | 23 | 0% |
| Baboons | 92 | 0% |
| Squirrel monkey | 8 | 0% |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 20 | 0% |
| Domestic fowl | 56759 | 2.96% |
| Other birds | 14633 | 0.76% |
| Reptiles | 4958 | 0.26% |
| Rana | 36 | 0% |
| Xenopus | 10078 | 0.53% |
| Other Amphibians | 2081 | 0.11% |
| Zebra fish | 13893 | 0.72% |
| Other Fish | 293589 | 15.3% |
| Cephalopods | 440 | 0.02% |
| Total | 1918402 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 1611211 | 85.67% |
| Animals born in the EU but not at a registered breeder | 185781 | 9.88% |
| Animals born in rest of Europe | 59305 | 3.15% |
| Animals born in rest of world | 24313 | 1.29% |
| Total | 1880610 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 126 | 5.44% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 182 | 7.85% |
| Animals born in America | 12 | 0.52% |
| Animals born in Africa | 1979 | 85.38% |
| Animals born elsewhere | 19 | 0.82% |
| Total | 2318 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 | 5 | 0.22% |
| F1 | 1030 | 44.43% |
| F2 or greater | 1272 | 54.87% |
| Self-sustaining colony | 11 | 0.47% |
| Total | 2318 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 809504 | 42.2% |
| Translational and applied research | 482233 | 25.14% |
| Regulatory use and Routine production | 517479 | 26.97% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 635 | 0.03% |
| Preservation of species | 16750 | 0.87% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 34195 | 1.78% |
| Forensic enquiries | 28 | 0% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 57578 | 3% |
| Total | 1918402 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 81024 | 10.01% |
| Cardiovascular Blood and Lymphatic System | 30831 | 3.81% |
| Nervous System | 133609 | 16.51% |
| Respiratory System | 7721 | 0.95% |
| Gastrointestinal System including Liver | 33673 | 4.16% |
| Musculoskeletal System | 14431 | 1.78% |
| Immune System | 81497 | 10.07% |
| Urogenital/Reproductive System | 14140 | 1.75% |
| Sensory Organs (skin, eyes and ears) | 12221 | 1.51% |
| Endocrine System/Metabolism | 63208 | 7.81% |
| Multisystemic | 36302 | 4.48% |
| Ethology / Animal Behaviour /Animal Biology | 226122 | 27.93% |
| Other basic research | 74725 | 9.23% |
| Total | 809504 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 95944 | 19.9% |
| Human Infectious Disorders | 39380 | 8.17% |
| Human Cardiovascular Disorders | 10632 | 2.2% |
| Human Nervous and Mental Disorders | 51007 | 10.58% |
| Human Respiratory Disorders | 1530 | 0.32% |
| Human Gastrointestinal Disorders including Liver | 11753 | 2.44% |
| Human Musculoskeletal Disorders | 12804 | 2.66% |
| Human Immune Disorders | 19730 | 4.09% |
| Human Urogenital/Reproductive Disorders | 727 | 0.15% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 10749 | 2.23% |
| Human Endocrine/Metabolism Disorders | 17398 | 3.61% |
| Other Human Disorders | 5443 | 1.13% |
| Animal Diseases and Disorders | 70126 | 14.54% |
| Animal Welfare | 749 | 0.16% |
| Diagnosis of diseases | 115230 | 23.9% |
| Plant diseases | 56 | 0.01% |
| Non-regulatory toxicology and ecotoxicology | 18975 | 3.93% |
| Total | 482233 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 236097 | 45.62% |
| Other efficacy and tolerance testing | 27122 | 5.24% |
| Toxicity and other safety testing including pharmacology | 104065 | 20.11% |
| Routine production | 150195 | 29.02% |
| Total | 517479 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 25789 | 10.92% |
| Pyrogenicity testing | 7689 | 3.26% |
| Batch potency testing | 164164 | 69.53% |
| Other quality controls | 38455 | 16.29% |
| Total | 236097 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 4796 | 4.61% |
| Skin irritation/corrosion | 823 | 0.79% |
| Skin sensitisation | 13287 | 12.77% |
| Eye irritation/corrosion | 283 | 0.27% |
| Repeated dose toxicity | 24301 | 23.35% |
| Carcinogenicity | 412 | 0.4% |
| Genotoxicity | 736 | 0.71% |
| Reproductive toxicity | 16635 | 15.99% |
| Developmental toxicity | 6451 | 6.2% |
| Neurotoxicity | 18 | 0.02% |
| Kinetics | 12205 | 11.73% |
| Pharmaco-dynamics (incl safety pharmacology) | 10704 | 10.29% |
| Phototoxicity | 403 | 0.39% |
| Ecotoxicity | 11352 | 10.91% |
| Safety testing in food and feed area | 294 | 0.28% |
| Target animal safety | 58 | 0.06% |
| Other toxicity/safety testing | 1307 | 1.26% |
| Total | 104065 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 706 | 14.72% |
| Other lethal methods | 1256 | 26.19% |
| Non lethal methods | 2834 | 59.09% |
| Total | 4796 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 13624 | 56.06% |
| 29 - 90 days | 5861 | 24.12% |
| > 90 days | 4816 | 19.82% |
| Total | 24301 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 10156 | 89.46% |
| Chronic toxicity | 1078 | 9.5% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation | 42 | 0.37% |
| Other ecotoxicity | 76 | 0.67% |
| Total | 11352 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 73841 | 49.16% |
| Monoclonal antibody by mouse ascites method | 46128 | 30.71% |
| Other product types | 30226 | 20.12% |
| Total | 150195 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 340076 | 65.72% |
| Legislation on medicinal products for veterinary use and their residues | 79098 | 15.29% |
| Medical devices legislation | 66507 | 12.85% |
| Industrial chemicals legislation | 12412 | 2.4% |
| Plant protection product legislation | 3970 | 0.77% |
| Biocides legislation | 439 | 0.08% |
| Food legislation including food contact material | 715 | 0.14% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 13556 | 2.62% |
| Cosmetics legislation |  |  |
| Other legislation | 706 | 0.14% |
| Total | 517479 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 497155 | 96.07% |
| Legislation satisfying national requirements only [within EU] | 1318 | 0.25% |
| Legislation satisfying Non-EU requirements only | 19006 | 3.67% |
| Total | 517479 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 1882928 | 98.15% |
| Yes | 35474 | 1.85% |
| Total | 1918402 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 105941 | 5.52% |
| Mild [up to and including] | 766947 | 39.98% |
| Moderate | 726836 | 37.89% |
| Severe | 318678 | 16.61% |
| Total | 1918402 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 1874323 | 97.7% |
| Yes | 44079 | 2.3% |
| Total | 1918402 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1501546 | 78.27% |
| Genetically altered without a harmful phenotype | 372200 | 19.4% |
| Genetically altered with a harmful phenotype | 44656 | 2.33% |
| Total | 1918402 | 100.00% |

## France: Narrative 2017

**1. General information on any changes in trends observed since the previous reporting period (2016).**

The 2017 survey comprises the responses of 552 establishments authorised to use animals for scientific purposes, representing an increase of 8.2% compared to 2016, which reflects an improved response rate to the survey.

The number of animals is decreasing (1,914,174 in 2017 compared to 1,918,481 in 2016, amounting to a decrease of 4,307 animals or 0.22%). This decrease is all the more significant since the number of respondents to the 2017 survey is considerably higher than it was in 2016. This trend will be reviewed once the 2018 figures are available at the end of 2019.

The decrease observed is significant and supported by the fact the survey response rate has increased by around 8%.

Apart from the number of animals, the type of species used in experimental procedures, the degree of severity and the proportion of genetically modified animals remain extremely close to the previous year’s figures.

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

The statistics are not yet fully comparable from one year to the next, because France is still in a transitional period in order to implement the Directive. Subject to that reservation, we can nevertheless detect the following trends:

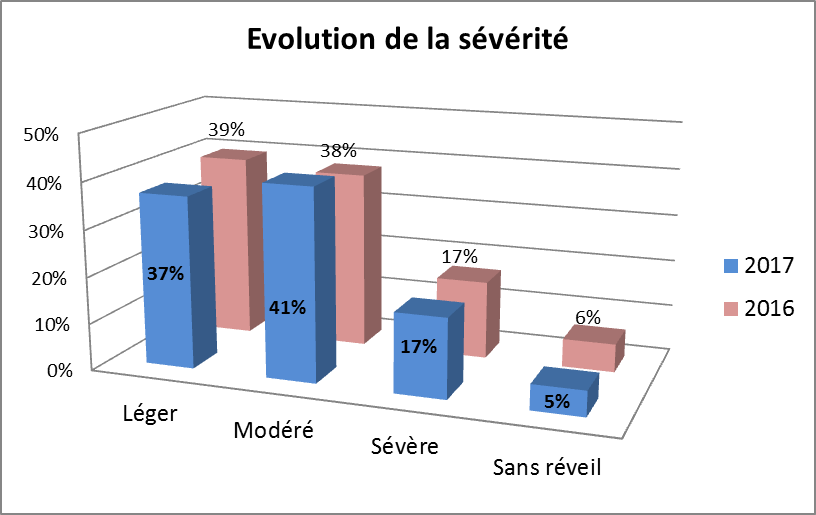
- stable use of non-human primates and a decrease in the number of domestic carnivores (dogs and cats) compared to 2016, which can be linked with concerted efforts made for several years to reduce the use of these sensitive species;

- an increase in the proportion of F2 generation non-human primates, reflecting a gradual shift towards achieving the 100% target set for 2022;

- stable use of genetically modified animals and a large reduction in the proportion of harmful genotypes (2.8% of animals in 2017).

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

The actual severity is very stable from one year to the next. There has been a slight increase in the number of animals used in moderate procedures compared to mild procedures (see graph below). However, this change does not appear to be significant: it could be the result of establishments applying the severity assessment criteria better, thanks to the educational work carried out by the ethics committees and the Ministry responsible for research.



Key to graph:

|  |  |  |  |
| --- | --- | --- | --- |
| **Changes in severity** | | | |
| Mild | Moderate | Severe | Non-recovery |

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

France continues to promote the principles of replacement, refinement and reduction very actively, in particular through an ambitious training programme for staff in charge of both caring for animals and designing and carrying out scientific projects. The work of the National Commission for Animal Testing (CNEA) and the National Ethical Reflection Committee on Animal Testing (CNREEA), each of which meets several times a year, is also crucial.

The national platform for the development of alternative methods (FRANCOPA), which is a member of the European ECOPA network and brings together all stakeholders, also works to promote the three Rs.

The French authorities can also draw on the expertise of almost 130 ethical committees spread throughout France, which, on a local level, all help researchers think more about ethical issues, raise awareness of these three principles and encourage the sharing of best practice.

We believe that the decrease in the average number of animals used per establishment, referred to above (question 1), is partly the result of these efforts.

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

As in previous years, the ‘other fish’ category remains very large, corresponding to 13.8% of the animals used (267,800 animals). This category includes farmed fish such as trout, eel, seabass and salmon, the reproduction, physiology and diet of which are the subject of numerous studies, particularly by the National Institute for Agricultural Research (INRA).

The ‘other birds’ category still covers 1.4% of animals (27,200 animals), compared to 43,100 ‘domestic fowl’.

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

No authorisations were granted in 2017 for requests exceeding the ‘severe’ classification.

## France: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1134517 | 59.27% |
| Rats | 183714 | 9.6% |
| Guinea-Pigs | 45034 | 2.35% |
| Hamsters (Syrian) | 6529 | 0.34% |
| Hamsters (Chinese) | 167 | 0.01% |
| Mongolian gerbil | 429 | 0.02% |
| Other Rodents | 957 | 0.05% |
| Rabbits | 127204 | 6.65% |
| Cats | 867 | 0.05% |
| Dogs | 4106 | 0.21% |
| Ferrets | 148 | 0.01% |
| Other carnivores | 27 | 0% |
| Horses, donkeys and cross-breeds | 305 | 0.02% |
| Pigs | 10346 | 0.54% |
| Goats | 838 | 0.04% |
| Sheep | 5396 | 0.28% |
| Cattle | 1777 | 0.09% |
| Prosimians | 86 | 0% |
| Marmoset and tamarins | 224 | 0.01% |
| Cynomolgus monkey | 3279 | 0.17% |
| Rhesus monkey | 71 | 0% |
| Vervets (Chlorocebus spp.) | 38 | 0% |
| Baboons | 32 | 0% |
| Squirrel monkey | 7 | 0% |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) | 9 | 0% |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 18525 | 0.97% |
| Domestic fowl | 43144 | 2.25% |
| Other birds | 27225 | 1.42% |
| Reptiles | 3462 | 0.18% |
| Rana | 118 | 0.01% |
| Xenopus | 4897 | 0.26% |
| Other Amphibians | 742 | 0.04% |
| Zebra fish | 21879 | 1.14% |
| Other Fish | 268074 | 14% |
| Cephalopods | 1 | 0% |
| Total | 1914174 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 1564017 | 83.58% |
| Animals born in the EU but not at a registered breeder | 204920 | 10.95% |
| Animals born in rest of Europe | 48681 | 2.6% |
| Animals born in rest of world | 53666 | 2.87% |
| Total | 1871284 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| 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 |
| F0 |  |  |
| F1 | 885 | 38.41% |
| F2 or greater | 1285 | 55.77% |
| Self-sustaining colony | 134 | 5.82% |
| Total | 2304 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 731041 | 38.19% |
| Translational and applied research | 479372 | 25.04% |
| Regulatory use and Routine production | 574030 | 29.99% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 4918 | 0.26% |
| Preservation of species | 18786 | 0.98% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 35512 | 1.86% |
| Forensic enquiries | 8 | 0% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 70507 | 3.68% |
| Total | 1914174 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 94213 | 12.89% |
| Cardiovascular Blood and Lymphatic System | 32577 | 4.46% |
| Nervous System | 141408 | 19.34% |
| Respiratory System | 12314 | 1.68% |
| Gastrointestinal System including Liver | 28076 | 3.84% |
| Musculoskeletal System | 17501 | 2.39% |
| Immune System | 92193 | 12.61% |
| Urogenital/Reproductive System | 19906 | 2.72% |
| Sensory Organs (skin, eyes and ears) | 5435 | 0.74% |
| Endocrine System/Metabolism | 40708 | 5.57% |
| Multisystemic | 20896 | 2.86% |
| Ethology / Animal Behaviour /Animal Biology | 164456 | 22.5% |
| Other basic research | 61358 | 8.39% |
| Total | 731041 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 120343 | 25.1% |
| Human Infectious Disorders | 52555 | 10.96% |
| Human Cardiovascular Disorders | 15203 | 3.17% |
| Human Nervous and Mental Disorders | 46348 | 9.67% |
| Human Respiratory Disorders | 6669 | 1.39% |
| Human Gastrointestinal Disorders including Liver | 12373 | 2.58% |
| Human Musculoskeletal Disorders | 14481 | 3.02% |
| Human Immune Disorders | 19048 | 3.97% |
| Human Urogenital/Reproductive Disorders | 2240 | 0.47% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 7760 | 1.62% |
| Human Endocrine/Metabolism Disorders | 12502 | 2.61% |
| Other Human Disorders | 9742 | 2.03% |
| Animal Diseases and Disorders | 37943 | 7.92% |
| Animal Welfare | 216 | 0.05% |
| Diagnosis of diseases | 97413 | 20.32% |
| Plant diseases | 89 | 0.02% |
| Non-regulatory toxicology and ecotoxicology | 24447 | 5.1% |
| Total | 479372 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Neurotoxicity |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 702 | 21.31% |
| Other lethal methods | 561 | 17.03% |
| Non lethal methods | 2031 | 61.66% |
| Total | 3294 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 12892 | 53.16% |
| 29 - 90 days | 6543 | 26.98% |
| > 90 days | 4815 | 19.86% |
| Total | 24250 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 10955 | 80.95% |
| Chronic toxicity | 1107 | 8.18% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation | 846 | 6.25% |
| Other ecotoxicity | 625 | 4.62% |
| Total | 13533 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | 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 to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 334865 | 58.34% |
| Legislation on medicinal products for veterinary use and their residues | 82088 | 14.3% |
| Medical devices legislation | 64309 | 11.2% |
| Industrial chemicals legislation | 12737 | 2.22% |
| Plant protection product legislation | 4541 | 0.79% |
| Biocides legislation | 757 | 0.13% |
| Food legislation including food contact material | 698 | 0.12% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 73260 | 12.76% |
| Cosmetics legislation |  |  |
| Other legislation | 775 | 0.14% |
| Total | 574030 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 552522 | 96.25% |
| Legislation satisfying national requirements only [within EU] | 2643 | 0.46% |
| Legislation satisfying Non-EU requirements only | 18865 | 3.29% |
| Total | 574030 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 1873588 | 97.88% |
| Yes | 40586 | 2.12% |
| Total | 1914174 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 103094 | 5.39% |
| Mild [up to and including] | 703783 | 36.77% |
| Moderate | 780853 | 40.79% |
| Severe | 326444 | 17.05% |
| Total | 1914174 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 1868750 | 97.63% |
| Yes | 45424 | 2.37% |
| Total | 1914174 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1485568 | 77.61% |
| Genetically altered without a harmful phenotype | 375530 | 19.62% |
| Genetically altered with a harmful phenotype | 53076 | 2.77% |
| Total | 1914174 | 100.00% |

# Germany

## Germany: Narrative 2015

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

In 2015, approximately 2 million vertebrates and cephalopods were used in Germany in animal experiments within the meaning of Section 7(2) of the German Animal Welfare Act (Tierschutzgesetz). Section 7(2) of the Animal Welfare Act defines the term ‘animal experiment’. The figures are virtually unchanged compared to the previous year. Approximately 82% of the test animals used were rodents, mostly mice and rats, whereby mice comprised approximately 68% of the animals used. Approximately 8% of the animals were fish, approximately 5% were rabbits and approximately 2% were birds.

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

Killing for scientific purposes

In addition to the guidelines of the EU Laboratory Animals Directive, Germany also includes animals that were killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals’ organs or cell material for scientific purposes. Approximately 755,000 animals were used to this end in 2015, which means that overall approximately 34,000 fewer animals were used than in the previous year.

Genetically modified animals

The number of genetically modified animals has risen slightly in comparison to the previous year. Approximately 1,115,000 of the total number of animals used were genetically modified. As such, the percentage of these animals was approximately 40% (in 2014 this was approximately 34%). In particular mice (91%) and fish (7%) were used.

Primates

The number of primates used also rose slightly. In 2015 a total of 3,141 primates were used, 293 more than in the previous year.

Dogs and cats

The number of dogs and cats used amounted to 4,491 and 1,112 respectively, used in particular to research animal diseases and for the statutory toxicity and safety testing of animal and human medicines. There are no relevant differences compared to the previous year.

Scientific purposes

Although many scientific questions can be answered nowadays through the use of cell cultures, computer-assisted procedures and other alternative methods, it is not yet possible to do without the use of animals for medical research and other scientific purposes. For instance, approximately 48% of the animals used in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act were used for basic research and approximately 15% were used for researching human and animal diseases. Approximately 31% of the animals were used in the manufacture and quality control of medical products or for toxicological safety tests. Approximately 6% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

This means that as compared to 2014 there was an increase in the areas of basic research (approximately 5%) and the manufacture and quality control of medical products or toxicological safety tests (approximately 6%), while in the area of other purposes there was a decrease of approximately 10%.

* **Basic research**

Within basic research, research into the nervous system (approximately 14%) and the immune system (approximately 27%) was particularly important in 2015. As such, research into the immune system showed an increase of approximately 10% compared to the previous year.

* **Human and animal diseases**

Under research into human and animal diseases, there was an emphasis on the area of human cancers, for which approximately 37% of test animals used in this field of research were utilised. Here, too, there was an increase of approximately 10% as compared to 2014.

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

With regard to the severity of experiments, it is apparent that the severity classification in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act was predominantly ‘low’ (approximately 63%). Here a slight increase as compared to the previous year (approximately 60%) can be seen. The share of animal experiments classified as ‘medium’ or ‘severe’ was approximately 24% and 5% respectively. A slight decrease can be seen as compared to the previous year (21% and 6% respectively). The share of animal experiments that were carried out entirely under general anaesthesia and from which the animal never regained consciousness was approximately 8%. Here as well, a decrease can be seen as compared to 2014 (13%).

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

The BMEL is endeavouring to reduce the number of animals used in experiments and provides financial support to the Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen (Foundation for the promotion of alternate and complementary methods to reduce animal experiments), among other organisations, and awards the annual Animal Welfare Research Prize promoting methodological work with the goal of reducing and replacing animal experiments. This prize consists of a monetary award of €15,000. In addition, the German government’s involvement in reducing the number of animals used in experiments is part of the BMEL’s initiative ‘Minding animals – new ways to improve animal welfare’. In the context of this initiative, the Centre for Documentation and Evaluation of Alternatives to Animal Experiments (Zentralstelle zur Erfassung und Bewertung von Ersatz- und Ergänzungsmethoden zum Tierversuch, ZEBET) within the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung) was expanded into the German Centre for the Protection of Laboratory Animals (Deutsches Zentrum zum Schutz von Versuchstieren, Bf3R).

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

Category ‘other animal species’

In this category, particularly in the areas ‘other rodent species’ and ‘other fish species’, there are a greater number of additional animal species.

Under rodents, the common vole was used in particular. This primarily concerns animals caught in the wild which were re-released after the experiment was finished. These animals were mainly used in the context of research into common vole populations and their development on agricultural land. As a rule the severity classification for the animals involved was ‘low’.

For fish, primarily local wild fish (e.g. common bream, brown trout, common roach, stickleback) were used in the context of basic ethological research. Here, too, this primarily concerns animals caught in the wild which were re-released after the experiment was finished. And here too the severity classification was ‘low’ as a rule.

Category ‘other uses’

The emphasis in this category is in the areas ‘basic research’ and ‘regulatory purposes’.

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

* creating and genotyping new genetically modified animal bloodlines as models for human and animal diseases;
* molecular developmental genetics;
* studies of evolutionary changes in humans and animals;
* research into various new methods for marker, blood and biopsy sampling with the goal of refining these methods;
* research into the structure and function of G-protein-coupled receptors;
* research in the field of human and animal microbiology;
* research in the context of gerontology.

As a rule the severity classification for the animals involved was ‘low’.

In addition, in the area of **regulatory experiments** the following topics of focus were particularly apparent:

* testing new diagnostic and therapeutic procedures in the field of human cancers;
* determining population development in common vole populations on agricultural land in the context of safety tests (e.g. plant protection products);
* propagation of pathogens for developing in vitro diagnostics;
* pharmacodynamic research in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

As a rule the severity classification for the animals involved was ‘low’.

Category ‘other legal provisions’

In the context of this category, predominantly experiments were carried out to test substances hazardous to water in accordance with the German Administrative Provision concerning the Water Resources Act (Verwaltungsvorschrift zum Wasserhaushaltsgesetz). The severity classification for the animals involved in these experiments varied widely overall (from ‘low’ to ‘severe’).

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

In 2015 there were no experiments carried out in Germany in the context of which the classification exceeded ‘severe’.

## Germany: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1400822 | 68.49% |
| Rats | 263318 | 12.87% |
| Guinea-Pigs | 18237 | 0.89% |
| Hamsters (Syrian) | 1390 | 0.07% |
| Hamsters (Chinese) | 30 | 0% |
| Mongolian gerbil | 4568 | 0.22% |
| Other Rodents | 12793 | 0.63% |
| Rabbits | 110988 | 5.43% |
| Cats | 1112 | 0.05% |
| Dogs | 4491 | 0.22% |
| Ferrets | 230 | 0.01% |
| Other carnivores | 686 | 0.03% |
| Horses, donkeys and cross-breeds | 1507 | 0.07% |
| Pigs | 12305 | 0.6% |
| Goats | 904 | 0.04% |
| Sheep | 2290 | 0.11% |
| Cattle | 4029 | 0.2% |
| Prosimians | 102 | 0% |
| Marmoset and tamarins | 292 | 0.01% |
| Cynomolgus monkey | 2678 | 0.13% |
| Rhesus monkey | 39 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons | 6 | 0% |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) | 1 | 0% |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 1383 | 0.07% |
| Domestic fowl | 25658 | 1.25% |
| Other birds | 13663 | 0.67% |
| Reptiles | 501 | 0.02% |
| Rana | 132 | 0.01% |
| Xenopus | 4038 | 0.2% |
| Other Amphibians | 2190 | 0.11% |
| Zebra fish | 88147 | 4.31% |
| Other Fish | 66731 | 3.26% |
| Cephalopods |  |  |
| Total | 2045261 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 1888405 | 94.58% |
| Animals born in the EU but not at a registered breeder | 82266 | 4.12% |
| Animals born in rest of Europe | 11491 | 0.58% |
| Animals born in rest of world | 14466 | 0.72% |
| Total | 1996628 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 414 | 17.31% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 1237 | 51.71% |
| Animals born in America | 9 | 0.38% |
| Animals born in Africa | 732 | 30.6% |
| Animals born elsewhere |  |  |
| Total | 2392 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 505 | 21.11% |
| F2 or greater | 1204 | 50.33% |
| Self-sustaining colony | 683 | 28.55% |
| Total | 2392 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 975689 | 47.7% |
| Translational and applied research | 312138 | 15.26% |
| Regulatory use and Routine production | 629182 | 30.76% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 5991 | 0.29% |
| Preservation of species | 29297 | 1.43% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 49389 | 2.41% |
| Forensic enquiries | 15 | 0% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 43560 | 2.13% |
| Total | 2045261 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 81162 | 8.32% |
| Cardiovascular Blood and Lymphatic System | 81552 | 8.36% |
| Nervous System | 140795 | 14.43% |
| Respiratory System | 33612 | 3.44% |
| Gastrointestinal System including Liver | 26877 | 2.75% |
| Musculoskeletal System | 18068 | 1.85% |
| Immune System | 263000 | 26.96% |
| Urogenital/Reproductive System | 20090 | 2.06% |
| Sensory Organs (skin, eyes and ears) | 27615 | 2.83% |
| Endocrine System/Metabolism | 43757 | 4.48% |
| Multisystemic | 49023 | 5.02% |
| Ethology / Animal Behaviour /Animal Biology | 31730 | 3.25% |
| Other basic research | 158408 | 16.24% |
| Total | 975689 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 115200 | 36.91% |
| Human Infectious Disorders | 21784 | 6.98% |
| Human Cardiovascular Disorders | 16246 | 5.2% |
| Human Nervous and Mental Disorders | 47429 | 15.19% |
| Human Respiratory Disorders | 15252 | 4.89% |
| Human Gastrointestinal Disorders including Liver | 8736 | 2.8% |
| Human Musculoskeletal Disorders | 3253 | 1.04% |
| Human Immune Disorders | 14081 | 4.51% |
| Human Urogenital/Reproductive Disorders | 5321 | 1.7% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 3123 | 1% |
| Human Endocrine/Metabolism Disorders | 20409 | 6.54% |
| Other Human Disorders | 2224 | 0.71% |
| Animal Diseases and Disorders | 20203 | 6.47% |
| Animal Welfare | 4743 | 1.52% |
| Diagnosis of diseases | 4539 | 1.45% |
| Plant diseases | 21 | 0.01% |
| Non-regulatory toxicology and ecotoxicology | 9574 | 3.07% |
| Total | 312138 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 235332 | 37.4% |
| Other efficacy and tolerance testing | 45385 | 7.21% |
| Toxicity and other safety testing including pharmacology | 256282 | 40.73% |
| Routine production | 92183 | 14.65% |
| Total | 629182 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 43768 | 18.6% |
| Pyrogenicity testing | 6992 | 2.97% |
| Batch potency testing | 184434 | 78.37% |
| Other quality controls | 138 | 0.06% |
| Total | 235332 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 8608 | 3.36% |
| Skin irritation/corrosion | 894 | 0.35% |
| Skin sensitisation | 11170 | 4.36% |
| Eye irritation/corrosion | 225 | 0.09% |
| Repeated dose toxicity | 22769 | 8.88% |
| Carcinogenicity | 5053 | 1.97% |
| Genotoxicity | 4167 | 1.63% |
| Reproductive toxicity | 22388 | 8.74% |
| Developmental toxicity | 15019 | 5.86% |
| Neurotoxicity | 90 | 0.04% |
| Kinetics | 37692 | 14.71% |
| Pharmaco-dynamics (incl safety pharmacology) | 88650 | 34.59% |
| Phototoxicity | 12 | 0% |
| Ecotoxicity | 31374 | 12.24% |
| Safety testing in food and feed area |  |  |
| Target animal safety | 1601 | 0.62% |
| Other toxicity/safety testing | 6570 | 2.56% |
| Total | 256282 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 3559 | 41.35% |
| Other lethal methods | 117 | 1.36% |
| Non lethal methods | 4932 | 57.3% |
| Total | 8608 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 17256 | 75.79% |
| 29 - 90 days | 3132 | 13.76% |
| > 90 days | 2381 | 10.46% |
| Total | 22769 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 8021 | 25.57% |
| Chronic toxicity | 6288 | 20.04% |
| Reproductive ecotoxicity | 1643 | 5.24% |
| Endocrine activity | 8258 | 26.32% |
| Bioaccumulation | 1858 | 5.92% |
| Other ecotoxicity | 5306 | 16.91% |
| Total | 31374 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 86209 | 93.52% |
| Monoclonal antibody by mouse ascites method | 894 | 0.97% |
| Other product types | 5080 | 5.51% |
| Total | 92183 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 441537 | 70.18% |
| Legislation on medicinal products for veterinary use and their residues | 38179 | 6.07% |
| Medical devices legislation | 61866 | 9.83% |
| Industrial chemicals legislation | 50563 | 8.04% |
| Plant protection product legislation | 31544 | 5.01% |
| Biocides legislation | 1200 | 0.19% |
| Food legislation including food contact material | 38 | 0.01% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 1638 | 0.26% |
| Cosmetics legislation |  |  |
| Other legislation | 2617 | 0.42% |
| Total | 629182 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 593854 | 94.39% |
| Legislation satisfying national requirements only [within EU] | 19377 | 3.08% |
| Legislation satisfying Non-EU requirements only | 15951 | 2.54% |
| Total | 629182 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 1999020 | 97.74% |
| Yes | 46241 | 2.26% |
| Total | 2045261 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 159720 | 7.81% |
| Mild [up to and including] | 1282093 | 62.69% |
| Moderate | 489855 | 23.95% |
| Severe | 113593 | 5.55% |
| Total | 2045261 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 1889941 | 92.41% |
| Yes | 155320 | 7.59% |
| Total | 2045261 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1304619 | 63.79% |
| Genetically altered without a harmful phenotype | 626034 | 30.61% |
| Genetically altered with a harmful phenotype | 114608 | 5.6% |
| Total | 2045261 | 100.00% |

## Germany: Narrative 2016

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

In 2016, approximately 2 million vertebrates and cephalopods were used in Germany in animal experiments within the meaning of Section 7(2) of the German Animal Welfare Act (Tierschutzgesetz). Section 7(2) of the Animal Welfare Act defines the term ‘animal experiment’. The figures are virtually unchanged compared to the previous year. Approximately 79% of the test animals used were rodents, mostly mice and rats, whereby mice comprised approximately 66% of the animals used. Approximately 12% of the animals were fish, approximately 5% were rabbits and approximately 2% were birds.

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

Killing for scientific purposes

In addition to the guidelines of the EU Laboratory Animals Directive, Germany also includes animals that were killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals’ organs or cell material for scientific purposes. Approximately 726,000 animals were used to this end in 2016, which means that overall approximately 29,000 fewer animals were used than in the previous year.

Genetically modified animals

The number of genetically modified animals has risen slightly in comparison to the previous year. Approximately 1,200,000 of the total number of animals used were genetically modified. As such, the percentage of these animals was approximately 42% (in 2015 this was approximately 40%). In particular mice (86%) and fish (12%) were used.

Primates

The number of primates used also showed a definite decrease. In 2015 a total of 2,462 primates were used, 679 fewer than in the previous year.

Dogs and cats

The number of dogs and cats used amounted to 3,977 and 766 respectively, used in particular to research animal diseases and for the statutory toxicity and safety testing of animal and human medicines. As compared to the previous year, there was a decrease in the number of dogs (4,491 in 2015) and cats (1,112 in 2015).

Scientific purposes

Although many scientific questions can be answered nowadays through the use of cell cultures, computer-assisted procedures and other alternative methods, it is not yet possible to do without the use of animals for medical research and other scientific purposes. For instance, approximately 53% of the animals used in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act were used for basic research and approximately 14% were used for researching human and animal diseases. Approximately 26% of the animals were used in the manufacture and quality control of medical products or for toxicological safety tests. Approximately 7% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

This means that as compared to 2015 there was an increase in the area of basic research (approximately 5%), while in the area of the manufacture and quality control of medical products or toxicological safety tests there was a decrease of approximately 6%.

* **Basic research**

Within basic research, research into the nervous system (approximately 15%) and the immune system (approximately 20%) was particularly important in 2016. As such, research into the immune system showed a decrease of approximately 7% compared to the previous year.

* **Human and animal diseases**

Under research into human and animal diseases, there was an emphasis on the area of human cancers, for which approximately 37% of test animals used in this field of research were utilised. No change can be seen here as compared to 2015.

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

With regard to the severity of experiments, it is apparent that the severity classification in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act was predominantly ‘low’ (approximately 63%). The share of animal experiments classified as ‘medium’ or ‘severe’ was approximately 23% and 7% respectively. Compared to the previous year, the number of experiments classified as ‘severe’ showed a slight increase of approximately 2%. The share of animal experiments that were carried out entirely under general anaesthesia and from which the animal never regained consciousness was approximately 7% and thereby at the level of the previous year (approximately 8%).

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

The BMEL is endeavouring to reduce the number of animals used in experiments and provides financial support to the Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen (Foundation for the promotion of alternate and complementary methods to reduce animal experiments), among other organisations, and awards the annual Animal Welfare Research Prize promoting methodological work with the goal of reducing and replacing animal experiments. In 2016 the amount of the prize was increased from €15,000 to €25,000. In addition, the German government’s involvement in reducing the number of animals used in experiments is part of the BMEL’s initiative ‘Minding animals - new ways to improve animal welfare’.

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

Category ‘other animal species’

In this category, particularly in the areas ‘other fish species’ and ‘other bird species’, there are a greater number of additional animal species.

For fish, primarily local wild fish (e.g. grayling, common roach, stickleback, common nase) were used in the contexts of basic ethological research and research into species conservation. This partially concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification was ‘low’.

Among birds, primarily turkeys and local wild bird species (e.g. tit, pheasant, common buzzard, pigeon) were used. While turkeys were mainly used in the context of researching various animal diseases, the various wild bird species were used in the context of basic ethological research. This primarily concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification for the animals involved was ‘low’.

Category ‘other uses’

The emphasis in this category is in the areas ‘basic research’ and ‘regulatory purposes’.

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

* creating and genotyping new genetically modified animal bloodlines as models for human and animal diseases;
* molecular developmental genetics;
* research into various new methods for marker, blood and biopsy sampling with the goal of refining these methods;
* research in the field of human and animal microbiology;
* research in the context of gerontology.

As a rule the severity classification for the animals involved was ‘low’.

In addition, in the area of regulatory experiments the following topics of focus were particularly apparent:

* testing new diagnostic and therapeutic procedures in the field of human cancers;
* determining population development in common vole populations on agricultural land in the context of safety tests (e.g. plant protection products);
* propagation of pathogens for developing in vitro diagnostics;
* pharmacodynamic research in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

As a rule the severity classification for the animals involved was ‘low’.

Category ‘other legal provisions’

In the context of this category the following other legal provisions are particularly referred to:

* test of substances hazardous to water in accordance with the German Administrative Provision concerning the Water Resources Act (Verwaltungsvorschrift zum Wasserhaushaltsgesetz);
* test of products in accordance with Regulation (EC) No 1272/2008 (fibre persistence test);
* test of products in the framework of the German Infection Protection Act (Infektionsschutzgesetz);
* test of products in accordance with the German Animal Vaccine Regulation (Tierimpfstoffverordnung).

The severity classification for the animals involved in these experiments varied widely overall (from ‘low’ to ‘severe’).

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

In 2016 there were no experiments carried out in Germany in the context of which the classification exceeded ‘severe’.

## Germany: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1400971 | 65.83% |
| Rats | 244274 | 11.48% |
| Guinea-Pigs | 14184 | 0.67% |
| Hamsters (Syrian) | 1101 | 0.05% |
| Hamsters (Chinese) | 2 | 0% |
| Mongolian gerbil | 4769 | 0.22% |
| Other Rodents | 6639 | 0.31% |
| Rabbits | 98331 | 4.62% |
| Cats | 766 | 0.04% |
| Dogs | 3964 | 0.19% |
| Ferrets | 130 | 0.01% |
| Other carnivores | 474 | 0.02% |
| Horses, donkeys and cross-breeds | 1270 | 0.06% |
| Pigs | 16727 | 0.79% |
| Goats | 223 | 0.01% |
| Sheep | 3750 | 0.18% |
| Cattle | 5432 | 0.26% |
| Prosimians | 117 | 0.01% |
| Marmoset and tamarins | 113 | 0.01% |
| Cynomolgus monkey | 2058 | 0.1% |
| Rhesus monkey | 86 | 0% |
| Vervets (Chlorocebus spp.) | 18 | 0% |
| Baboons | 8 | 0% |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) | 18 | 0% |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 1143 | 0.05% |
| Domestic fowl | 29853 | 1.4% |
| Other birds | 16554 | 0.78% |
| Reptiles | 454 | 0.02% |
| Rana | 930 | 0.04% |
| Xenopus | 5237 | 0.25% |
| Other Amphibians | 2675 | 0.13% |
| Zebra fish | 178224 | 8.37% |
| Other Fish | 87759 | 4.12% |
| Cephalopods |  |  |
| Total | 2128254 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 1951771 | 94.31% |
| Animals born in the EU but not at a registered breeder | 94479 | 4.57% |
| Animals born in rest of Europe | 9258 | 0.45% |
| Animals born in rest of world | 14101 | 0.68% |
| Total | 2069609 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 192 | 10.89% |
| Animals born in rest of Europe | 2 | 0.11% |
| Animals born in Asia | 1039 | 58.93% |
| Animals born in America |  |  |
| Animals born in Africa | 530 | 30.06% |
| Animals born elsewhere |  |  |
| Total | 1763 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 403 | 22.86% |
| F2 or greater | 895 | 50.77% |
| Self-sustaining colony | 465 | 26.38% |
| Total | 1763 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 1117731 | 52.52% |
| Translational and applied research | 307138 | 14.43% |
| Regulatory use and Routine production | 554982 | 26.08% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 8101 | 0.38% |
| Preservation of species | 40387 | 1.9% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 48931 | 2.3% |
| Forensic enquiries | 28 | 0% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 50956 | 2.39% |
| Total | 2128254 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 84836 | 7.59% |
| Cardiovascular Blood and Lymphatic System | 101807 | 9.11% |
| Nervous System | 168180 | 15.05% |
| Respiratory System | 24355 | 2.18% |
| Gastrointestinal System including Liver | 31097 | 2.78% |
| Musculoskeletal System | 19328 | 1.73% |
| Immune System | 220107 | 19.69% |
| Urogenital/Reproductive System | 25928 | 2.32% |
| Sensory Organs (skin, eyes and ears) | 28599 | 2.56% |
| Endocrine System/Metabolism | 117143 | 10.48% |
| Multisystemic | 137863 | 12.33% |
| Ethology / Animal Behaviour /Animal Biology | 35228 | 3.15% |
| Other basic research | 123260 | 11.03% |
| Total | 1117731 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 115230 | 37.52% |
| Human Infectious Disorders | 22052 | 7.18% |
| Human Cardiovascular Disorders | 14597 | 4.75% |
| Human Nervous and Mental Disorders | 41343 | 13.46% |
| Human Respiratory Disorders | 16124 | 5.25% |
| Human Gastrointestinal Disorders including Liver | 10359 | 3.37% |
| Human Musculoskeletal Disorders | 3572 | 1.16% |
| Human Immune Disorders | 14685 | 4.78% |
| Human Urogenital/Reproductive Disorders | 3773 | 1.23% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 5713 | 1.86% |
| Human Endocrine/Metabolism Disorders | 14638 | 4.77% |
| Other Human Disorders | 4223 | 1.37% |
| Animal Diseases and Disorders | 23117 | 7.53% |
| Animal Welfare | 7202 | 2.34% |
| Diagnosis of diseases | 3412 | 1.11% |
| Plant diseases | 17 | 0.01% |
| Non-regulatory toxicology and ecotoxicology | 7081 | 2.31% |
| Total | 307138 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 186497 | 33.6% |
| Other efficacy and tolerance testing | 45456 | 8.19% |
| Toxicity and other safety testing including pharmacology | 228227 | 41.12% |
| Routine production | 94802 | 17.08% |
| Total | 554982 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 27627 | 14.81% |
| Pyrogenicity testing | 347 | 0.19% |
| Batch potency testing | 155904 | 83.6% |
| Other quality controls | 2619 | 1.4% |
| Total | 186497 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 7255 | 3.18% |
| Skin irritation/corrosion | 758 | 0.33% |
| Skin sensitisation | 8604 | 3.77% |
| Eye irritation/corrosion | 200 | 0.09% |
| Repeated dose toxicity | 18970 | 8.31% |
| Carcinogenicity | 799 | 0.35% |
| Genotoxicity | 2743 | 1.2% |
| Reproductive toxicity | 14000 | 6.13% |
| Developmental toxicity | 17916 | 7.85% |
| Neurotoxicity | 166 | 0.07% |
| Kinetics | 30657 | 13.43% |
| Pharmaco-dynamics (incl safety pharmacology) | 92116 | 40.36% |
| Phototoxicity |  |  |
| Ecotoxicity | 27424 | 12.02% |
| Safety testing in food and feed area | 86 | 0.04% |
| Target animal safety | 3905 | 1.71% |
| Other toxicity/safety testing | 2628 | 1.15% |
| Total | 228227 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 4278 | 58.97% |
| Other lethal methods | 301 | 4.15% |
| Non lethal methods | 2676 | 36.88% |
| Total | 7255 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 12698 | 66.94% |
| 29 - 90 days | 4491 | 23.67% |
| > 90 days | 1781 | 9.39% |
| Total | 18970 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 6189 | 22.57% |
| Chronic toxicity | 10807 | 39.41% |
| Reproductive ecotoxicity | 1465 | 5.34% |
| Endocrine activity | 5940 | 21.66% |
| Bioaccumulation | 2831 | 10.32% |
| Other ecotoxicity | 192 | 0.7% |
| Total | 27424 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 88584 | 93.44% |
| Monoclonal antibody by mouse ascites method | 2147 | 2.26% |
| Other product types | 4071 | 4.29% |
| Total | 94802 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 389067 | 70.1% |
| Legislation on medicinal products for veterinary use and their residues | 29785 | 5.37% |
| Medical devices legislation | 56928 | 10.26% |
| Industrial chemicals legislation | 36967 | 6.66% |
| Plant protection product legislation | 33617 | 6.06% |
| Biocides legislation | 2077 | 0.37% |
| Food legislation including food contact material | 3 | 0% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 3068 | 0.55% |
| Cosmetics legislation |  |  |
| Other legislation | 3470 | 0.63% |
| Total | 554982 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 501983 | 90.45% |
| Legislation satisfying national requirements only [within EU] | 51318 | 9.25% |
| Legislation satisfying Non-EU requirements only | 1681 | 0.3% |
| Total | 554982 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 2071372 | 97.33% |
| Yes | 56882 | 2.67% |
| Total | 2128254 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 146265 | 6.87% |
| Mild [up to and including] | 1324548 | 62.24% |
| Moderate | 500009 | 23.49% |
| Severe | 157432 | 7.4% |
| Total | 2128254 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 2027088 | 95.25% |
| Yes | 101166 | 4.75% |
| Total | 2128254 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1273498 | 59.84% |
| Genetically altered without a harmful phenotype | 723600 | 34% |
| Genetically altered with a harmful phenotype | 131156 | 6.16% |
| Total | 2128254 | 100.00% |

## Germany: Narrative 2017

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

In 2017, approximately 2 million vertebrates and cephalopods were used in Germany in animal experiments within the meaning of Section 7(2) of the German Animal Welfare Act (Tierschutzgesetz). Section 7(2) of the Animal Welfare Act defines the term ‘animal experiment’. The figures are virtually unchanged compared to the previous year. Approximately 80% of the test animals used were rodents, mostly mice and rats, whereby mice comprised approximately 66% of the animals used. Approximately 12% of the animals were fish, approximately 5% were rabbits and approximately 2% were birds. Here, too, the figures are virtually unchanged compared to the previous year.

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

Killing for scientific purposes

In addition to the guidelines of the EU Laboratory Animals Directive, Germany also includes animals that were killed for scientific purposes without first having undergone procedures or treatments, for instance in order to use these animals’ organs or cell material for scientific purposes. Approximately 736,000 animals were used to this end in 2017, which means that overall approximately 11,000 more animals were used than in the previous year. Correspondingly, these animals are not included in the numbers of experimental animals submitted to the European Commission.

Genetically modified animals

The number of genetically modified animals has remained largely stable in comparison to the previous year. Approximately 1,150,000 of the total number of animals used were genetically modified. As such, the percentage of these animals was approximately 41% (in 2016 this was approximately 42%). In particular mice (89%) and fish (10%) were used.

Primates

However, the number of primates used showed a definite increase. In 2017 a total of 3,525 primates were used, 1,063 more than in the previous year.

Simians have a genome that is comparable to that of humans, and their total bodily function is also more similar to that of humans. Therefore it is likely that some diseases that cannot be imitated well in the mouse by means of genetic modification can present well in simians in this way. These genetically modified simians could result in a major step towards better understanding very significant, hitherto incurable and terminal diseases and therefore put new therapies within our grasp.

Dogs and cats

The number of dogs and cats used amounted to 3,334 and 718 respectively, used in particular for statutory testing and for applied research. As compared to the previous year, there was an overall decrease in the number of dogs (3,977 in 2016) and cats (766 in 2016).

Scientific purposes

Although many scientific questions can be answered nowadays through the use of cell cultures, computer-assisted procedures and other alternative methods, it is not yet possible to do without the use of animals for medical research and other scientific purposes. For instance, approximately 50% of the animals used in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act were used for basic research and approximately 15% were used for researching human and animal diseases. Approximately 27% of the animals were used in the manufacture and quality control of medical products or for toxicological safety tests. Approximately 8% were needed for other purposes, such as training or further education or for breeding genetically modified animals.

This means that as compared to 2016 there was a slight decrease in the area of basic research (approximately 3%), while the other areas each saw a minimal increase of approximately 1%.

* **Basic research**

Within basic research, research into the nervous system (approximately 21%) and the immune system (approximately 20%) was particularly important in 2017. As such, research into the nervous system showed an increase of approximately 6% compared to the previous year.

* **Human and animal diseases**

Under research into human and animal diseases, there was an emphasis on the area of human cancers, for which approximately 41% of test animals used in this field of research were utilised. This is a slight increase as compared to 2016 (approximately 37%).

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

With regard to the severity of experiments, it is apparent that the severity classification in animal experiments within the meaning of Section 7(2) of the Animal Welfare Act was predominantly ‘low’ (approximately 59%). The share of animal experiments classified as ‘medium’ or ‘severe’ was approximately 27% and 5% respectively. Compared to the previous year, the number of experiments classified as ‘medium’ showed a slight increase of 4%, while the number of experiments classified as ‘severe’ showed a slight decrease of approximately 2%. The share of animal experiments that were carried out entirely under general anaesthesia and from which the animal never regained consciousness was approximately 9% and thereby at a slightly higher level than the previous year (approximately 7%).

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

The German Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft, BMEL) is endeavouring to reduce the number of animals used in experiments. For this reason various projects are initiated and supported with the goal of replacing animal experiments with alternative methods as soon as possible. These projects include establishing and operating the German Centre for the Protection of Laboratory Animals (Deutsches Zentrum zum Schutz von Versuchstieren, Bf3R), promoting research by the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR), supporting the Stiftung zur Förderung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen (Foundation for the promotion of alternate and complementary methods to reduce animal experiments) and annually awarding the BMEL’s Animal Welfare Research Prize. In 2016 the amount of the prize was increased from €15,000 to €25,000.

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

Category ‘other animal species’

In this category, particularly in the areas ‘other fish species’ and ‘other bird species’, there are a greater number of additional animal species.

For fish, primarily local wild fish (e.g. grayling, common roach, stickleback, brown trout) were used in the contexts of basic ethological research and research into species conservation. This partially concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification was ‘low’.

Among birds, primarily turkeys and local wild bird species (e.g. tit, duck, common buzzard, pigeon) were used. While turkeys were mainly used in the context of researching various animal diseases, the various wild bird species were used in the context of basic ethological research. This primarily concerned animals caught in the wild which were re-released after the experiment was finished. As a rule the severity classification for the animals involved was ‘low’.

Moreover, in the areas ‘other carnivores’ and ‘other amphibians’ there were a smaller number of additional species. For instance, among carnivores minks were particularly used in the context of vaccine tolerability testing, while in the area of amphibians primarily the common toad, fire salamander, axolotl and common frog were used with the aim of protecting the natural environment in the interest of human and animal health or welfare.

Category ‘other uses’

The emphasis in this category is in the areas ‘basic research’ and ‘regulatory purposes’.

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

* creating and genotyping new genetically modified animal bloodlines as models for human and animal diseases;
* molecular developmental genetics;
* research into various new methods for marker, blood and biopsy sampling with the goal of refining these methods;
* research in the field of human and animal microbiology;
* research in the context of gerontology.

As a rule the severity classification for the animals involved was between ‘low’ and ‘medium’.

In addition, in the area of regulatory experiments the following topics of focus were particularly apparent:

* testing new diagnostic and therapeutic procedures in the field of human cancers;
* testing the effectiveness and mechanism of feed additives;
* pharmacodynamic research in the context of developing therapies in the area of human or animal tumour diseases (e.g. radiopharmaceuticals).

As a rule the severity classification for the animals involved was between ‘low’ and ‘medium’.

Category ‘other legal provisions’

In the context of this category the following other legal provisions are particularly referred to:

* test of substances hazardous to water in accordance with the German Administrative Provision concerning the Water Resources Act (Verwaltungsvorschrift zum Wasserhaushaltsgesetz);
* test of products in accordance with Regulation (EC) No 1272/2008 (fibre persistence test);
* test of products in the framework of the German Infection Protection Act (Infektionsschutzgesetz);
* test of products in accordance with the German Animal Vaccine Regulation (Tierimpfstoffverordnung).

The severity classification for the animals involved in these experiments varied widely overall (from ‘low’ to ‘severe’).

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

In 2017 there were no experiments carried out in Germany in the context of which the classification exceeded ‘severe’.

## Germany: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1368447 | 66.15% |
| Rats | 255449 | 12.35% |
| Guinea-Pigs | 14851 | 0.72% |
| Hamsters (Syrian) | 1222 | 0.06% |
| Hamsters (Chinese) | 8 | 0% |
| Mongolian gerbil | 4255 | 0.21% |
| Other Rodents | 9950 | 0.48% |
| Rabbits | 92661 | 4.48% |
| Cats | 718 | 0.03% |
| Dogs | 3330 | 0.16% |
| Ferrets | 196 | 0.01% |
| Other carnivores | 535 | 0.03% |
| Horses, donkeys and cross-breeds | 1209 | 0.06% |
| Pigs | 17347 | 0.84% |
| Goats | 212 | 0.01% |
| Sheep | 3053 | 0.15% |
| Cattle | 6332 | 0.31% |
| Prosimians | 87 | 0% |
| Marmoset and tamarins | 224 | 0.01% |
| Cynomolgus monkey | 3002 | 0.15% |
| Rhesus monkey | 117 | 0.01% |
| Vervets (Chlorocebus spp.) | 15 | 0% |
| Baboons | 14 | 0% |
| Squirrel monkey | 1 | 0% |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) | 12 | 0% |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 1352 | 0.07% |
| Domestic fowl | 24920 | 1.2% |
| Other birds | 12000 | 0.58% |
| Reptiles | 369 | 0.02% |
| Rana | 377 | 0.02% |
| Xenopus | 4546 | 0.22% |
| Other Amphibians | 2652 | 0.13% |
| Zebra fish | 141676 | 6.85% |
| Other Fish | 97674 | 4.72% |
| Cephalopods |  |  |
| Total | 2068813 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 1900118 | 93.64% |
| Animals born in the EU but not at a registered breeder | 100821 | 4.97% |
| Animals born in rest of Europe | 15127 | 0.75% |
| Animals born in rest of world | 13056 | 0.64% |
| Total | 2029122 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 360 | 13.39% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 1699 | 63.21% |
| Animals born in America |  |  |
| Animals born in Africa | 628 | 23.36% |
| Animals born elsewhere | 1 | 0.04% |
| Total | 2688 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 338 | 12.57% |
| F2 or greater | 1786 | 66.44% |
| Self-sustaining colony | 564 | 20.98% |
| Total | 2688 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 1039225 | 50.23% |
| Translational and applied research | 304599 | 14.72% |
| Regulatory use and Routine production | 556946 | 26.92% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 8491 | 0.41% |
| Preservation of species | 41156 | 1.99% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 53121 | 2.57% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 65275 | 3.16% |
| Total | 2068813 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 91387 | 8.79% |
| Cardiovascular Blood and Lymphatic System | 109053 | 10.49% |
| Nervous System | 216128 | 20.8% |
| Respiratory System | 23579 | 2.27% |
| Gastrointestinal System including Liver | 33087 | 3.18% |
| Musculoskeletal System | 25657 | 2.47% |
| Immune System | 202581 | 19.49% |
| Urogenital/Reproductive System | 23426 | 2.25% |
| Sensory Organs (skin, eyes and ears) | 27801 | 2.68% |
| Endocrine System/Metabolism | 57885 | 5.57% |
| Multisystemic | 57475 | 5.53% |
| Ethology / Animal Behaviour /Animal Biology | 46306 | 4.46% |
| Other basic research | 124860 | 12.01% |
| Total | 1039225 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 125614 | 41.24% |
| Human Infectious Disorders | 18388 | 6.04% |
| Human Cardiovascular Disorders | 16923 | 5.56% |
| Human Nervous and Mental Disorders | 38573 | 12.66% |
| Human Respiratory Disorders | 13371 | 4.39% |
| Human Gastrointestinal Disorders including Liver | 15898 | 5.22% |
| Human Musculoskeletal Disorders | 3939 | 1.29% |
| Human Immune Disorders | 11659 | 3.83% |
| Human Urogenital/Reproductive Disorders | 4784 | 1.57% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 6500 | 2.13% |
| Human Endocrine/Metabolism Disorders | 12138 | 3.98% |
| Other Human Disorders | 1227 | 0.4% |
| Animal Diseases and Disorders | 17368 | 5.7% |
| Animal Welfare | 6271 | 2.06% |
| Diagnosis of diseases | 2488 | 0.82% |
| Plant diseases | 69 | 0.02% |
| Non-regulatory toxicology and ecotoxicology | 9389 | 3.08% |
| Total | 304599 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Phototoxicity |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 4136 | 39.93% |
| Other lethal methods | 182 | 1.76% |
| Non lethal methods | 6039 | 58.31% |
| Total | 10357 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 13183 | 68.89% |
| 29 - 90 days | 4136 | 21.61% |
| > 90 days | 1817 | 9.5% |
| Total | 19136 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | 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 to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 372333 | 66.85% |
| Legislation on medicinal products for veterinary use and their residues | 23641 | 4.24% |
| Medical devices legislation | 54817 | 9.84% |
| Industrial chemicals legislation | 50724 | 9.11% |
| Plant protection product legislation | 46229 | 8.3% |
| Biocides legislation | 2366 | 0.42% |
| Food legislation including food contact material | 14 | 0% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 3554 | 0.64% |
| Cosmetics legislation |  |  |
| Other legislation | 3268 | 0.59% |
| Total | 556946 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 543850 | 97.65% |
| Legislation satisfying national requirements only [within EU] | 4078 | 0.73% |
| Legislation satisfying Non-EU requirements only | 9018 | 1.62% |
| Total | 556946 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 2031810 | 98.21% |
| Yes | 37003 | 1.79% |
| Total | 2068813 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 178095 | 8.61% |
| Mild [up to and including] | 1226990 | 59.31% |
| Moderate | 548621 | 26.52% |
| Severe | 115107 | 5.56% |
| Total | 2068813 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 1891562 | 91.43% |
| Yes | 177251 | 8.57% |
| Total | 2068813 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1241283 | 60% |
| Genetically altered without a harmful phenotype | 658801 | 31.84% |
| Genetically altered with a harmful phenotype | 168729 | 8.16% |
| Total | 2068813 | 100.00% |

# Greece

## Greece: Narrative 2015

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

An increasing trend in the use of animals used for scientific purposes may be observed in 2015 compared to 2014. This is justified due to the fact that a lot of European research projects, which were funded by the European Union (ERC) were performed. 2015 has been a period where applications to receive funding from HORIZON 2020 were pending or were in the process to be approved.

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

A) A significant use of fish is depicted in Greek statistical data in 2015 compared to other MS. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as “mild”.

B) A 4-fold increase of use of domestic fowls is being recorded for 2015 and can be attributed the authorisation of more relevant protocols in a user establishment with the implementation of “mild” procedures.

C) A decrease in the use of mice is noted compared to 2014, which can be attributed to the research projects performed

D) There is an increasing trend regarding the reuse of animals in the context of an attempt to reduce the number of animals used for scientific purposes.

E) A significant increase in the use of genetically altered animals without a harmful genotype by approximately 20% can be attributed to the HORIZON 2020 related projects.

F) The use of dogs and cats is mainly focused on basic veterinary research purposes aiming to better study and manage special conditions that affect companion animals, such wound and fracture healing or gastrointestinal reflux.

G) The category referred as “animals born in rest of world” is related to genetically altered rodent provided from USA Institutes for special projects.

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

An increase of “severe” use of animals is reported for 2015 compared to 2014 and is attributed to projects which included complicated surgical techniques, oncology and toxicology tests for regulatory use and routine production.

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

Laboratory Animal Science accredited courses take place in Greece annually, which promote this principle.

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

A significant proportion of other fish is reported in Greece for 2015. Greece is a leading country in Mediterranean fish production and significant research is carried out in this field compared to other MS. *Sparus aurata* and *Dicentrarchus labrax* are the leading species, with *Argyrosomous regius* and *Seriola dumerili* to follow. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”.

In one case legislation on medicinal products for veterinary use and their residues is recorded.

Rodents have been used for various ‘other” purposes in 2015, but not in an exceptional trend.

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

No such case reported for 2015.

## Greece: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 28849 | 53.67% |
| Rats | 2205 | 4.1% |
| Guinea-Pigs | 11 | 0.02% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 611 | 1.14% |
| Cats | 47 | 0.09% |
| Dogs | 4 | 0.01% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 430 | 0.8% |
| Goats |  |  |
| Sheep | 8 | 0.01% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey | 3 | 0.01% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 1606 | 2.99% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians | 200 | 0.37% |
| Zebra fish | 4675 | 8.7% |
| Other Fish | 15099 | 28.09% |
| Cephalopods |  |  |
| Total | 53748 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 53337 | 99.96% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 20 | 0.04% |
| Total | 53357 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 1 | 100% |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 1 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 1 | 100% |
| Self-sustaining colony |  |  |
| Total | 1 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 38599 | 71.81% |
| Translational and applied research | 6463 | 12.02% |
| Regulatory use and Routine production | 7589 | 14.12% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1097 | 2.04% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 53748 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 4102 | 10.63% |
| Cardiovascular Blood and Lymphatic System | 6710 | 17.38% |
| Nervous System | 1541 | 3.99% |
| Respiratory System | 124 | 0.32% |
| Gastrointestinal System including Liver | 896 | 2.32% |
| Musculoskeletal System | 908 | 2.35% |
| Immune System | 3325 | 8.61% |
| Urogenital/Reproductive System | 179 | 0.46% |
| Sensory Organs (skin, eyes and ears) | 745 | 1.93% |
| Endocrine System/Metabolism | 1110 | 2.88% |
| Multisystemic | 1098 | 2.84% |
| Ethology / Animal Behaviour /Animal Biology | 14299 | 37.05% |
| Other basic research | 3562 | 9.23% |
| Total | 38599 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 915 | 14.16% |
| Human Infectious Disorders | 470 | 7.27% |
| Human Cardiovascular Disorders | 1 | 0.02% |
| Human Nervous and Mental Disorders | 967 | 14.96% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver | 160 | 2.48% |
| Human Musculoskeletal Disorders | 1825 | 28.24% |
| Human Immune Disorders | 205 | 3.17% |
| Human Urogenital/Reproductive Disorders | 12 | 0.19% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 90 | 1.39% |
| Human Endocrine/Metabolism Disorders | 83 | 1.28% |
| Other Human Disorders | 404 | 6.25% |
| Animal Diseases and Disorders |  |  |
| Animal Welfare | 165 | 2.55% |
| Diagnosis of diseases | 788 | 12.19% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 378 | 5.85% |
| Total | 6463 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Toxicity and other safety testing including pharmacology | 7580 | 99.88% |
| Routine production | 9 | 0.12% |
| Total | 7589 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 800 | 10.55% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Safety testing in food and feed area | 6780 | 89.45% |
| Total | 7580 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 800 | 100% |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total | 800 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 9 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 9 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 9 | 0.12% |
| Legislation on medicinal products for veterinary use and their residues | 800 | 10.54% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 6780 | 89.34% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 7589 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 7589 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 7589 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 53358 | 99.27% |
| Yes | 390 | 0.73% |
| Total | 53748 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 949 | 1.77% |
| Mild [up to and including] | 37804 | 70.34% |
| Moderate | 11905 | 22.15% |
| Severe | 3090 | 5.75% |
| Total | 53748 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 51409 | 95.65% |
| Yes | 2339 | 4.35% |
| Total | 53748 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 40705 | 75.73% |
| Genetically altered without a harmful phenotype | 11085 | 20.62% |
| Genetically altered with a harmful phenotype | 1958 | 3.64% |
| Total | 53748 | 100.00% |

## Greece: Narrative 2016

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

Any significant changes of trends observed in 2016 compared to 2015 regarding the purpose of authorised projects can be attributed to their nature and number. This is directly related to funding resources and the choice of research purpose by user establishments.

A significant decrease in the use of animals for the creation of new genetic lines is reported and can be attributed to the lack of relevant funding by European research projects or absence of relevant application forms by researchers.

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

A) A significant use of fish is depicted in Greek statistical data in 2016 compared to other MS. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as “mild”.

B) A 2-fold increase of use of domestic fowls is being recorded for 2016 and can be attributed to the authorisation of more relevant protocols in a user establishment with the implementation of “mild” procedures.

C) A decrease in the use of mice is noted compared to 2015, which can be attributed to the research projects performed during 2016.

D) A significant decrease in the use of genetically altered animals without a harmful phenotype by approximately 5% and an increase of genetically altered animals with a harmful phenotype can be attributed to relevant authorised projects.

E) The use of dogs and cats is mainly focused on basic veterinary research purposes aiming to better study and manage special conditions that affect companion animals, such wound and fracture healing or gastrointestinal reflux.

F) The category referred as “animals born in rest of world” is related to genetically altered rodent provided from USA Institutes for special projects.

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

No particular change in trends in actual severities are reported.

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

Laboratory Animal Science accredited courses take place in Greece annually, which promote this principle.

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

A significant proportion of other fish is reported in Greece for 2016. Greece is a leading country in Mediterranean fish production and significant research is carried out in this field compared to other MS. *Sparus aurata* and *Dicentrarchus labrax* are the leading species, with *Argyrosomous regius* and *Seriola dumerili* to follow. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”.

Rodents have been used for mouse development from epiblast derived cells in 2016, but not in an exceptional trend.

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

No such case reported for 2016.

## Greece: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 23946 | 52.65% |
| Rats | 2222 | 4.89% |
| Guinea-Pigs | 13 | 0.03% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 491 | 1.08% |
| Cats | 13 | 0.03% |
| Dogs | 3 | 0.01% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 333 | 0.73% |
| Goats |  |  |
| Sheep | 12 | 0.03% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey | 3 | 0.01% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 3200 | 7.04% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 130 | 0.29% |
| Other Fish | 15117 | 33.24% |
| Cephalopods |  |  |
| Total | 45483 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 45127 | 99.83% |
| Animals born in the EU but not at a registered breeder | 30 | 0.07% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 48 | 0.11% |
| Total | 45205 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 1 | 100% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 1 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 1 | 100% |
| Self-sustaining colony |  |  |
| Total | 1 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 33690 | 74.07% |
| Translational and applied research | 4514 | 9.92% |
| Regulatory use and Routine production | 6630 | 14.58% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 649 | 1.43% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 45483 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 2377 | 7.06% |
| Cardiovascular Blood and Lymphatic System | 2855 | 8.47% |
| Nervous System | 1753 | 5.2% |
| Respiratory System | 335 | 0.99% |
| Gastrointestinal System including Liver | 915 | 2.72% |
| Musculoskeletal System | 502 | 1.49% |
| Immune System | 1300 | 3.86% |
| Urogenital/Reproductive System | 97 | 0.29% |
| Sensory Organs (skin, eyes and ears) | 1284 | 3.81% |
| Endocrine System/Metabolism | 742 | 2.2% |
| Multisystemic | 3075 | 9.13% |
| Ethology / Animal Behaviour /Animal Biology | 14957 | 44.4% |
| Other basic research | 3498 | 10.38% |
| Total | 33690 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 1319 | 29.22% |
| Human Infectious Disorders | 224 | 4.96% |
| Human Cardiovascular Disorders | 385 | 8.53% |
| Human Nervous and Mental Disorders | 526 | 11.65% |
| Human Respiratory Disorders | 422 | 9.35% |
| Human Gastrointestinal Disorders including Liver | 204 | 4.52% |
| Human Musculoskeletal Disorders | 841 | 18.63% |
| Human Immune Disorders | 135 | 2.99% |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 67 | 1.48% |
| Human Endocrine/Metabolism Disorders | 136 | 3.01% |
| Other Human Disorders | 207 | 4.59% |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases | 48 | 1.06% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 4514 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 6630 | 100% |
| Total | 6630 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Safety testing in food and feed area | 6630 | 100% |
| Total | 6630 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 6630 | 100% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 6630 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 6630 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 6630 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 45206 | 99.39% |
| Yes | 277 | 0.61% |
| Total | 45483 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 1873 | 4.12% |
| Mild [up to and including] | 32156 | 70.7% |
| Moderate | 8903 | 19.57% |
| Severe | 2551 | 5.61% |
| Total | 45483 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 45053 | 99.05% |
| Yes | 430 | 0.95% |
| Total | 45483 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 34912 | 76.76% |
| Genetically altered without a harmful phenotype | 7683 | 16.89% |
| Genetically altered with a harmful phenotype | 2888 | 6.35% |
| Total | 45483 | 100.00% |

## Greece: Narrative 2017

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

A significant increase in the use of animals for the creation of new genetic lines is reported and can be attributed to the increase of funding by European research projects.

A significant increase in the number of animals undergone “non-recovery” procedures has been reported. This is proportional to the number of animals used for higher education of training for the acquisition, training of improvement of vocational skills.

A new user establishment was authorised in 2017, which performs research projects on the protection of natural environment in the interests of the health of welfare of humans and animals. This is a new category of purposes in Greece.

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

A) A significant use of fish is depicted in Greek statistical data in 2016 compared to other MS. This is due to the fact that Greece is a Mediterranean country and has a number of user establishments dealing with studies on fish biology, behaviour/ethology and production methods of aquaculture species. *Dicentrarchus labrax* and *Sparus aurata* are the main species used. In user establishments, fishes are maintained under similar commercial production conditions, and most of the projects consist of variations in the rearing parameters (temperature, photoperiod, dissolved oxygen, tank size, feed type and frequency, rearing density, etc.) that may cause stress to the animals and are classified as “mild”.

B) A significant decrease in the use of domestic fowl is reported due to lack of relevant projects performed in 2017 by a user establishment.

C) Regarding the use of cephalopods (first time for Greece in 2017):

The application of the protocol had the objective to assess the sensitivity and immune response of *O. vulgaris* against common fish pathogens under different physicochemical water parameters (i.e. different temperatures). Animals are infected either intramuscularly or intravenously, hemolymph is collected for the assessment of immune stimulation and at the end of the experiment, organ samples are collected to assess immune responses and bacteria presence internally. All procedures are carried out under anesthesia, while organ sampling is performed after euthanasia with an overdose of anesthetic. In 2017, the protocol was applied once in 33 animals. From these, 9 individuals either died or used for the collection of samples and for 24 individuals, the protocol was characterized as mild. *O. vulgaris* were used by a newly authorised user establishment.

D) Regarding the use of animals for the protection of natural environment in the interests of the health or welfare of human beings or animals, that is recorded for the first time in 2017, these were used by a newly authorised user establishment.

E) It has to be noted that the use of various species differs among each year according to the protocols authorised and funding received by user establishments. Minor changing trends can be recorded.

F) It has to be noted that the use of animals for translational and applied research has increased by approximately 40% in total. This percentage in general differs among each year according to the protocols authorised and funding received by user establishments.

G) It has to be noted that the use of animals for various systems either for basic or translational and applied research varies among each year according to the nature of protocols chosen by researchers.

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

A) Animals with “Non recovery” severity seem to have diminished due to a decrease in higher education trainings programs that are performed with the use of live animals in Greece.

B) The application of experimental protocols on teleosts by a newly authorised user establishment had the objective to assess either resistance of fish to fish pathogens or the efficacy of vaccines. These protocols were classified as severe because mortality is caused near to or more than > 70%. For 2017, gilthead sea bream and European sea bass were used.

C) A significant increase in the use of animals in translational/applied research for human cancer has been noted in 2017 compared to 2016 which has resulted in the relevant increase of the severe use of those animals. This can attributed to the increase of funding research programmes in this sector.

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

Laboratory animal science training courses are organised annually in Greece.

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

A) A significant proportion of other fish is reported in Greece for 2017. Greece is a leading country in Mediterranean fish production and significant research is carried out in this field compared to other MS. *Sparus aurata* and *Dicentrarchus labrax* are the leading species, with *Argyrosomous regius* and *Seriola dumerili* to follow. Procedures on fish include behavioural studies or drug testing, which cause stress to the animals and are classified as “mild”.

B) A number of rodents have been reported under ‘Translational/ Applied research”: Other human disorders, as having been used in multisystemic protocols including arthritis and enteropathy.

C) A number of rodents have been reported for aging studies using “mild” procedures.

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

No such case reported for 2017.

## Greece: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 25479 | 54.52% |
| Rats | 2438 | 5.22% |
| Guinea-Pigs | 6 | 0.01% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 213 | 0.46% |
| Cats | 8 | 0.02% |
| Dogs | 41 | 0.09% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 289 | 0.62% |
| Goats |  |  |
| Sheep | 8 | 0.02% |
| Cattle | 3 | 0.01% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey | 1 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 6 | 0.01% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 1859 | 3.98% |
| Other Fish | 16346 | 34.98% |
| Cephalopods | 33 | 0.07% |
| Total | 46730 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 45596 | 98.55% |
| Animals born in the EU but not at a registered breeder | 33 | 0.07% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 640 | 1.38% |
| Total | 46269 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 27573 | 59% |
| Translational and applied research | 8058 | 17.24% |
| Regulatory use and Routine production | 6887 | 14.74% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 3093 | 6.62% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1119 | 2.39% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 46730 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 923 | 3.35% |
| Cardiovascular Blood and Lymphatic System | 1315 | 4.77% |
| Nervous System | 1204 | 4.37% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 428 | 1.55% |
| Musculoskeletal System | 520 | 1.89% |
| Immune System | 2225 | 8.07% |
| Urogenital/Reproductive System | 242 | 0.88% |
| Sensory Organs (skin, eyes and ears) | 988 | 3.58% |
| Endocrine System/Metabolism | 843 | 3.06% |
| Multisystemic | 99 | 0.36% |
| Ethology / Animal Behaviour /Animal Biology | 14686 | 53.26% |
| Other basic research | 4100 | 14.87% |
| Total | 27573 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| 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 Urogenital/Reproductive Disorders |  |  |
| 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 Diseases and Disorders |  |  |
| Animal Welfare | 40 | 0.5% |
| Diagnosis of diseases | 230 | 2.85% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 64 | 0.79% |
| Total | 8058 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 6887 | 100% |
| Total | 6887 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Pharmaco-dynamics (incl safety pharmacology) | 10 | 0.15% |
| Safety testing in food and feed area | 6877 | 99.85% |
| Total | 6887 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 10 | 0.15% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 6877 | 99.85% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 6887 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 6887 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 6887 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 46269 | 99.01% |
| Yes | 461 | 0.99% |
| Total | 46730 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 3646 | 7.8% |
| Mild [up to and including] | 29392 | 62.9% |
| Moderate | 9198 | 19.68% |
| Severe | 4494 | 9.62% |
| Total | 46730 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 42770 | 91.53% |
| Yes | 3960 | 8.47% |
| Total | 46730 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 31622 | 67.67% |
| Genetically altered without a harmful phenotype | 12982 | 27.78% |
| Genetically altered with a harmful phenotype | 2126 | 4.55% |
| Total | 46730 | 100.00% |

# Hungary

## Hungary: Narrative 2015

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

The total number of animals used for experimental and other scientific purposes in 2015 was 195 603 which represents 2.7 % decrease compared to the same figure of 2014. The number of re-uses has been decreased by 56% (from 6584 to 2924).

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

The increase was 10.8% in the number of mice, 3.65% in case of rats, 23.22% for guinea-pigs and 29.08% in the case of rabbits. Both the number and the proportion of rodents increased since 2014 (hamsters and other rodents represents only a small percentage of rodents), the proportion of them is about 63% (it was 57% in 2014 and 61% in 2013).

The number of used birds is still very high (50 117), and the proportion of domestic fowls grew among them from 89.39% to 96.23% (mainly because of the decrease in the number of other poultry species).

The number of used cats was more than 4 times higher than in 2014 (60 compared to 14), in contrast the number of dogs decreased by 42% (from 859 to 495).

There was a 10% decrease in the number of pigs (in opposition to the growing tendency during the last few years). Notable changes can be observed also in the proportion of other farm animals (sheep, cattle), but their number is relatively low which could cause fluctuation.

The number of zebra fish and other fishes decreased by 83% and more than 25%. The number of amphibians also decreased by about 25% (form 8373 to 6286), but it is still high compared to the period between 2007 and 2012 (it was ranged between 340 and 1807). The number of reptiles is only 12 compared to 62 in 2014.

When analysed by the purposes of the use of animals a large decrease can be observed in the fundamental biological research segment (more than 47%), and the number of animals used in education has also decreased (by nearly 62%). On the other hand remarkable increase can be observed in applied and translational research (almost 28%) – which was a key reason for the increase in the number of used rodents –, in regulatory and routine production (16.59%), and also in the number of animals used for the preservation of species (more than 70%) and used for the protection of the natural environment (which is 133 times more than in 2014).

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

The proportion of non-recoveries was dropped from 21.61% to 12.78%, the proportion of severe uses from 6.90% to 6.01%, and the moderate uses from 16.55% to 14.12%. On the other hand mild uses increased from 54.95% to 67.10%.

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

Due to the stringent national measures the use of non-human primates for scientific purposes has been replaced by other methods where possible and the number of them is very low in Hungary. The use of non-human primates occurs only when there is not any alternative method.

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

*Xenopus spp*., *Rana temporaria* or *Rana pipiens* were not used in 2015; therefore the ratio of other amphibians is 100%. High number of *Bufo bufo* (5400 individuals, 85.91% of all amphibians), and also *Lissotriton vulgaris* (526 individuals) and *Rana dalmatina* (360 individuals) used for the preservation of species and for the protection of the natural environment in the interest of the health or welfare of human beings or animals.

The ratio of other fish is 69.23% mainly due to the high number of *Poecilia reticulata* used in regulatory ecotoxicology tests (2250 individuals, 49.82% of other fish) and farm fish species (e.g. *Cyprinus carpio*).

The ratio of other category in routine production is 100% (it is worth to note that the total number of animals used for routine production is quite low, only 603 individuals, so a single project can greatly influence the ratio).

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

Cases where the 'severe' classification is exceeded did not occur.

## Hungary: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 84650 | 43.28% |
| Rats | 35037 | 17.91% |
| Guinea-Pigs | 4113 | 2.1% |
| Hamsters (Syrian) | 1 | 0% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 36 | 0.02% |
| Rabbits | 5256 | 2.69% |
| Cats | 60 | 0.03% |
| Dogs | 495 | 0.25% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 2884 | 1.47% |
| Goats |  |  |
| Sheep | 110 | 0.06% |
| Cattle | 20 | 0.01% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey | 3 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 48230 | 24.66% |
| Other birds | 1887 | 0.96% |
| Reptiles | 12 | 0.01% |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians | 6286 | 3.21% |
| Zebra fish | 2007 | 1.03% |
| Other Fish | 4516 | 2.31% |
| Cephalopods |  |  |
| Total | 195603 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 174024 | 90.32% |
| Animals born in the EU but not at a registered breeder | 15917 | 8.26% |
| Animals born in rest of Europe | 2236 | 1.16% |
| Animals born in rest of world | 499 | 0.26% |
| Total | 192676 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 3 | 100% |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 3 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 3 | 100% |
| Self-sustaining colony |  |  |
| Total | 3 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 38544 | 19.71% |
| Translational and applied research | 63815 | 32.62% |
| Regulatory use and Routine production | 84310 | 43.1% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 6006 | 3.07% |
| Preservation of species | 960 | 0.49% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1968 | 1.01% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 195603 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 5013 | 13.01% |
| Cardiovascular Blood and Lymphatic System | 2813 | 7.3% |
| Nervous System | 12887 | 33.43% |
| Respiratory System | 299 | 0.78% |
| Gastrointestinal System including Liver | 2069 | 5.37% |
| Musculoskeletal System | 382 | 0.99% |
| Immune System | 3075 | 7.98% |
| Urogenital/Reproductive System | 2459 | 6.38% |
| Sensory Organs (skin, eyes and ears) | 239 | 0.62% |
| Endocrine System/Metabolism | 2249 | 5.83% |
| Multisystemic | 2259 | 5.86% |
| Ethology / Animal Behaviour /Animal Biology | 2443 | 6.34% |
| Other basic research | 2357 | 6.12% |
| Total | 38544 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 2223 | 3.48% |
| Human Infectious Disorders | 228 | 0.36% |
| Human Cardiovascular Disorders | 499 | 0.78% |
| Human Nervous and Mental Disorders | 43979 | 68.92% |
| Human Respiratory Disorders | 81 | 0.13% |
| Human Gastrointestinal Disorders including Liver | 278 | 0.44% |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders | 580 | 0.91% |
| Human Urogenital/Reproductive Disorders | 179 | 0.28% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 74 | 0.12% |
| Human Endocrine/Metabolism Disorders | 116 | 0.18% |
| Other Human Disorders | 294 | 0.46% |
| Animal Diseases and Disorders | 11335 | 17.76% |
| Animal Welfare | 492 | 0.77% |
| Diagnosis of diseases | 1981 | 3.1% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 1476 | 2.31% |
| Total | 63815 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 49504 | 58.72% |
| Other efficacy and tolerance testing | 192 | 0.23% |
| Toxicity and other safety testing including pharmacology | 34011 | 40.34% |
| Routine production | 603 | 0.72% |
| Total | 84310 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 17400 | 35.15% |
| Pyrogenicity testing | 952 | 1.92% |
| Batch potency testing | 30891 | 62.4% |
| Other quality controls | 261 | 0.53% |
| Total | 49504 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 16836 | 49.5% |
| Skin irritation/corrosion | 336 | 0.99% |
| Skin sensitisation | 4800 | 14.11% |
| Eye irritation/corrosion | 329 | 0.97% |
| Repeated dose toxicity | 3705 | 10.89% |
| Carcinogenicity |  |  |
| Neurotoxicity |  |  |
| Phototoxicity |  |  |
| Safety testing in food and feed area |  |  |
| Genotoxicity | 643 | 1.89% |
| Reproductive toxicity | 1048 | 3.08% |
| Developmental toxicity | 667 | 1.96% |
| Kinetics | 486 | 1.43% |
| Pharmaco-dynamics (incl safety pharmacology) | 392 | 1.15% |
| Ecotoxicity | 3936 | 11.57% |
| Target animal safety | 694 | 2.04% |
| Other toxicity/safety testing | 139 | 0.41% |
| Total | 34011 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 15320 | 91% |
| Other lethal methods |  |  |
| Non lethal methods | 1516 | 9% |
| Total | 16836 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 2226 | 60.08% |
| 29 - 90 days | 615 | 16.6% |
| > 90 days | 864 | 23.32% |
| Total | 3705 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 3936 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 3936 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 603 | 100% |
| Total | 603 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 25232 | 29.93% |
| Legislation on medicinal products for veterinary use and their residues | 51951 | 61.62% |
| Medical devices legislation | 30 | 0.04% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation | 4664 | 5.53% |
| Biocides legislation | 3 | 0% |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment | 180 | 0.21% |
| Cosmetics legislation |  |  |
| Other legislation | 2250 | 2.67% |
| Total | 84310 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 83159 | 98.63% |
| Legislation satisfying national requirements only [within EU] | 310 | 0.37% |
| Legislation satisfying Non-EU requirements only | 841 | 1% |
| Total | 84310 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 192679 | 98.51% |
| Yes | 2924 | 1.49% |
| Total | 195603 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 24993 | 12.78% |
| Mild [up to and including] | 131240 | 67.1% |
| Moderate | 27617 | 14.12% |
| Severe | 11753 | 6.01% |
| Total | 195603 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 194120 | 99.24% |
| Yes | 1483 | 0.76% |
| Total | 195603 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 188601 | 96.42% |
| Genetically altered without a harmful phenotype | 6574 | 3.36% |
| Genetically altered with a harmful phenotype | 428 | 0.22% |
| Total | 195603 | 100.00% |

## Hungary: Narrative 2016

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

The total number of animals used for experimental and other scientific purposes in 2016 was 170 075 which represents about 13% decrease compared to the same figure of 2015 (there was also a downward trend in the last few years). The number of re-uses has also been decreased by 15% (from 2924 to 2493).

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

The vast majority (92.39%) of used animals – as in previous years – were warm-blooded vertebrates. There was increase in the proportion of mammals (form 67.82% to 75.14%) and amphibians (from 3.21% to 4.79%), while the proportion of birds and fish decreased (the birds from 25.62% to 17.25% and the fish from 3.30% to 2.82%).

The proportion of rodents among mammals is about the same as last year. The increase was 10.63% in the number of rats and 23.85% in case of guinea-pigs. On the other hand there was an about 11% decrease in the number of mice. Hamsters and other rodents represent only a small percentage of rodents. The number of rabbits decreased by 35.65%.

The number of used cats was more than 4 times lower than in 2015 (14 compared to 60), in contrast the number of dogs increased by 27.27% (from 495 to 630). No non-human primate was used in 2016 (compared to the 3 Rhesus monkeys in 2015).

There was a 25.83% increase in the number of pigs. Notable decrease can be observed in the proportion of other farm animals (sheep, cattle), but their number is relatively low which could cause fluctuation.

There was an about 41% decrease in the number of used birds. The number of domestic fowl decreased by 43.39%, while the number of other birds increased by 8 %.

The number of other fishes decreased by 35%. The proportion of zebra fish is almost the same as in 2015. The number of other amphibians increased by 29.45% (form 6286 to 8137). The number of reptiles is only 2 compared to 12 in 2015.

When analysed by the purposes of the use of animals a large decrease can be observed in regulatory and routine production (about 25%) and in the number of animals used for the protection of the natural environment (nearly 85%). On the other hand remarkable increase can be observed in the number of animals used for the preservation of species (which is more than 5 times more than in 2015), used in education (more than 36%) and in the fundamental biological research segment (5.53%). The proportion of animals in applied and translational research is almost the same as in 2015.

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

The proportion of mild uses was dropped from 67.10% to 48.80%. On the other hand moderate uses increased from 14.12% to 23.98%, severe uses from 6.01% to 8.19% and non-recoveries from 12.78% to 19.03%.

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

Due to the stringent national measures the use of non-human primates for scientific purposes has been replaced by other methods where possible and the number of them is very low in Hungary. The use of non-human primates occurs only when there is not any alternative method.

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

Only 6 *Rana temporaria* or *Rana pipiens* were used in 2016; therefore the ratio of other amphibians is 99.93%. High number of *Bufo bufo* (4830 individuals, 59.31% of all amphibians) and *Rana dalmatina* (3270 individuals, 40.16% of all amphibians) were used.

The ratio of other fish is 61.11% mainly due to the high number of farm fish species (e.g. *Cyprinus carpio, Oncorhynchus mykiss*) and *Poecilia reticulata* used in regulatory ecotoxicology tests.

The ratio of other category in routine production is 45.15% (it is worth to note that the total number of animals used for routine production is quite low, only 846 individuals, so a single project can greatly influence the ratio).

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

Cases where the 'severe' classification is exceeded did not occur.

## Hungary: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 76079 | 44.73% |
| Rats | 38762 | 22.79% |
| Guinea-Pigs | 5094 | 3% |
| Hamsters (Syrian) | 63 | 0.04% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 40 | 0.02% |
| Rabbits | 3363 | 1.98% |
| Cats | 14 | 0.01% |
| Dogs | 630 | 0.37% |
| Ferrets | 8 | 0% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 3629 | 2.13% |
| Goats |  |  |
| Sheep | 91 | 0.05% |
| Cattle | 16 | 0.01% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 27304 | 16.05% |
| Other birds | 2039 | 1.2% |
| Reptiles | 2 | 0% |
| Rana | 6 | 0% |
| Xenopus |  |  |
| Other Amphibians | 8137 | 4.78% |
| Zebra fish | 1866 | 1.1% |
| Other Fish | 2932 | 1.72% |
| Cephalopods |  |  |
| Total | 170075 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 147713 | 88.14% |
| Animals born in the EU but not at a registered breeder | 19479 | 11.62% |
| Animals born in rest of Europe | 40 | 0.02% |
| Animals born in rest of world | 350 | 0.21% |
| Total | 167582 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 40678 | 23.92% |
| Translational and applied research | 57752 | 33.96% |
| Regulatory use and Routine production | 62895 | 36.98% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 950 | 0.56% |
| Preservation of species | 5112 | 3.01% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 2688 | 1.58% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 170075 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 3669 | 9.02% |
| Cardiovascular Blood and Lymphatic System | 2451 | 6.03% |
| Nervous System | 15998 | 39.33% |
| Respiratory System | 993 | 2.44% |
| Gastrointestinal System including Liver | 3428 | 8.43% |
| Musculoskeletal System | 663 | 1.63% |
| Immune System | 3088 | 7.59% |
| Urogenital/Reproductive System | 1759 | 4.32% |
| Sensory Organs (skin, eyes and ears) | 721 | 1.77% |
| Endocrine System/Metabolism | 2204 | 5.42% |
| Multisystemic | 2112 | 5.19% |
| Ethology / Animal Behaviour /Animal Biology | 1634 | 4.02% |
| Other basic research | 1958 | 4.81% |
| Total | 40678 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 3290 | 5.7% |
| Human Infectious Disorders | 1367 | 2.37% |
| Human Cardiovascular Disorders | 508 | 0.88% |
| Human Nervous and Mental Disorders | 26418 | 45.74% |
| Human Respiratory Disorders | 239 | 0.41% |
| Human Gastrointestinal Disorders including Liver | 758 | 1.31% |
| Human Musculoskeletal Disorders | 29 | 0.05% |
| Human Immune Disorders | 354 | 0.61% |
| Human Urogenital/Reproductive Disorders | 3 | 0.01% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 50 | 0.09% |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders | 36 | 0.06% |
| Animal Diseases and Disorders | 15687 | 27.16% |
| Animal Welfare | 478 | 0.83% |
| Diagnosis of diseases | 4509 | 7.81% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 4026 | 6.97% |
| Total | 57752 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 25445 | 40.46% |
| Other efficacy and tolerance testing | 70 | 0.11% |
| Toxicity and other safety testing including pharmacology | 36534 | 58.09% |
| Routine production | 846 | 1.35% |
| Total | 62895 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 11247 | 44.2% |
| Pyrogenicity testing | 646 | 2.54% |
| Batch potency testing | 13252 | 52.08% |
| Other quality controls | 300 | 1.18% |
| Total | 25445 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 19234 | 52.65% |
| Skin irritation/corrosion | 184 | 0.5% |
| Skin sensitisation | 5438 | 14.88% |
| Eye irritation/corrosion | 131 | 0.36% |
| Repeated dose toxicity | 3804 | 10.41% |
| Carcinogenicity |  |  |
| Neurotoxicity |  |  |
| Phototoxicity |  |  |
| Safety testing in food and feed area |  |  |
| Genotoxicity | 1272 | 3.48% |
| Reproductive toxicity | 340 | 0.93% |
| Developmental toxicity | 1656 | 4.53% |
| Kinetics | 875 | 2.4% |
| Pharmaco-dynamics (incl safety pharmacology) | 204 | 0.56% |
| Ecotoxicity | 2555 | 6.99% |
| Target animal safety | 130 | 0.36% |
| Other toxicity/safety testing | 711 | 1.95% |
| Total | 36534 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 16581 | 86.21% |
| Other lethal methods |  |  |
| Non lethal methods | 2653 | 13.79% |
| Total | 19234 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 466 | 12.25% |
| 29 - 90 days | 126 | 3.31% |
| > 90 days | 3212 | 84.44% |
| Total | 3804 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 2555 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 2555 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 114 | 13.48% |
| Monoclonal antibody by mouse ascites method | 350 | 41.37% |
| Other product types | 382 | 45.15% |
| Total | 846 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 27171 | 43.2% |
| Legislation on medicinal products for veterinary use and their residues | 31160 | 49.54% |
| Medical devices legislation | 21 | 0.03% |
| Industrial chemicals legislation | 2966 | 4.72% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 526 | 0.84% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 1051 | 1.67% |
| Total | 62895 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 61739 | 98.16% |
| Legislation satisfying national requirements only [within EU] | 723 | 1.15% |
| Legislation satisfying Non-EU requirements only | 433 | 0.69% |
| Total | 62895 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 167582 | 98.53% |
| Yes | 2493 | 1.47% |
| Total | 170075 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 32367 | 19.03% |
| Mild [up to and including] | 82993 | 48.8% |
| Moderate | 40784 | 23.98% |
| Severe | 13931 | 8.19% |
| Total | 170075 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 168864 | 99.29% |
| Yes | 1211 | 0.71% |
| Total | 170075 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 162097 | 95.31% |
| Genetically altered without a harmful phenotype | 7170 | 4.22% |
| Genetically altered with a harmful phenotype | 808 | 0.48% |
| Total | 170075 | 100.00% |

## Hungary: Narrative 2017

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

The total number of animals used for experimental and other scientific purposes in 2017 was 141 183 which represents about 17% decrease compared to the same figure of 2016 (there was also a downward trend in the last few years). The number of re-uses has been increased by 300% (from 2493 to 7520).

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

The vast majority (97.58%) of used animals were warm-blooded vertebrates. There was increase in the proportion of mammals (form 75.14% to 78.28%) and birds (from 17.25% to 19.30%), while the proportion of amphibians and fish decreased (amphibians from 4.79% to 0.0% and the fish from 2.82% to 2.42%).

The proportion of rodents among mammals increased from 93.93% to 95.92%. There was 19% decrease in the number of mice and 30% in the number of rats. In case of guinea-pigs was 11% increase. On the other hand there was a dramatically increase at other rodents. Hamsters decreased to 0%. The number of rabbits decreased by 53%.

The number of used cats was a small increase (14 compared to 16). The number of dogs decreased by 36% (from 630 to 463). Two non-human primate was used in 2017 (compared to the 0 Rhesus monkeys in 2016).

There was 33.72% decrease in the number of pigs. Notable decrease can be observed in the proportion of other sheep, but increase in case of cattle, but their number is relatively low which could cause fluctuation.

The number of domestic fowl decreased by 7.82%, while the number of other birds increased by 2.2 %.

The proportion of zebra fish increased by 16.8% and other fish decreased by 59.95%. The number of other amphibians dramatically decreased to 0% (form 8137). The number of reptiles is 0 compared to 2 in 2016.

When analysed by the purposes of the use of animals a small increase can be observed in regulatory and routine production (about 6.3%) and in the number of animals used for the protection of the natural environment and preservation of species decreased to 0%. The proportion of basic research, animals in applied and translational research shows decrease than in 2016.

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

The proportion of mild uses was increased from 48.80% to 49.85%. and moderate uses also from 23.98% to 28.60%, severe uses from 8.19% to 12.76%. It means there was 30% increase in number of severe procedures. This increase was highly influented by two projects with animal diseases and disorders purpose. It contains 5071 Gallus gallus domesticus and 1224 Sus scrofa domesticus.

On the other hand non-recoveries decreased from 19.03% to 8.79%.

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

Due to the stringent national measures the use of non-human primates for scientific purposes has been replaced by other methods where possible and the number of them is very low in Hungary. The use of non-human primates occurs only when there is not any alternative method.

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

The number of other amphibians dramatically decreased from 8137 to 0 in 2017. The reason is there is an establishment, where in 2016 investigated *Rana dalmatina, Bufo bufo, Lissortion vulgaris*. There was mainly eggs collection at the natural habitat and after incubation investigated juvenils and natural predators. At the end of the project more than 3700 amphibians were released into their habitat. These projects were categorized into protection of the natural environment and preservation of species. It explains the dramatically decrease to 0 value in purpose category.

The number of used rabbits decreased by 53%. In 2016 there were projects a batch safety testing project with 1097 rabbits and a pyrogenicity testing with 606 rabbits. The reason for the 53% decrease is this 2 projects ended in 2016.

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

Cases where the 'severe' classification is exceeded did not occur.

## Hungary: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 65876 | 46.8% |
| Rats | 33946 | 24.12% |
| Guinea-Pigs | 5765 | 4.1% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 1583 | 1.12% |
| Cats | 16 | 0.01% |
| Dogs | 463 | 0.33% |
| Ferrets | 4 | 0% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 2405 | 1.71% |
| Goats |  |  |
| Sheep |  |  |
| Cattle | 33 | 0.02% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey | 2 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 25169 | 17.88% |
| Other birds | 2084 | 1.48% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 2243 | 1.59% |
| Other Fish | 1174 | 0.83% |
| Cephalopods |  |  |
| Total | 140763 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 126683 | 95.08% |
| Animals born in the EU but not at a registered breeder | 5062 | 3.8% |
| Animals born in rest of Europe | 1187 | 0.89% |
| Animals born in rest of world | 309 | 0.23% |
| Total | 133241 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 2 | 100% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 2 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 2 | 100% |
| Self-sustaining colony |  |  |
| Total | 2 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 38539 | 27.38% |
| Translational and applied research | 41847 | 29.73% |
| Regulatory use and Routine production | 58007 | 41.21% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 2370 | 1.68% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 140763 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 3346 | 8.68% |
| Cardiovascular Blood and Lymphatic System | 3406 | 8.84% |
| Nervous System | 16498 | 42.81% |
| Respiratory System | 718 | 1.86% |
| Gastrointestinal System including Liver | 1865 | 4.84% |
| Musculoskeletal System | 189 | 0.49% |
| Immune System | 4412 | 11.45% |
| Urogenital/Reproductive System | 1678 | 4.35% |
| Sensory Organs (skin, eyes and ears) | 488 | 1.27% |
| Endocrine System/Metabolism | 1417 | 3.68% |
| Multisystemic | 2369 | 6.15% |
| Ethology / Animal Behaviour /Animal Biology | 526 | 1.36% |
| Other basic research | 1627 | 4.22% |
| Total | 38539 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| 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 Respiratory Disorders |  |  |
| 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% |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders | 224 | 0.54% |
| Animal Diseases and Disorders | 9410 | 22.49% |
| Animal Welfare | 4573 | 10.93% |
| Diagnosis of diseases | 788 | 1.88% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 460 | 1.1% |
| Total | 41847 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Neurotoxicity |  |  |
| Phototoxicity |  |  |
| Safety testing in food and feed area |  |  |
| Target animal safety |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 14255 | 80.82% |
| Other lethal methods |  |  |
| Non lethal methods | 3384 | 19.18% |
| Total | 17639 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of 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 use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 1028 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 1028 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | 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 to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 25062 | 43.21% |
| Legislation on medicinal products for veterinary use and their residues | 28770 | 49.6% |
| Medical devices legislation | 516 | 0.89% |
| Industrial chemicals legislation | 834 | 1.44% |
| Plant protection product legislation | 2167 | 3.74% |
| Biocides legislation |  |  |
| Food legislation including food contact material | 461 | 0.79% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 197 | 0.34% |
| Total | 58007 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 56731 | 97.8% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only | 1276 | 2.2% |
| Total | 58007 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 133243 | 94.66% |
| Yes | 7520 | 5.34% |
| Total | 140763 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 12410 | 8.82% |
| Mild [up to and including] | 70383 | 50% |
| Moderate | 39954 | 28.38% |
| Severe | 18016 | 12.8% |
| Total | 140763 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 139882 | 99.37% |
| Yes | 881 | 0.63% |
| Total | 140763 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 132229 | 93.94% |
| Genetically altered without a harmful phenotype | 7898 | 5.61% |
| Genetically altered with a harmful phenotype | 636 | 0.45% |
| Total | 140763 | 100.00% |

# Ireland

## Ireland: Narrative 2015

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

* There was a 1% increase in animal uses from 2014 to 2015.
* There was a 31% drop in procedures reported as severe from 2014 to 2015.

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

* Although the majority of animals are still used for regulatory purposes, basic research overtook translational research as the second most common project purpose. The increase in numbers used for basic research went from 34,512 in 2014 to 42,347 in 2015, an increase of 23%. The species that account for most of this increase in basic research were cattle, pigs and fish, in particular cattle of which there were 7,246 uses in 2015 compared to 2,712 uses in 2014. A significant amount of agricultural research is performed in Ireland, and much of this is reported (based on our advice) as ‘Basic research – ethology/animal behaviour/animal biology’ because it involves feeding trials and investigation into reproductive efficiency. For example, over 2000 cattle were used for a single epidemiological study of the key factors affecting reproductive efficiency of beef cattle herds. This could potentially also be considered as translational research but it doesn’t quite fit into the categories ‘animal diseases and disorders’ nor ‘animal welfare’.

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

* Non-recovery: 1% (2014) to 2% (2015)
* Mild: 28% (2014) to 50% (2015)
* Moderate: 32% (2014) to 22% (2015)
* Severe: 40% (2014) to 27% (2015)
* Overall there was a drop in severe and moderate procedures and an increase in mild and non-recovery procedures. The reason for this is unknown; but we would be cautious about over-interpreting this as it may be due to people becoming more accustomed to recording actual severity properly, rather than recording what they were prospectively authorised for.

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

* In 2015 we made it mandatory for humane endpoints to be implemented for LD50 tests in Ireland; however progress is slow re-validating the different assays so this has not impacted on the statistics, and the eventual impact on the statistics will probably be minimal, as animals will have already reached a ‘severe’ severity when they are culled. We have also been in frequent contact with pharmaceutical companies producing botulinum toxin products in relation to the replacement of animal tests with non-animal assays so we would hope to see a drop in LD50 testing over the next few years when more of these cell-based assays become available for use.
* In 2015 we also contacted all pharmaceutical companies using rabbit pyrogen testing for their products in Ireland requesting they switch to an alternative or provide robust scientific justification for the use of an animal test. This communication has not had a major impact on the statistics for 2015 with 570 rabbits used for pyrogen testing in 2015 (versus 597 in 2014) but we would hope that the positive impact of this dialogue becomes evident in the 2016 statistics..

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

* We did not have many animals reported under the ‘other’ category because we combed through each submission and made sure that if there was an appropriate pre-existing category available, that it was chosen. However, it should be noted that as previously mentioned, a lot of the agricultural research in Ireland could be considered translational, yet there is no appropriate translational category. Animal diseases and disorders is not accurate because these are healthy animals and animal welfare is not appropriate either as most of the research is not to benefit the animal, but to improve yields (e.g. milk, meat) and efficiency and therefore benefit the farmer and the economy. Perhaps there could be a translational category appropriate for this type of work?

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

* The severe classification was not exceeded in 2015.

## Ireland: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 190585 | 83.47% |
| Rats | 9876 | 4.33% |
| Guinea-Pigs | 1929 | 0.84% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 2490 | 1.09% |
| Cats | 164 | 0.07% |
| Dogs | 587 | 0.26% |
| Ferrets | 621 | 0.27% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 127 | 0.06% |
| Pigs | 2372 | 1.04% |
| Goats | 71 | 0.03% |
| Sheep | 1112 | 0.49% |
| Cattle | 11119 | 4.87% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 20 | 0.01% |
| Domestic fowl | 113 | 0.05% |
| Other birds | 572 | 0.25% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus | 420 | 0.18% |
| Other Amphibians |  |  |
| Zebra fish | 1489 | 0.65% |
| Other Fish | 4672 | 2.05% |
| Cephalopods |  |  |
| Total | 228339 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 209587 | 92.77% |
| Animals born in the EU but not at a registered breeder | 15014 | 6.65% |
| Animals born in rest of Europe | 129 | 0.06% |
| Animals born in rest of world | 1195 | 0.53% |
| Total | 225925 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 42179 | 18.47% |
| Translational and applied research | 22516 | 9.86% |
| Regulatory use and Routine production | 157872 | 69.14% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 815 | 0.36% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 389 | 0.17% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 4568 | 2% |
| Total | 228339 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 1061 | 2.52% |
| Cardiovascular Blood and Lymphatic System | 429 | 1.02% |
| Nervous System | 8542 | 20.25% |
| Respiratory System | 473 | 1.12% |
| Gastrointestinal System including Liver | 2943 | 6.98% |
| Musculoskeletal System | 278 | 0.66% |
| Immune System | 13168 | 31.22% |
| Urogenital/Reproductive System | 2378 | 5.64% |
| Sensory Organs (skin, eyes and ears) | 1543 | 3.66% |
| Endocrine System/Metabolism | 578 | 1.37% |
| Multisystemic | 1601 | 3.8% |
| Ethology / Animal Behaviour /Animal Biology | 9185 | 21.78% |
| Other basic research |  |  |
| Total | 42179 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 1209 | 5.37% |
| Human Infectious Disorders | 1413 | 6.28% |
| Human Cardiovascular Disorders | 1002 | 4.45% |
| Human Nervous and Mental Disorders | 4173 | 18.53% |
| Human Respiratory Disorders | 562 | 2.5% |
| Human Gastrointestinal Disorders including Liver | 300 | 1.33% |
| Human Musculoskeletal Disorders | 1776 | 7.89% |
| Human Immune Disorders | 540 | 2.4% |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 1133 | 5.03% |
| Human Endocrine/Metabolism Disorders | 139 | 0.62% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 9656 | 42.89% |
| Animal Welfare | 240 | 1.07% |
| Diagnosis of diseases | 373 | 1.66% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 22516 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 156621 | 99.21% |
| Other efficacy and tolerance testing | 640 | 0.41% |
| Toxicity and other safety testing including pharmacology | 611 | 0.39% |
| Routine production |  |  |
| Total | 157872 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 6021 | 3.84% |
| Pyrogenicity testing | 570 | 0.36% |
| Batch potency testing | 150030 | 95.79% |
| Other quality controls |  |  |
| Total | 156621 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Ecotoxicity | 559 | 91.49% |
| Target animal safety | 52 | 8.51% |
| Total | 611 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 559 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 559 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 155248 | 98.34% |
| Legislation on medicinal products for veterinary use and their residues | 2047 | 1.3% |
| Medical devices legislation | 18 | 0.01% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 559 | 0.35% |
| Total | 157872 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 157872 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 157872 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 225925 | 98.94% |
| Yes | 2414 | 1.06% |
| Total | 228339 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 3020 | 1.32% |
| Mild [up to and including] | 113368 | 49.65% |
| Moderate | 49705 | 21.77% |
| Severe | 62246 | 27.26% |
| Total | 228339 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 226472 | 99.18% |
| Yes | 1867 | 0.82% |
| Total | 228339 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 212262 | 92.96% |
| Genetically altered without a harmful phenotype | 15476 | 6.78% |
| Genetically altered with a harmful phenotype | 601 | 0.26% |
| Total | 228339 | 100.00% |

## Ireland: Narrative 2016

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

* There was a 1% decrease on number of uses reported from 2015.
* There was 21% drop in reported reuse.
* Basic research has reduced by 33% and Translational and applied has increased by 14%.
* The number of uses for Maintenance of colonies of established GA animals not used in other procedures has dropped by 80%.

It is difficult to say with certainty what the reasons for these changes are.

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

As in previous years, in 2016 mice were still the most commonly used species representing 85% of overall animal use. Significant changes in species from 2015 to 2016 include the drop in the number of uses of cattle by 46% and the increased use of ‘other fish’ (e.g. salmon, eels and trout) by 125%. The decrease in cattle use relates to the completion of a particularly large country-wide cattle study in 2015. The increase in the use of ‘other fish’ relates to the increased tracking of eel and salmon stocks in Ireland (using tagging methods) due to concerns regarding their conservation status.

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

* Majority of procedures are still mild (44%)
* Moderate procedures have increased from 22 to 26% of use
* Severe procedures have increased from 27 to 29%
* Non-recovery procedures have dropped from 2% to 1%

Clear trends in relation to severity may take a few more years to emerge as users are still becoming acquainted with the new reporting requirements.

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

The HPRA has made specific proactive efforts in communicating with contract research organisations and pharmaceutical companies in relation to the introduction of non-animal alternatives for regulatory tests, e.g. rabbit pyrogen and LD50 testing, as well as the introduction of earlier humane endpoints (for LD50 testing). However, due to the complex and protracted process involved in gaining regulatory acceptance and approval for such changes to regulatory testing protocols, an impact on the annual statistics is not expected until the 2018 report at the earliest.

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

The category ‘other fish’ represented 5% of animal use. This primarily represents wild fish being studied for conservation projects. For example, European eels are a critically endangered species and Irish salmon stocks are critically low, so monitoring projects are required to improve the survival of these species

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

This was not exceeded nor was exemption granted at all during 2016.

## Ireland: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 192121 | 84.66% |
| Rats | 9892 | 4.36% |
| Guinea-Pigs | 964 | 0.42% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 1228 | 0.54% |
| Cats | 271 | 0.12% |
| Dogs | 356 | 0.16% |
| Ferrets | 404 | 0.18% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 204 | 0.09% |
| Pigs | 1209 | 0.53% |
| Goats | 30 | 0.01% |
| Sheep | 1323 | 0.58% |
| Cattle | 6044 | 2.66% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 196 | 0.09% |
| Other birds | 674 | 0.3% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus | 60 | 0.03% |
| Other Amphibians |  |  |
| Zebra fish | 1439 | 0.63% |
| Other Fish | 10519 | 4.64% |
| Cephalopods |  |  |
| Total | 226934 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 209821 | 93.28% |
| Animals born in the EU but not at a registered breeder | 14166 | 6.3% |
| Animals born in rest of Europe | 455 | 0.2% |
| Animals born in rest of world | 487 | 0.22% |
| Total | 224929 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 28340 | 12.49% |
| Translational and applied research | 26230 | 11.56% |
| Regulatory use and Routine production | 170976 | 75.34% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 235 | 0.1% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 250 | 0.11% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 903 | 0.4% |
| Total | 226934 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 213 | 0.75% |
| Cardiovascular Blood and Lymphatic System | 803 | 2.83% |
| Nervous System | 3876 | 13.68% |
| Respiratory System | 1081 | 3.81% |
| Gastrointestinal System including Liver | 2388 | 8.43% |
| Musculoskeletal System | 68 | 0.24% |
| Immune System | 6667 | 23.53% |
| Urogenital/Reproductive System | 4 | 0.01% |
| Sensory Organs (skin, eyes and ears) | 553 | 1.95% |
| Endocrine System/Metabolism | 101 | 0.36% |
| Multisystemic | 717 | 2.53% |
| Ethology / Animal Behaviour /Animal Biology | 11868 | 41.88% |
| Other basic research | 1 | 0% |
| Total | 28340 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 1566 | 5.97% |
| Human Infectious Disorders | 947 | 3.61% |
| Human Cardiovascular Disorders | 2086 | 7.95% |
| Human Nervous and Mental Disorders | 9308 | 35.49% |
| Human Respiratory Disorders | 80 | 0.3% |
| Human Gastrointestinal Disorders including Liver | 369 | 1.41% |
| Human Musculoskeletal Disorders | 538 | 2.05% |
| Human Immune Disorders | 1130 | 4.31% |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 1553 | 5.92% |
| Human Endocrine/Metabolism Disorders | 584 | 2.23% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 7691 | 29.32% |
| Animal Welfare | 360 | 1.37% |
| Diagnosis of diseases | 18 | 0.07% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 26230 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 169714 | 99.26% |
| Other efficacy and tolerance testing |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 1262 | 0.74% |
| Total | 170976 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 1630 | 0.96% |
| Pyrogenicity testing | 506 | 0.3% |
| Batch potency testing | 167549 | 98.72% |
| Other quality controls | 29 | 0.02% |
| Total | 169714 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Kinetics | 12 | 0.95% |
| Pharmaco-dynamics (incl safety pharmacology) | 30 | 2.38% |
| Ecotoxicity | 1180 | 93.5% |
| Target animal safety | 40 | 3.17% |
| Total | 1262 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 1180 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 1180 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 167227 | 97.81% |
| Legislation on medicinal products for veterinary use and their residues | 2540 | 1.49% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 1209 | 0.71% |
| Total | 170976 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 139897 | 81.82% |
| Legislation satisfying national requirements only [within EU] | 29 | 0.02% |
| Legislation satisfying Non-EU requirements only | 31050 | 18.16% |
| Total | 170976 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 224929 | 99.12% |
| Yes | 2005 | 0.88% |
| Total | 226934 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 2357 | 1.04% |
| Mild [up to and including] | 99442 | 43.82% |
| Moderate | 58832 | 25.92% |
| Severe | 66303 | 29.22% |
| Total | 226934 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 225555 | 99.39% |
| Yes | 1379 | 0.61% |
| Total | 226934 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 216565 | 95.43% |
| Genetically altered without a harmful phenotype | 8360 | 3.68% |
| Genetically altered with a harmful phenotype | 2009 | 0.89% |
| Total | 226934 | 100.00% |

## Ireland: Narrative 2017

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

* There was a 7% increase in animal use from the previous year (2016)
* This increase is accounted for by an increase in regulatory testing which is 80% of all testing.
* The use of cattle has dropped by 46% from the previous year, cats have dropped by 100% and dogs by 75%.
* There was a 67% decrease on reuse from the previous year.
* Basic research has dropped by 70% and Translational and Applied research has increased by 14%.
* There is a 28% drop in number of uses reported for ‘Maintenance of colonies of established GA animals not used in other procedures’.

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

* The 7% increase in animal numbers is due to increased regulatory testing, largely due to increased batch potency testing. The main reason for this was a breakdown of a non-animal alternative test, resulting in increased animal testing. Another smaller proportion of this increase was due to the use of additional animals for the validation of humane endpoints for batch potency testing.
* The reduction in cattle was due to the completion of a very large country-wide agricultural project. The reduction in dogs and cats was due to the closure of a dog and cat facility.
* The drop in basic research and increase in translational is not likely due to a true change in the type of research being conducted, but likely more accurate reporting.
* The reason for the drop in uses reported for ‘maintenance of colonies of established GA animals not used in other procedures’ is not known, but could be due to more efficient GA breeding.

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

There was a very slight increase in mild procedures (44 to 47%) and a slight decrease in moderate procedures (26 to 23%) but otherwise the proportions remained the same.

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

* We focused a lot of efforts in ensuring that there is a move to non-animal alternatives for batch potency testing; however this is not reflected in the figures in 2017, but it is expected that it will be reflected in the 2018 figures on. For the animals that still must be used for this type of testing, we have also required the establishment to work on implementing humane endpoints for these tests. This should, over time, reduce the animals in the ‘severe’ actual severity category, but this is not yet reflected in the figures.
* We have also put efforts into ensuring that rabbit pyrogen testing is only carried out where justified, by contacting the pharmaceutical companies that employ this type of testing. Since 2014 there has been a 48% reduction in this type of testing.

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

There was no significant use of the ‘other’ categories at all. With regards to species, ‘other fish’ account for 4% of animal use and ‘other birds’ less than 1%. These relates to studies of wild animals, such as tagging and conservation projects.

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

This was not exceeded during 2017.

## Ireland: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 206908 | 85.39% |
| Rats | 16858 | 6.96% |
| Guinea-Pigs | 518 | 0.21% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 400 | 0.17% |
| Cats |  |  |
| Dogs | 89 | 0.04% |
| Ferrets | 442 | 0.18% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 60 | 0.02% |
| Pigs | 1547 | 0.64% |
| Goats | 11 | 0% |
| Sheep | 1321 | 0.55% |
| Cattle | 3244 | 1.34% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 40 | 0.02% |
| Other birds | 823 | 0.34% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus | 18 | 0.01% |
| Other Amphibians |  |  |
| Zebra fish | 236 | 0.1% |
| Other Fish | 9787 | 4.04% |
| Cephalopods |  |  |
| Total | 242302 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 227994 | 94.36% |
| Animals born in the EU but not at a registered breeder | 13065 | 5.41% |
| Animals born in rest of Europe | 121 | 0.05% |
| Animals born in rest of world | 447 | 0.18% |
| Total | 241627 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 8558 | 3.53% |
| Translational and applied research | 29815 | 12.3% |
| Regulatory use and Routine production | 194816 | 80.4% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 8366 | 3.45% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 274 | 0.11% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 473 | 0.2% |
| Total | 242302 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 391 | 4.57% |
| Cardiovascular Blood and Lymphatic System | 5 | 0.06% |
| Nervous System | 2068 | 24.16% |
| Respiratory System | 724 | 8.46% |
| Gastrointestinal System including Liver | 1111 | 12.98% |
| Musculoskeletal System | 192 | 2.24% |
| Immune System | 991 | 11.58% |
| Urogenital/Reproductive System | 238 | 2.78% |
| Sensory Organs (skin, eyes and ears) | 54 | 0.63% |
| Endocrine System/Metabolism | 139 | 1.62% |
| Multisystemic | 6 | 0.07% |
| Ethology / Animal Behaviour /Animal Biology | 2635 | 30.79% |
| Other basic research | 4 | 0.05% |
| Total | 8558 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 754 | 2.53% |
| Human Infectious Disorders | 780 | 2.62% |
| Human Cardiovascular Disorders | 1195 | 4.01% |
| Human Nervous and Mental Disorders | 9381 | 31.46% |
| Human Respiratory Disorders | 277 | 0.93% |
| Human Gastrointestinal Disorders including Liver | 1114 | 3.74% |
| Human Musculoskeletal Disorders | 747 | 2.51% |
| Human Immune Disorders | 8230 | 27.6% |
| Human Urogenital/Reproductive Disorders | 50 | 0.17% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 2057 | 6.9% |
| Human Endocrine/Metabolism Disorders | 444 | 1.49% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 2115 | 7.09% |
| Animal Welfare | 2553 | 8.56% |
| Diagnosis of diseases | 118 | 0.4% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 29815 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 194247 | 99.71% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 540 | 0.28% |
| Routine production | 29 | 0.01% |
| Total | 194816 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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% |
| Other quality controls |  |  |
| Total | 194247 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Ecotoxicity | 500 | 92.59% |
| Target animal safety | 40 | 7.41% |
| Total | 540 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 500 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 500 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 29 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 29 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 185727 | 95.33% |
| Legislation on medicinal products for veterinary use and their residues | 8589 | 4.41% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 500 | 0.26% |
| Total | 194816 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 194784 | 99.98% |
| Legislation satisfying national requirements only [within EU] | 32 | 0.02% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 194816 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 241627 | 99.72% |
| Yes | 675 | 0.28% |
| Total | 242302 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 2283 | 0.94% |
| Mild [up to and including] | 114261 | 47.16% |
| Moderate | 55162 | 22.77% |
| Severe | 70596 | 29.14% |
| Total | 242302 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 241716 | 99.76% |
| Yes | 586 | 0.24% |
| Total | 242302 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 234806 | 96.91% |
| Genetically altered without a harmful phenotype | 5737 | 2.37% |
| Genetically altered with a harmful phenotype | 1759 | 0.73% |
| Total | 242302 | 100.00% |

# Italy

## Italy: Narrative 2015

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

In 2015, the total number of animals used in testing was 581,935, the first time this figure had fallen below 600,000. In general, the decrease in 2015 as compared to the previous year reflects the downward trend in the total number of animals used in testing, which has consistently remained below the one million mark since 1999.

In 2015, rodents and rabbits accounted for 91.19% of the animal species used. Within these species, there was an increase in the number of rats, rabbits and ‘other rodents’ used, while on the other hand there was a marked decrease from 485,820 to 373,483 in the number of mice used.

On the whole there has been a decrease in the use of other animal species, except for a slight increase as regards domestic fowl (from 28,215 in 2014 to 30,984 in 2015).

The total number of animals used went from 691,666 in 2014 to 581,935 in 2015, a percentage decrease of -15.86%. (See Table 1)

**Table 1**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Animal species | 2014 | % of the 2014 total | 2015 | % of the 2015 total | DIFFERENCE IN THE NUMBER OF ANIMALS | % DIFFERENCE 2014 / 2015 |
| Rodents and rabbits | 639,914 | 92.52 | 530,677 | 91.19 | -109,237 | -17.07 |
| Other animal species | 51,752 | 7.48 | 51,258 | 8.81 | -494 | -0.95 |
| **Total (all species)** | **691,666** | **100.00** | **581,935** | **100.00** | **-109,737** | **-15.86** |

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

37.26% of the animals were used in basic biological studies.

24.92% of the animals were used in translational or applied research.

36.07% of the animals were used for regulatory use and routine production.

1.75% of the animals were used for other purposes.

No animals were used for forensic enquiries.

**Table 2**

|  |  |  |  |
| --- | --- | --- | --- |
| Purpose of studies | 2014  % | 2015  % | % DIFFERENCE |
| Basic research | 41.84 | 37.26 | -4.58 |
| Translational research | 31.77 | 24.92 | -6.85 |
| Regulatory testing | 25.45 | 36.07 | 10.62 |
| Other | 0.94 | 1.75 | 0.81 |

2015 saw an increase in the number of animals used for regulatory testing, while there was a decrease in the number of animals used for both basic research and translational research and a very slight increase for other purposes (see Table 2).

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

Data collection on the level of suffering felt by animals was recorded for the second time in 2015. A comparison between 2014 and 2015 shows that more than 47% of the animals experienced a ‘mild’ level of suffering, followed by 39% of animals with ‘moderate’ suffering, with neither the ‘non-recovery’ nor ‘severe’ suffering levels exceeding 7% (see Table 3).

**Table 3**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Suffering level / Year | **Non-recovery** | **Mild (up to and including)** | **Moderate** | **Severe** |
| 2014 | 4.89 | 49.09 | 42.90 | 3.12 |
| 2015 | 6.16 | 47.58 | 39.44 | 6.82 |

1. **Particular efforts to promote the principle of replacement, reduction and refinement and its impact on statistics if any.**

Legislative Decree No 26/2014, which transposes the European Directive, designated the **laboratory of the cell substrates and cellular immunology department** of the Lombardy and Emilia-Romagna Animal Disease Prevention Institute as the single contact point charged with providing advice on the suitability and regulatory appropriateness of alternative approaches proposed for validation studies.

That Decree earmarks funding for the development and validation of alternative methods and for staff training. This funding is €1 million annually for the 2014-2016 period, broken down as follows:

* 50% to be paid to the regions and autonomous provinces to finance training and refresher courses for staff of authorised establishments;
* 50% to be paid to Animal Disease Prevention Institutes for research and development of alternative methods.

Monies from levying the new State administrative fines (see Article 40(25)) are also allocated to the development and validation of alternative methods.

Also worth noting is the work of the Animal Welfare Bodies (*Organismi Preposti al Benessere Animale* (OPBAs)) under Article 25 of Legislative Decree No 26/2014. OPBAs are required to issue a reasoned opinion on research projects that are to be submitted for ministerial authorisation, verifying the correct application of the Three Rs principle and assessing the possibility of replacing one or more procedures with alternative methods and, where possible, also reducing the number of animals used.

As far as staff training is concerned, various conferences, workshops and courses were organised by the National Reference Centre for Animal Welfare in Brescia, universities and other research institutes. The Ministry of Health sends its own experts as lecturers to such training events.

The Ministry provided training at no fewer than ten training courses in 2015.

1. **Further breakdown on the use of ‘other’ categories if a significant proportion of animal use is reported under this category.**

Nothing to report.

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

There were no cases in which the ‘severe’ classification was exceeded.

## Italy: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 373666 | 63.69% |
| Rats | 130972 | 22.32% |
| Guinea-Pigs | 16668 | 2.84% |
| Hamsters (Syrian) | 488 | 0.08% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 494 | 0.08% |
| Rabbits | 9775 | 1.67% |
| Cats |  |  |
| Dogs | 601 | 0.1% |
| Ferrets | 14 | 0% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 1746 | 0.3% |
| Goats | 4 | 0% |
| Sheep | 235 | 0.04% |
| Cattle | 733 | 0.12% |
| Prosimians |  |  |
| Marmoset and tamarins | 3 | 0% |
| Cynomolgus monkey | 278 | 0.05% |
| Rhesus monkey | 4 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) | 8 | 0% |
| Other species of New World Monkeys (Ceboidea) | 24 | 0% |
| Apes |  |  |
| Other Mammals | 16 | 0% |
| Domestic fowl | 33020 | 5.63% |
| Other birds | 750 | 0.13% |
| Reptiles | 100 | 0.02% |
| Rana |  |  |
| Xenopus | 422 | 0.07% |
| Other Amphibians | 7 | 0% |
| Zebra fish | 11331 | 1.93% |
| Other Fish | 5328 | 0.91% |
| Cephalopods | 12 | 0% |
| Total | 586699 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 544052 | 93.53% |
| Animals born in the EU but not at a registered breeder | 35311 | 6.07% |
| Animals born in rest of Europe | 1167 | 0.2% |
| Animals born in rest of world | 1181 | 0.2% |
| Total | 581711 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 4 | 1.79% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 112 | 50% |
| Animals born in America |  |  |
| Animals born in Africa | 108 | 48.21% |
| Animals born elsewhere |  |  |
| Total | 224 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 54 | 24.11% |
| F2 or greater | 169 | 75.45% |
| Self-sustaining colony | 1 | 0.45% |
| Total | 224 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 218615 | 37.26% |
| Translational and applied research | 146213 | 24.92% |
| Regulatory use and Routine production | 211615 | 36.07% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 76 | 0.01% |
| Preservation of species | 228 | 0.04% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1042 | 0.18% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 8910 | 1.52% |
| Total | 586699 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 61958 | 28.34% |
| Cardiovascular Blood and Lymphatic System | 9112 | 4.17% |
| Nervous System | 83400 | 38.15% |
| Respiratory System | 4470 | 2.04% |
| Gastrointestinal System including Liver | 7690 | 3.52% |
| Musculoskeletal System | 5485 | 2.51% |
| Immune System | 22940 | 10.49% |
| Urogenital/Reproductive System | 2015 | 0.92% |
| Sensory Organs (skin, eyes and ears) | 1556 | 0.71% |
| Endocrine System/Metabolism | 4640 | 2.12% |
| Multisystemic | 5293 | 2.42% |
| Ethology / Animal Behaviour /Animal Biology | 7120 | 3.26% |
| Other basic research | 2936 | 1.34% |
| Total | 218615 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 40751 | 27.87% |
| Human Infectious Disorders | 17960 | 12.28% |
| Human Cardiovascular Disorders | 2606 | 1.78% |
| Human Nervous and Mental Disorders | 21148 | 14.46% |
| Human Respiratory Disorders | 17944 | 12.27% |
| Human Gastrointestinal Disorders including Liver | 2428 | 1.66% |
| Human Musculoskeletal Disorders | 2809 | 1.92% |
| Human Immune Disorders | 6644 | 4.54% |
| Human Urogenital/Reproductive Disorders | 2842 | 1.94% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 1908 | 1.3% |
| Human Endocrine/Metabolism Disorders | 7589 | 5.19% |
| Other Human Disorders | 3820 | 2.61% |
| Animal Diseases and Disorders | 365 | 0.25% |
| Animal Welfare | 466 | 0.32% |
| Diagnosis of diseases | 16369 | 11.2% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 564 | 0.39% |
| Total | 146213 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 108737 | 51.38% |
| Other efficacy and tolerance testing | 36979 | 17.47% |
| Toxicity and other safety testing including pharmacology | 62965 | 29.75% |
| Routine production | 2934 | 1.39% |
| Total | 211615 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 26087 | 23.99% |
| Pyrogenicity testing | 4007 | 3.69% |
| Batch potency testing | 75036 | 69.01% |
| Other quality controls | 3607 | 3.32% |
| Total | 108737 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 15574 | 24.73% |
| Skin irritation/corrosion | 583 | 0.93% |
| Skin sensitisation | 10312 | 16.38% |
| Eye irritation/corrosion | 54 | 0.09% |
| Repeated dose toxicity | 8137 | 12.92% |
| Carcinogenicity | 873 | 1.39% |
| Genotoxicity | 378 | 0.6% |
| Reproductive toxicity | 6583 | 10.46% |
| Developmental toxicity | 4162 | 6.61% |
| Neurotoxicity | 200 | 0.32% |
| Kinetics | 5513 | 8.76% |
| Pharmaco-dynamics (incl safety pharmacology) | 504 | 0.8% |
| Phototoxicity | 164 | 0.26% |
| Ecotoxicity | 3985 | 6.33% |
| Safety testing in food and feed area | 4970 | 7.89% |
| Target animal safety | 196 | 0.31% |
| Other toxicity/safety testing | 777 | 1.23% |
| Total | 62965 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 6296 | 40.43% |
| Other lethal methods | 120 | 0.77% |
| Non lethal methods | 9158 | 58.8% |
| Total | 15574 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 4350 | 53.46% |
| 29 - 90 days | 2841 | 34.91% |
| > 90 days | 946 | 11.63% |
| Total | 8137 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 3319 | 83.29% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity | 666 | 16.71% |
| Total | 3985 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 1115 | 38% |
| Monoclonal antibody by mouse ascites method | 1520 | 51.81% |
| Other product types | 299 | 10.19% |
| Total | 2934 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 133861 | 63.26% |
| Legislation on medicinal products for veterinary use and their residues | 31907 | 15.08% |
| Medical devices legislation | 16980 | 8.02% |
| Industrial chemicals legislation | 8704 | 4.11% |
| Plant protection product legislation | 734 | 0.35% |
| Biocides legislation | 1749 | 0.83% |
| Food legislation including food contact material | 11973 | 5.66% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 706 | 0.33% |
| Cosmetics legislation |  |  |
| Other legislation | 5001 | 2.36% |
| Total | 211615 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 204055 | 96.43% |
| Legislation satisfying national requirements only [within EU] | 2085 | 0.99% |
| Legislation satisfying Non-EU requirements only | 5475 | 2.59% |
| Total | 211615 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 581935 | 99.19% |
| Yes | 4764 | 0.81% |
| Total | 586699 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 36159 | 6.16% |
| Mild [up to and including] | 279151 | 47.58% |
| Moderate | 231395 | 39.44% |
| Severe | 39994 | 6.82% |
| Total | 586699 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 582552 | 99.29% |
| Yes | 4147 | 0.71% |
| Total | 586699 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 463538 | 79.01% |
| Genetically altered without a harmful phenotype | 110917 | 18.91% |
| Genetically altered with a harmful phenotype | 12244 | 2.09% |
| Total | 586699 | 100.00% |

## Italy: Narrative 2016

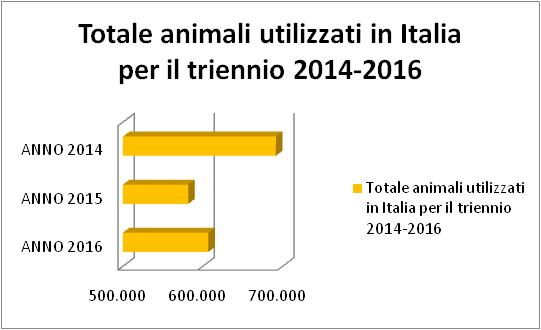
**Introduction**

The data for Italy for 2016 are from the Ministry of Health – Directorate-General for Animal Health and Veterinary Medicines – Office 6 – Animal Welfare. They were collected via the National Electronic Database and, after suitability testing, were sent to the European Commission through the DECLARE platform.

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

In 2016, the total number of animals used in testing was 607,097, i.e. slightly more than 600,000. This was lower than in 2014 (691,666 animals; -12.23%) and slightly higher than in 2015 (581,935; +4.32%) (see Figure 1). In any case, the data confirm the downward trend in the total number of animals used in testing, which has remained below the one million mark since 1999.

**Figure 1**



*Translation of legend: Total number of animals used in Italy 2014-2016*

**In 2016, rodents and rabbits accounted for 90.36% of the animal species used.** Within these species, there was an increase in the number of mice and rabbits as compared to 2015, while the use of rats decreased slightly.

For other animal species – which, in 2016, accounted for 9.64% of the total – there was an increase in the use of domestic fowl, fish (zebrafish) and amphibians (Xenopus). (See Table 1)

**Table 1**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Animal species | 2014 | % of the 2014 total | 2015 | % of the 2015 total | 2016 | % of the 2016 total | DIFFERENCE IN THE NUMBER OF ANIMALS 2014 / 2016 | % DIFFERENCE 2014 / 2016 |
| Rodents and rabbits | 639,914 | 92.52 | 530,677 | 91.19 | 548,578 | 90.36 | -91,336 | -14.27 |
| Other animal species | 51,752 | 7.48 | 51,258 | 8.81 | 58,519 | 9.64 | 6,767 | 13.07 |
| **Total (all species)** | **691,666** | **100.00** | **581,935** | **100.00** | **607,097** | **100.00** | **-84,569** | **-12.23** |

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

35.42% of the animals were used in basic biological studies.

26.54% were used in translational or applied research.

37.11% were used for regulatory use and routine production.

0.93% for other purposes.

No animals were used for forensic enquiries.

**Table 2**

|  |  |  |  |
| --- | --- | --- | --- |
| Purpose of studies | 2014  % | 2016  % | DIFFERENCE 2014 / 2016  % |
| Basic research | 41.84 | 35.42 | -6.42 |
| Translational research | 31.77 | 26.54 | -5.23 |
| Regulatory testing | 25.45 | 37.11 | 11.66 |
| Other | 0.94 | 0.93 | -0.01 |

The downward trend in the number of animals used in basic research and translational research was confirmed in 2016.

The use of animals in regulatory testing (experiments that are compulsory under national, European and international law) was the most common purpose. (See Table 2)

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

Data collection on the level of suffering felt by animals was recorded for the third time in 2016. Comparing 2014, 2015 and 2016 shows that there were no material variations in the ‘non‑recovery’ and ‘mild’ suffering levels, while there has been an increase in the ‘severe’ category (see Table 3).

**Table 3**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Suffering level / Year | **Non-recovery** | **Mild (up to and including)** | **Moderate** | **Severe** |
| 2014 | 4.89% | 49.09% | 42.90% | 3.12% |
| 2015 | 6.16% | 47.58% | 39.44% | 6.82% |
| 2016 | 4.81% | 50.42% | 34.11% | 10.66% |

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

Legislative Decree No 26/2014, which transposes the European Directive, designated the **laboratory of the cell substrates and cellular immunology department** of the Lombardy and Emilia-Romagna Animal Disease Prevention Institute as the single contact point charged with providing advice on the suitability and regulatory appropriateness of alternative approaches proposed for validation studies.

That Decree earmarks funding for the development and validation of alternative methods and for staff training. This funding is € 1 million annually for the 2014-2016 period, broken down as follows:

* 50% to be paid to the regions and autonomous provinces to finance training and refresher courses for staff of authorised establishments;
* 50% to be paid to Animal Disease Prevention Institutes for research and development of alternative methods.

Monies from levying the new State administrative fines (see Article 40(25)) are also allocated to the development and validation of alternative methods.

***Animal Welfare Bodies (OPBAs)***

In 2016, greater awareness among and increased capacity for intervention by the Animal Welfare Bodies (OPBAs) in assessing research projects so as to issue reasoned opinions made it possible to verify, to the best extent possible, the correct application of the Three Rs principle, particularly in the basic research and translational research sectors. The OPBAs’ work enabled an assessment of the possibility of replacing one or more procedures with alternative methods and, where possible, also reducing the number of animals to be used, thus giving rise to a general downward trend in animal use except in the regulatory sector.

As far as staff skills are concerned, conferences, workshops and courses were organised by the National Reference Centre for Animal Welfare in Brescia, universities and other research institutes, with experts from the Ministry of Health participating as lecturers. The Ministry provided training at a total of 15 training courses in 2016.

Lastly, it is worth stressing the importance of the first National Animal Welfare Conference, which was devised and organised by the Directorate-General for Animal Health and Veterinary Medicines (DGSAF) at the Ministry of Health. The Conference had the positive effect of putting the spotlight on the issue of animal welfare in all sectors. More specifically, one session was devoted entirely to the topic of protecting the animals used for scientific purposes. The speakers stressed the innovations and developments brought about by Legislative Decree No 26/2014, which transposed the European Directive, but also highlighted the problem areas in which it is necessary to keep working so as to ensure that projects are assessed ever more carefully while keeping to the deadlines set in the Directive.

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

Nothing to report.

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

There were no cases in which the ‘severe’ classification was exceeded.

## Italy: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 388976 | 63.59% |
| Rats | 128186 | 20.96% |
| Guinea-Pigs | 16977 | 2.78% |
| Hamsters (Syrian) | 553 | 0.09% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 143 | 0.02% |
| Rabbits | 15245 | 2.49% |
| Cats |  |  |
| Dogs | 486 | 0.08% |
| Ferrets | 7 | 0% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 19 | 0% |
| Pigs | 1534 | 0.25% |
| Goats | 53 | 0.01% |
| Sheep | 232 | 0.04% |
| Cattle | 115 | 0.02% |
| Prosimians |  |  |
| Marmoset and tamarins | 9 | 0% |
| Cynomolgus monkey | 488 | 0.08% |
| Rhesus monkey | 6 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) | 8 | 0% |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 36701 | 6% |
| Other birds | 468 | 0.08% |
| Reptiles | 57 | 0.01% |
| Rana |  |  |
| Xenopus | 771 | 0.13% |
| Other Amphibians | 8 | 0% |
| Zebra fish | 14664 | 2.4% |
| Other Fish | 6001 | 0.98% |
| Cephalopods |  |  |
| Total | 611707 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 557983 | 91.97% |
| Animals born in the EU but not at a registered breeder | 46168 | 7.61% |
| Animals born in rest of Europe | 835 | 0.14% |
| Animals born in rest of world | 1690 | 0.28% |
| Total | 606676 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 139 | 33.02% |
| Animals born in America |  |  |
| Animals born in Africa | 282 | 66.98% |
| Animals born elsewhere |  |  |
| Total | 421 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 94 | 22.33% |
| F2 or greater | 327 | 77.67% |
| Self-sustaining colony |  |  |
| Total | 421 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 216654 | 35.42% |
| Translational and applied research | 162406 | 26.55% |
| Regulatory use and Routine production | 226969 | 37.1% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 1551 | 0.25% |
| Preservation of species | 167 | 0.03% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1787 | 0.29% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 2173 | 0.36% |
| Total | 611707 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 59961 | 27.68% |
| Cardiovascular Blood and Lymphatic System | 9330 | 4.31% |
| Nervous System | 82143 | 37.91% |
| Respiratory System | 2755 | 1.27% |
| Gastrointestinal System including Liver | 4929 | 2.28% |
| Musculoskeletal System | 8391 | 3.87% |
| Immune System | 20124 | 9.29% |
| Urogenital/Reproductive System | 4933 | 2.28% |
| Sensory Organs (skin, eyes and ears) | 1689 | 0.78% |
| Endocrine System/Metabolism | 5655 | 2.61% |
| Multisystemic | 7227 | 3.34% |
| Ethology / Animal Behaviour /Animal Biology | 6098 | 2.81% |
| Other basic research | 3419 | 1.58% |
| Total | 216654 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 45578 | 28.06% |
| Human Infectious Disorders | 29058 | 17.89% |
| Human Cardiovascular Disorders | 2074 | 1.28% |
| Human Nervous and Mental Disorders | 19042 | 11.72% |
| Human Respiratory Disorders | 17539 | 10.8% |
| Human Gastrointestinal Disorders including Liver | 4221 | 2.6% |
| Human Musculoskeletal Disorders | 6107 | 3.76% |
| Human Immune Disorders | 5657 | 3.48% |
| Human Urogenital/Reproductive Disorders | 1334 | 0.82% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 3540 | 2.18% |
| Human Endocrine/Metabolism Disorders | 3441 | 2.12% |
| Other Human Disorders | 6573 | 4.05% |
| Animal Diseases and Disorders | 4309 | 2.65% |
| Animal Welfare | 81 | 0.05% |
| Diagnosis of diseases | 13214 | 8.14% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 638 | 0.39% |
| Total | 162406 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 111607 | 49.17% |
| Other efficacy and tolerance testing | 48352 | 21.3% |
| Toxicity and other safety testing including pharmacology | 65075 | 28.67% |
| Routine production | 1935 | 0.85% |
| Total | 226969 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 24249 | 21.73% |
| Pyrogenicity testing | 4352 | 3.9% |
| Batch potency testing | 79363 | 71.11% |
| Other quality controls | 3643 | 3.26% |
| Total | 111607 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 11131 | 17.1% |
| Skin irritation/corrosion | 738 | 1.13% |
| Skin sensitisation | 11885 | 18.26% |
| Eye irritation/corrosion | 134 | 0.21% |
| Repeated dose toxicity | 8838 | 13.58% |
| Carcinogenicity | 229 | 0.35% |
| Genotoxicity | 307 | 0.47% |
| Reproductive toxicity | 955 | 1.47% |
| Developmental toxicity | 8593 | 13.2% |
| Neurotoxicity | 25 | 0.04% |
| Kinetics | 6155 | 9.46% |
| Pharmaco-dynamics (incl safety pharmacology) | 495 | 0.76% |
| Phototoxicity | 66 | 0.1% |
| Ecotoxicity | 3833 | 5.89% |
| Safety testing in food and feed area | 11049 | 16.98% |
| Target animal safety | 24 | 0.04% |
| Other toxicity/safety testing | 618 | 0.95% |
| Total | 65075 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 1003 | 9.01% |
| Other lethal methods | 439 | 3.94% |
| Non lethal methods | 9689 | 87.05% |
| Total | 11131 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 2794 | 31.61% |
| 29 - 90 days | 4214 | 47.68% |
| > 90 days | 1830 | 20.71% |
| Total | 8838 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 3317 | 86.54% |
| Chronic toxicity | 158 | 4.12% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity | 358 | 9.34% |
| Total | 3833 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 1089 | 56.28% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 846 | 43.72% |
| Total | 1935 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 147217 | 64.86% |
| Legislation on medicinal products for veterinary use and their residues | 35207 | 15.51% |
| Medical devices legislation | 18639 | 8.21% |
| Industrial chemicals legislation | 9129 | 4.02% |
| Plant protection product legislation | 401 | 0.18% |
| Biocides legislation | 1119 | 0.49% |
| Food legislation including food contact material | 11974 | 5.28% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 3283 | 1.45% |
| Total | 226969 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 215219 | 94.82% |
| Legislation satisfying national requirements only [within EU] | 1884 | 0.83% |
| Legislation satisfying Non-EU requirements only | 9866 | 4.35% |
| Total | 226969 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 607097 | 99.25% |
| Yes | 4610 | 0.75% |
| Total | 611707 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 29421 | 4.81% |
| Mild [up to and including] | 308396 | 50.42% |
| Moderate | 208660 | 34.11% |
| Severe | 65230 | 10.66% |
| Total | 611707 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 604369 | 98.8% |
| Yes | 7338 | 1.2% |
| Total | 611707 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 488643 | 79.88% |
| Genetically altered without a harmful phenotype | 108952 | 17.81% |
| Genetically altered with a harmful phenotype | 14112 | 2.31% |
| Total | 611707 | 100.00% |

## Italy: Narrative 2017

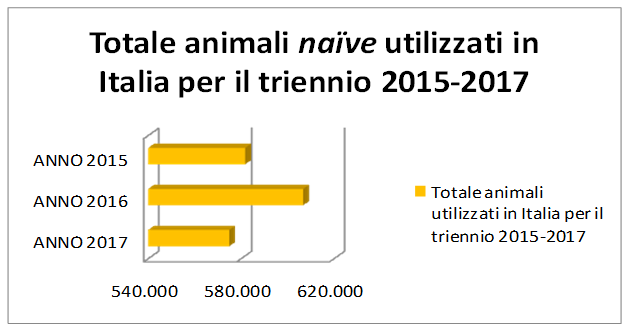
**Introduction**

The data for Italy for 2017 are from the Ministry of Health – Directorate-General for Animal Health and Veterinary Medicines – Office 6 – Animal Welfare. They were collected via the National Electronic Database and, after suitability testing, were sent to the European Commission through the DECLARE platform.

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

In 2017, the total number of animals used in testing for the first time (‘naïve’ animals) was 575,352, i.e. fewer than 600,000. This was lower than in 2015 (-1.20%) and 2016 (-5.54%) (see Figure 1). In any case, the data confirm the downward trend in the total number of animals used in testing, which has remained below the one million mark since 1999.

**Figure 1**

****

*Translation of legends:*

* *Total number of naïve animals used in Italy 2015-2017*
* *Total number of animals used in Italy 2015-2017*

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

In 2015-2017 (see Table 1), rodents and animals accounted for 89.55% of the animal species used, including reused animals. Within these species, there was a decrease in the number of rodents and a significant increase in the number of rabbits. The increase in the number of rabbits is explained by the fact that around 95% of them are used in regulatory testing, i.e. tests that are compulsory under European or international law.

With regard to regulatory tests on rabbits, 78% of rabbits were used for quality controls on batches of medicines for human use, medical devices and veterinary medicines.

Another increase was in the use of non-human primates in regulatory tests (toxicity and other safety tests) required by European and international law (from 86.75% in 2015 to 97.27% in 2017). In consequence, there was a percentage decrease in non-human primates used in basic research in the three-year period concerned (from 11.67% in 2015 to 0.68% in 2017).

The most frequently used species was Macaca fascicularis; 2017 saw an increase in the use of generation F1 animals owing to reduced availability of generation F2 animals from breeding establishments and suppliers of non-human primates and the simultaneous increase in the number of regulatory tests.

For other animal species, there was a continuous increase in the 2015-2017 period in the use of:

* zebrafish in basic and translational research in the area of oncology and gastrointestinal diseases and in regulatory testing (ecotoxicity);
* other fish in translational research in the area of animal diseases.

**Table 1**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Animal species** | % of the 2015 total | % of the 2016 total | % of the 2017 total | AVERAGE % - 2015-2017 | % DIFFERENCE 2015 / 2017 |
| Rodents | 89.02% | 87.43% | 84.73% | 87.06% | -4.82 % |
| Rabbits | 1.66% | 2.49% | 3.33% | 2.49% | +97.70% |
| Total rodents + rabbits | **90.68%** | **89.82%** | **88.06%** | **89.52%** | -2.89% |
| Other animal species | **9.32%** | **10.18%** | **11.94%** | **10.48%** | +28.11% |
| **Total (all species)** | **100.00%** | **100.00%** | **100.00%** | **100.00%** |  |

For 2017:

33.55% of the animals were used in basic biological studies.

26.48% were used in translational or applied research.

38.96% were used for regulatory use and routine production.

1.01% of the animals were used for other purposes.

No animals were used for forensic enquiries.

**Table 2**

**Animal uses by purpose of studies**

|  |  |  |  |
| --- | --- | --- | --- |
| Purpose of studies | % 2015 | % 2016 | % 2017 |
| Basic research | 37.26% | 35.42% | 33.55% |
| Translational research | 24.92% | 26.54% | 26.48% |
| Regulatory testing | 36.07% | 37.11% | 38.96% |
| Other | 1.75% | 0.93% | 1.01% |

The downward trend in the number of animals used for basic research was confirmed in 2017.

The use of animals for regulatory testing (experiments that are compulsory under national, European and international law) was the most common purpose and is continually increasing (see Table 2).

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

Data collection on the level of suffering felt by animals (see Table 3) was recorded for the fourth time in 2017.

**Table 3**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Suffering level / Year | **Non-recovery** | **Mild (up to and including)** | **Moderate** | **Severe** |
| 2015 | 6.16% | 47.58% | 39.44% | 6.82% |
| 2016 | 4.81% | 50.42% | 36.11% | 10.66% |
| 2017 | 5.49% | 48.45% | 30.55% | 15.50% |

Comparing the data for the 2015-2017 period shows that:

* there were no material variations in the ‘non-recovery’ and ‘mild’ suffering levels, which together represent 54%;
* there was a continuous decrease in the ‘moderate’ suffering level;
* there was an increase in the ‘severe’ category.

The animal species most concerned by the increase in the ‘severe’ suffering level is mice, at around 80%.

The correlation between the ‘severe’ suffering level and purpose is as follows:

* 46.62% for basic research (in particular for studies of central nervous system diseases and cancer);
* 37.14% for translational research (in particular for cancer);
* 15.89% for regulatory tests (in particular for toxicity);
* 0.35% for other purposes (maintenance of colonies of genetically altered animals).

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

Legislative Decree No 26/2014, which transposes the European Directive, designated the **laboratory of the cell substrates and cellular immunology department** of the Lombardy and Emilia-Romagna Animal Disease Prevention Institute as the single contact point charged with providing advice on the suitability and regulatory appropriateness of alternative approaches proposed for validation studies.

That Decree earmarked funding for the development and validation of alternative methods and for staff training. The funding was € 1 million annually for the 2014-2016 period, broken down as follows:

* 50% to be paid to the regions and autonomous provinces to finance training and refresher courses for staff of authorised establishments;
* 50% to be paid to Animal Disease Prevention Institutes for research and development of alternative methods.

Monies from levying the new State administrative fines (see Article 40(25)) are also allocated to the development and validation of alternative methods.

***National Committee for the Protection of Animals Used for Scientific Purposes***

The National Committee for the Protection of Animals Used for Scientific Purposes was set up in February 2017. It is made up of members representing academia, public scientific research institutions, the Ministry of Health, the Italian National Institute of Health and the National Reference Centre for Alternative Methods and Welfare and Care of Laboratory Animals.

After drawing up its rules of procedure, its activities included providing the Ministry of Health with advice on preparing the draft ministerial decree on staff training.

Since October 2017 the National Committee has been working on organising the work of the Animal Welfare Bodies (OBPAs) with the aim of harmonising that work, particularly as regards preliminary assessment of research projects with a view to issuing the reasoned opinion needed for authorisation applications for such projects.

To that end, the National Committee has launched a major initiative to raise awareness among OPBAs so as to harmonise their activities in both logistical and technical terms, and in particular to encourage the sharing of project assessment criteria.

***Animal Welfare Bodies (OPBAs)***

In general terms, 2017 saw the consolidation of greater awareness among and increased capacity for intervention by the Animal Welfare Bodies (OPBAs) in assessing research projects so as to issue reasoned opinions. This made it possible to verify, to the best possible extent, the correct application of the Three Rs principle, particularly as regards the replacement or reduction of animal use, with clear results in the basic research and translational research sectors.

As far as staff skills are concerned, conferences, workshops and courses were organised by various public or private bodies, with experts from the Ministry of Health participating as lecturers/speakers in 14 events.

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

The ‘other’ heading is used for the main sub-sectors, which mainly concern the regulatory field.

More specifically:

Animals used in routine production:

Other efficacy and tolerance testing (immunogenicity for human vaccines)

Other efficacy and tolerance testing (production of inactivated antigens for animal vaccines)

Animals used in the quality control sector:

Other quality controls (efficacy testing on rodenticides; testing for contaminants in veterinary medicines)

Animals used in the toxicity testing sector:

Other toxicity/safety testing (for drugs of abuse; for anomalous toxicity; for local tolerance)

Animals used in the acute and sub-acute toxicity methods sector:

Other lethal methods (testing in accordance with OECD 402 and OECD 423)

Animals used in the toxicity/ecotoxicity testing sector:

Other tests: (Diagnostic ecotoxicity testing)

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

There were no cases in which the ‘severe’ classification was exceeded.

## Italy: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 358128 | 61.74% |
| Rats | 118104 | 20.36% |
| Guinea-Pigs | 14357 | 2.48% |
| Hamsters (Syrian) | 277 | 0.05% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 647 | 0.11% |
| Rabbits | 19325 | 3.33% |
| Cats |  |  |
| Dogs | 639 | 0.11% |
| Ferrets | 42 | 0.01% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 17 | 0% |
| Pigs | 1657 | 0.29% |
| Goats | 23 | 0% |
| Sheep | 192 | 0.03% |
| Cattle | 279 | 0.05% |
| Prosimians |  |  |
| Marmoset and tamarins | 1 | 0% |
| Cynomolgus monkey | 569 | 0.1% |
| Rhesus monkey | 4 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 30 | 0.01% |
| Domestic fowl | 34715 | 5.98% |
| Other birds | 420 | 0.07% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus | 401 | 0.07% |
| Other Amphibians |  |  |
| Zebra fish | 19508 | 3.36% |
| Other Fish | 10715 | 1.85% |
| Cephalopods | 10 | 0% |
| Total | 580060 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 507078 | 88.22% |
| Animals born in the EU but not at a registered breeder | 65027 | 11.31% |
| Animals born in rest of Europe | 874 | 0.15% |
| Animals born in rest of world | 1825 | 0.32% |
| Total | 574804 | 100.00% |

### Source of non-human primates as registered at first use

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

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 137 | 25% |
| F2 or greater | 411 | 75% |
| Self-sustaining colony |  |  |
| Total | 548 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 194642 | 33.56% |
| Translational and applied research | 153743 | 26.5% |
| Regulatory use and Routine production | 225842 | 38.93% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 1697 | 0.29% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1598 | 0.28% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 2538 | 0.44% |
| Total | 580060 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 58513 | 30.06% |
| Cardiovascular Blood and Lymphatic System | 8635 | 4.44% |
| Nervous System | 74343 | 38.19% |
| Respiratory System | 1384 | 0.71% |
| Gastrointestinal System including Liver | 5792 | 2.98% |
| Musculoskeletal System | 6933 | 3.56% |
| Immune System | 13667 | 7.02% |
| Urogenital/Reproductive System | 2830 | 1.45% |
| Sensory Organs (skin, eyes and ears) | 3892 | 2% |
| Endocrine System/Metabolism | 4776 | 2.45% |
| Multisystemic | 3858 | 1.98% |
| Ethology / Animal Behaviour /Animal Biology | 5028 | 2.58% |
| Other basic research | 4991 | 2.56% |
| Total | 194642 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 46470 | 30.23% |
| Human Infectious Disorders | 21902 | 14.25% |
| Human Cardiovascular Disorders | 1852 | 1.2% |
| Human Nervous and Mental Disorders | 18498 | 12.03% |
| Human Respiratory Disorders | 16658 | 10.83% |
| Human Gastrointestinal Disorders including Liver | 2706 | 1.76% |
| Human Musculoskeletal Disorders | 6007 | 3.91% |
| Human Immune Disorders | 3875 | 2.52% |
| Human Urogenital/Reproductive Disorders | 2992 | 1.95% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 2457 | 1.6% |
| Human Endocrine/Metabolism Disorders | 3064 | 1.99% |
| Other Human Disorders | 5288 | 3.44% |
| Animal Diseases and Disorders | 7228 | 4.7% |
| Animal Welfare | 918 | 0.6% |
| Diagnosis of diseases | 13483 | 8.77% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 345 | 0.22% |
| Total | 153743 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Carcinogenicity |  |  |
| Phototoxicity |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 1211 | 11.41% |
| Other lethal methods | 755 | 7.11% |
| Non lethal methods | 8646 | 81.47% |
| Total | 10612 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of 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 use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 3930 | 93.04% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity | 294 | 6.96% |
| Total | 4224 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 2861 | 65.79% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 1488 | 34.21% |
| Total | 4349 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 143853 | 63.7% |
| Legislation on medicinal products for veterinary use and their residues | 37188 | 16.47% |
| Medical devices legislation | 19575 | 8.67% |
| Industrial chemicals legislation | 8715 | 3.86% |
| Plant protection product legislation | 595 | 0.26% |
| Biocides legislation | 624 | 0.28% |
| Food legislation including food contact material | 11492 | 5.09% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 1074 | 0.48% |
| Cosmetics legislation |  |  |
| Other legislation | 2726 | 1.21% |
| Total | 225842 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 209119 | 92.6% |
| Legislation satisfying national requirements only [within EU] | 3418 | 1.51% |
| Legislation satisfying Non-EU requirements only | 13305 | 5.89% |
| Total | 225842 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 575352 | 99.19% |
| Yes | 4708 | 0.81% |
| Total | 580060 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 31875 | 5.5% |
| Mild [up to and including] | 281069 | 48.46% |
| Moderate | 177180 | 30.55% |
| Severe | 89936 | 15.5% |
| Total | 580060 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 571715 | 98.56% |
| Yes | 8345 | 1.44% |
| Total | 580060 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 448697 | 77.35% |
| Genetically altered without a harmful phenotype | 112874 | 19.46% |
| Genetically altered with a harmful phenotype | 18489 | 3.19% |
| Total | 580060 | 100.00% |

# Latvia

## Latvia: Narrative 2015

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

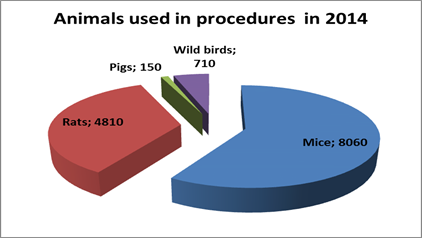
In 2014 competent authority has approved 8 projects, but in 2015 – 9, however since the previous year, animal amount used for scientific purposes have decreased from 13730 in 2014 to 5457 in 2015. During the 2014 active research was performed in 12 projects, but in 2015 – in 16 projects and one project was not realized because the lack of funding. Compeering previous period, in 2015 were realised more small projects with quite a small total animal amount not exceeding number of 100 animals per one project.

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

In 2015 new types of species were used in procedures – dogs (7), domestic fowl (40) and rabbits (35). Comparing 2014 and 2015 data using of pigs have decreased and wild birds have not been use because a lack of funding.

Animal species used in procedures in 2014 and 2015 are exposed on Figure 1. and Figure 2

**Figure 1**



**Figure 2**

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

All animals used in procedures come from EU origin, and biggest part 98.0% from the registered breeder.

**Figure 3**

In total 349 animals (6.40%) were used in planned severe procedures, including 81 mice and 182 rats for human nervous and mental disorders research. Procedures were appreciated as sever because of surgical intervention in brain cavity, but animals were not exposed to additional severe or moderate pain in long term. 74 mice and 12 rats from not planned severe procedures actually went through severe procedure because of individual reaction during surgery under anaesthesia (sudden death) and unexpected deterioration of health state (weight loss, hyperglycaemia), however mostly detecting heavier sufferings than were expected, animals were excluded from further steps of procedure and were humanely euthanized.

The biggest part 1977 (36.23%) of animals were exposed to planned moderate procedures, including 739 mice and 94 rats for human nervous and mental disorders research, 48 mice, 69 rats and 20 rabbits for human musculoskeletal disorders, 11 mice for nervous system (basic research), 37 mice for cancer, 78 mice for human immune disorders, 451 mice, 7 dogs and 15 rabbits for animal diseases and 367 mice for non-regulatory toxicology research (see Figure 3). 41 mice from not planned moderate procedures were exposed to moderate procedure because of individual reaction to adjuvant (not completed absorption and forming subcutaneous induration).

In mild procedures were used 1842 (33.75%) animals including 1565 mice for human nervous and mental disorders research, 62 mice for human immunes system disorders and 40 domestic fowl for animal diseases research; 64 rats exposed to mild surgical intervention (sham operated animals) and 4 mice from procedures with harder character because of not desired effect and pathological state forming were excluded from further research process and underwent only mild manipulations

In non-recovery procedures were used 1289 (23.62%) animals including 520 mice and 746 rats for non-regulatory toxicology and ecotoxicology and 23 pigs for educational purposes

In general observation there are evident changes in the basic research, where animal using were decreased significantly from 1280 (9.32%) in 2014 to 11 (0.20%), also the number of animals used for educational purposes comparing previous year decreased from 150 (1.09%) to 23 (0.42%) in 2015 as well as in 2015 animals were not used in protection of natural environment in the interests of the health animal beings. The highest amount of animal using remain unchanged in translation and applied research. This year reaching 99.38% (5423) of all used animals and increasing for 14.97% comparing with previous year. This is explained with trend between researchers mainly to devote their activities to investigation of new substances with therapeutic effect.

Reason for animal amount changes mentioned previous is a result of scientist more carefully planned work and choosing new less harmful research methods. During the continuously scientific work researchers are looking for new alternative methods and ways to minimize animal using in procedures and as it is seen from data in some projects animals are not used at all in this year instead of planned.

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

Scientific project authors strive to use *in silico* and *in vitro* methods in substance testing processes to detect most effective sample before animal using as well as explore literature and collaborate with other scientist doing research and use other surveys to avoid repeated studies and to use as little as possible animals in procedures. During the project evaluation process competent authority and experts ensures and verifies the project scientific utility and benefits, analyse possibility to replace animals with alternative methods as well as evaluate presented animal amount in procedures and research methods and techniques. Competent authority and experts verifies weather it is possible to achieve the objectives pursued in project according to the project plan.

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

In 2015, as the project was continued from 2014, 23 pigs were used in non-recovery procedures for higher education purposes (human and veterinary surgeons training). After procedure (surgical intervention) pigs were euthanized. As much as possible were done surgical procedures with each animal under anaesthesia and narcosis to decrease used animal amount in procedures.

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

During the year 2015 users have reported to competent authority that 8 rats exposed to narcosis unexpectedly died during the surgical manipulation. In 2015 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

## Latvia: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 4165 | 76.32% |
| Rats | 1187 | 21.75% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 35 | 0.64% |
| Cats |  |  |
| Dogs | 7 | 0.13% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 23 | 0.42% |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 40 | 0.73% |
| Other birds | 0 | 0% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 5457 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 5359 | 98.2% |
| Animals born in the EU but not at a registered breeder | 98 | 1.8% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 5457 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 11 | 0.2% |
| Translational and applied research | 5423 | 99.38% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 0 | 0% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 23 | 0.42% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 5457 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology |  |  |
| Cardiovascular Blood and Lymphatic System |  |  |
| Nervous System | 11 | 100% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System |  |  |
| Immune System |  |  |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 11 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 52 | 0.96% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders | 2763 | 50.95% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 141 | 2.6% |
| Human Immune Disorders | 270 | 4.98% |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 564 | 10.4% |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 1633 | 30.11% |
| Total | 5423 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 5457 | 100% |
| Yes |  |  |
| Total | 5457 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 1289 | 23.62% |
| Mild [up to and including] | 1842 | 33.75% |
| Moderate | 1977 | 36.23% |
| Severe | 349 | 6.4% |
| Total | 5457 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 5457 | 100% |
| Yes |  |  |
| Total | 5457 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 5457 | 100% |
| Genetically altered without a harmful phenotype |  |  |
| Genetically altered with a harmful phenotype |  |  |
| Total | 5457 | 100.00% |

## Latvia: Narrative 2016

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

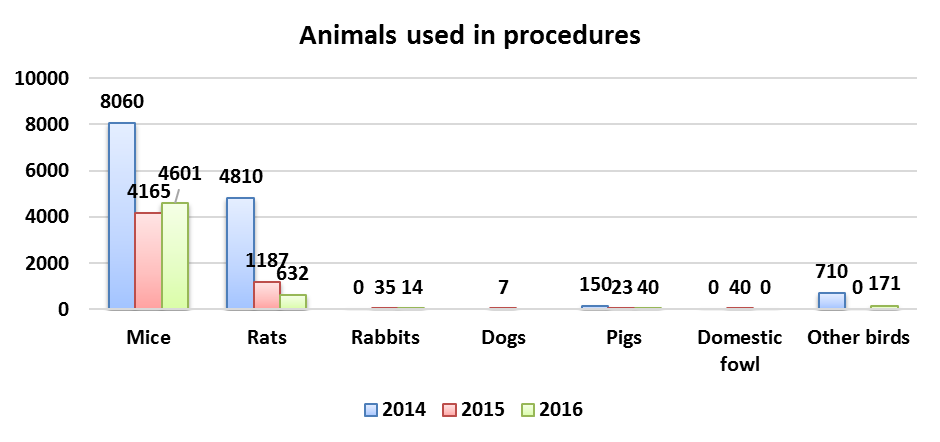
In 2015 competent authority has approved 9 projects, but in 2016 – 3. Since the previous year, animal amount used for scientific purposes have not significantly changed (5457 in 2015 and 5458 in 2016). During the 2015 active research was performed in 16 projects, but in 2016 – in 17 projects. In 2016 the first time researchers started to use genetically altered animals – 60 mice in moderate procedures for basic research (human nervous system).

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

Compeering last two years the total amount of used mice have increased from 76.32% in 2015 (n=4165) to 84.3% (n=4601) in 2016, but total amount of used rats have decreased from 21.75% (n=1.187) in 2015 to 11.58% (n=632) in 2016. The reason for these changes is connected with economical (new synthesised substances are very expensive and therefore usually are synthesised in small amounts that leads to great need for smaller animals used in further *in vivo* tests) animal welfare and 3Rs considerations (suggestions from project evaluation commission). In 2016 dogs and domestic fowl were not used because the end of the projects in previous year, but after financial improvement the part of wild nature research project was realized and 171 wild birds were exposed to mild procedure.

Animal species used in procedures in 2014, 2015 and 2016 are exposed on Figure 1.

**Figure 1**

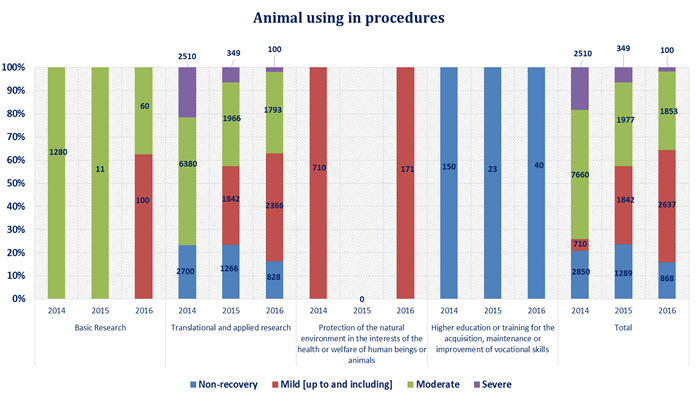


**3. Information on any changes in trends in actual severities and analysis of the reasons thereof.**

All animals used in procedures come from EU origin, and biggest part 95.9% from the registered breeder.

The biggest part of all animals were used in mild procedures (see Fig. 2) – 48.3% (n=2637) from which 2516 were used for planned mild procedures, but 121, which came from a control groups and sham operated groups of cardiovascular disease, human nervous and mental disorders research projects and in general were planned to expose to moderate procedures, but actually underwent easier or not all manipulations comparing to other experimental groups in the same procedure. Therefore previous mentioned animal (n=121) sufferings were evaluated as mild.

**Figure 2**



In total in 2016 animals were not used in planned severe procedures, but 100 animals (1.8%) in four projects actually went through severe procedure.

1. During mild procedure in human cardiovascular disease research project 4 mice lost weight more than 25 % and therefore animals were humanely killed and were not included in further manipulations.
2. During moderate procedure in human cancer research project 35 mice lost weight more than 25 % and therefore animals were humanely killed and were not included in further manipulations.
3. Because of specific individual features during moderate procedure in human infectious disorders research project 4 mice recovered very hard after long exposing to narcosis during electroporation and therefore animals were humanely killed and were not included in further manipulations.
4. During moderate procedure in human musculoskeletal disorders research project 1 rabbit died. The case was not convinced with procedure, but during the time of procedure previous unknown acquired digestion disorders exacerbated resulting with death.
5. During moderate procedure in animal diseases and disorders research, 56 mice died without previously detectable signs of suffering.

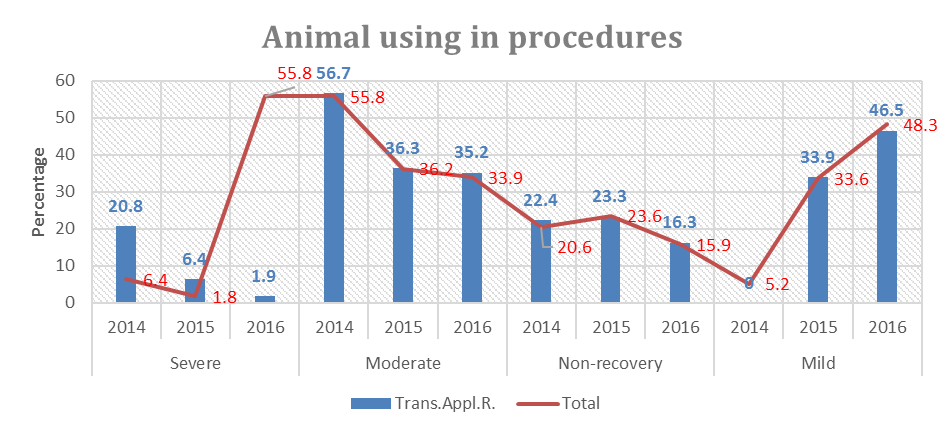
In moderate procedures in 2016 was used 1853 (33.95%) animals from which 1851 animals were exposed to planned moderate procedures, but 2 animals actually went through moderate procedures in human infections diseases research project because after using adjuvant (incomplete Freund's adjuvant) bad absorption in tissue was observed. Tissue thickening was remarked. It disappeared in 3-5days after injection was made. In moderate procedures 563 mice and 24 rats were used for trans/Appl human nervous and mental disorders, 48 mice, 418 mice for animal diseases and disorders research, 60 mice for basic nervous system research, 46 for human infectious and disorders research, 13 rabbits for musculoskeletal diseases and disorders and 158 mice for non-regulatory toxicology and ecotoxicology research (see Figure 3).

In 2016 868 (15.9%) animals were used in non-recovery procedures, including 260 mice and 560 rats in human cardiovascular disorders research projects and 40 pigs for higher education purposes (human and veterinary surgeons training).

In general observation there are evident changes in the basic research, where increased animal using in mild procedures (almost 2/3 form used animals for basic research), but still saving quite small amount – 3.2% (n=160) comparing with other research purposes.

The main research purpose is translation and applied research. This is explained with trend between researchers mainly to devote their activities to investigation of new substances with therapeutic effect. In this research branch for the last three years decreased animal using, especially in harder procedures (see Fig.3), but increased animal using in mild procedures. In 2014 animals were not used in mild procedures. In 2014 and 2015 biggest amount of animals were used in severe and moderate procedures, but in 2016 – in mild procedures (46.4%) and in the same time animal using in severe procedures were low (1.9%).

**Figure 3**



Reason for animal amount changes mentioned previous (tendency to decrease animal using in harmful procedures) is a result of scientist more carefully planned work and choosing new less harmful research methods. During the continuously scientific work researchers are looking for new alternative methods and ways to minimize animal using in procedures as well as project evaluation commission suggestions concerning 3RS principles are taken in notice. Moreover, project authors strive to use more *in vitro*, *in silico* and *ex vivo methods* (for example – isolated organs, cells or organelles instead of live animal using), especially for toxicity and effectivity first stage tests.

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

Scientific project authors strive to use *in silico,* *in vitro* and *ex vivo* methods in substance testing processes to detect most effective sample before animal using as well as explore literature and collaborate with other scientists doing research and use other surveys to avoid repeated studies and to use as little as possible animals in procedures. During the project evaluation process competent authority and experts ensures and verifies the project scientific utility and benefits, analyse possibility to replace animals with alternative methods as well as evaluate presented animal amount in procedures and research methods and techniques. Competent authority and experts verifies weather it is possible to achieve the objectives pursued in project according to the project plan.

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

In 2015, as the project was continued from 2014, 23 pigs were used in non-recovery procedures for higher education purposes (human and veterinary surgeons training), but in 2016 – 40 pigs. After procedure (surgical intervention) pigs were euthanized. As much as possible were done surgical procedures with each animal under anaesthesia and narcosis to decrease. Increase of pig using in non-recovery procedure probably is associated with more frequent training requests from surgeons.

Compeering previous year, in 2016 171 wild birds were used in wild nature research project. This project was authorized in previous year, but financial difficulties did not allow to realize project in 2015, but in 2016 after improvement of financial position, this project was resumed.

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

During the year 2016 users have not reported to competent authority that animals exposed to narcosis exceed classified “severe” procedure. In 2016 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

## Latvia: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 4601 | 84.3% |
| Rats | 632 | 11.58% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 14 | 0.26% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 40 | 0.73% |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds | 171 | 3.13% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 5458 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 5233 | 95.88% |
| Animals born in the EU but not at a registered breeder | 225 | 4.12% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 5458 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 160 | 2.93% |
| Translational and applied research | 5087 | 93.2% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 171 | 3.13% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 40 | 0.73% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 5458 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology |  |  |
| Cardiovascular Blood and Lymphatic System |  |  |
| Nervous System | 160 | 100% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System |  |  |
| Immune System |  |  |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 160 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 604 | 11.87% |
| Human Infectious Disorders | 108 | 2.12% |
| Human Cardiovascular Disorders | 2277 | 44.76% |
| Human Nervous and Mental Disorders | 1448 | 28.46% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 14 | 0.28% |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 478 | 9.4% |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 158 | 3.11% |
| Total | 5087 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 5458 | 100% |
| Yes |  |  |
| Total | 5458 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 868 | 15.9% |
| Mild [up to and including] | 2637 | 48.31% |
| Moderate | 1853 | 33.95% |
| Severe | 100 | 1.83% |
| Total | 5458 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 5458 | 100% |
| Yes |  |  |
| Total | 5458 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 5398 | 98.9% |
| Genetically altered without a harmful phenotype | 60 | 1.1% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 5458 | 100.00% |

## Latvia: Narrative 2017

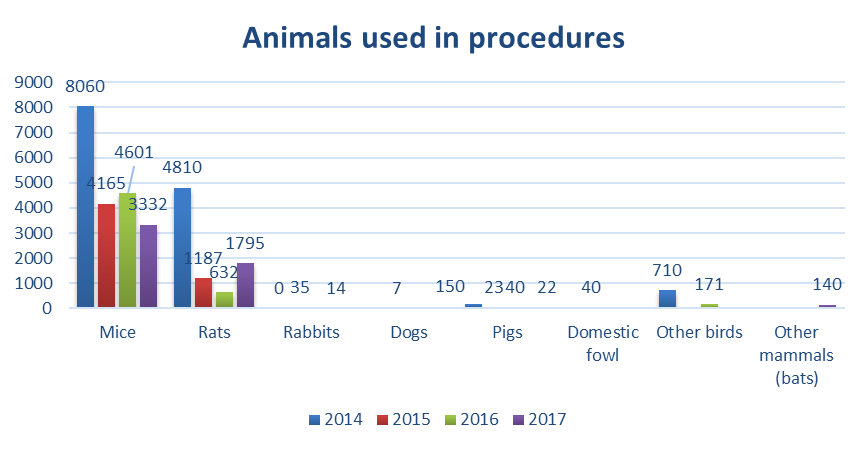
**1. General information on any changes in trends observed since the previous reporting period.**

In 2015 competent authority has approved 9 projects, in 2016 – 3, but in 2017 - 13. Since the previous years, animal amount used for scientific purposes have not significantly changed (5457 in 2015 and 5458 in 2016), but slightly decreased – 5289 in 2017. During the 2015 active licence was for 16 projects, in 2016 – for 17, but in 2017 – for 25 projects. However it does not mean that in all projects all procedures were performed and projects realised as planned. In some cases projects or procedures were stopped for a while because the lack of financing or additional research before preclinical trials. Year by year the science quickly develops and that is why researchers after getting new information concerning their research topic uses *in vitro* methodology as much as possible, and it results with decreasing total amount of animals. In most of cases, especially in long lasting projects (5-year projects), researchers use less animals as they have written down in project licence application.

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

Comparing last three years the total amount of used mice have increased from 76.32% in 2015 (n=4165) to 84.3% (n=4601) in 2016 but in 2017 – decreased 63.0% (3332) (see Fig.1). Total amount of used rats have decreased from 21.75% (n=1187) in 2015 to 11.58% (n=632) in 2016, but increased in 2017 to 33.94% (1795). The reason for these changes is that in 2017 researchers have realized more projects where rats were included. In some specific investigations or testing of new substances rats were preferred because of their size. Rat’s bigger size comparing to mice allow researchers to get more biological samples (for example – tissue, blood samples or tumour cells) for *in vitro* testing and in the same time also t allow to use less animals and get more necessary data. Compeering previous years in 2017 wild birds were not used for scientific purposes because of project ending however other wild species – bats (*Pipistrellus nathusii*) were used for mild procedures (basic research for white nose syndrome by taking blood samples for molecular analysis and investigation of their behaviour).

**Figure 1**



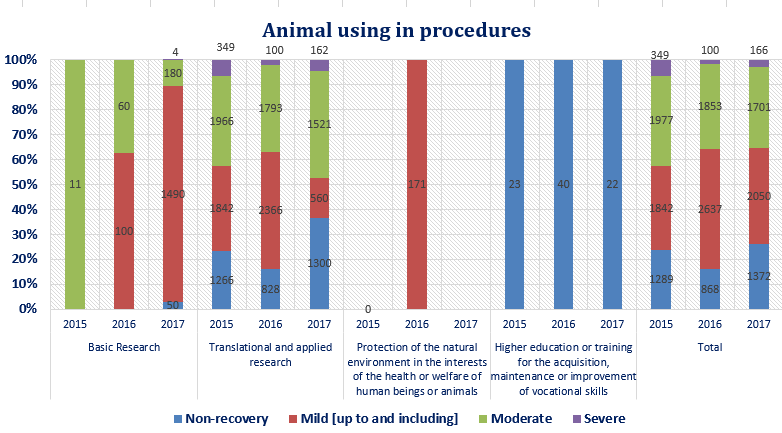
**3. Information on any changes in trends in actual severities and analysis of the reasons thereof.**

All animals used in procedures come from EU origin, and the biggest part 96.4% from the registered breeder.

The biggest part of all animals were used in mild procedures (see Fig. 2 and Fig. 3) – 38.76% (n=2050) from which 1919 were used for planned mild procedures, but

1. 2 mice because the lack of tumour development were killed before the end of planned moderate procedure ((Trans/Appl Research) Human Cancer) and actually were exposed to mild procedure;
2. 24 rats and 65 mice were used as control group in moderate procedure ((Trans/Appl Research) Human Nervous and Mental Disorders) and were shame operated that finally did not cause further disabilities or dysfunctions except skin cut and finally resulted as mild procedure;
3. 40 rats were used in moderate procedure ((Basic Research) Nervous System) as animals of control group and did not underwent all manipulations comparing to other experimental groups, therefore actually were exposed to mild procedure.

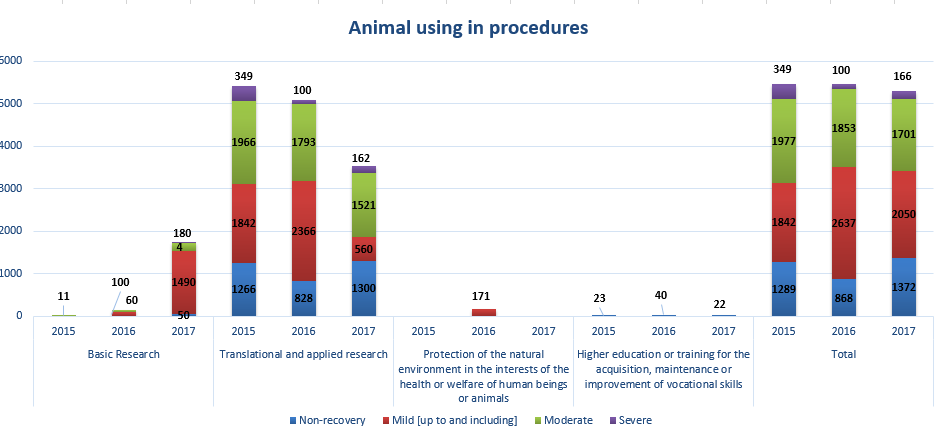
**Figure 2**



In total 166 (3.14%) animals in 2017 were used in severe procedures from which 114 animal were used for planned severe procedures (4 mice for (Basic Research) Oncology, and 110 mice for (Trans/Appl Research) Non-regulatory toxicology and ecotoxicology) but 52 mice and 2 rats from three projects went through severe not planned procedure.

1. During moderate procedure ((Trans/Appl Research) Human Nervous and Mental Disorders) 18 mice died during the surgical manipulations and did not wake up after anaesthesia.
2. During moderate procedure ((Trans/Appl Research) Human Cancer) 34 animals lost weight more then 25% and therefore animals were humanely killed and were not included in further manipulations.

**Figure 3**



In moderate procedures in 2017 was used 1701 (32.16%) animals from which 804 mice were used in (Trans/Appl Research) Human Cancer research, 249 mice and 94 rats for (Trans/Appl Research) Human Nervous and Mental Disorders research, 59 rats for (Basic Research) Nervous System research and 374 mice for (Trans/Appl Research) Animal Diseases and Disorders research.

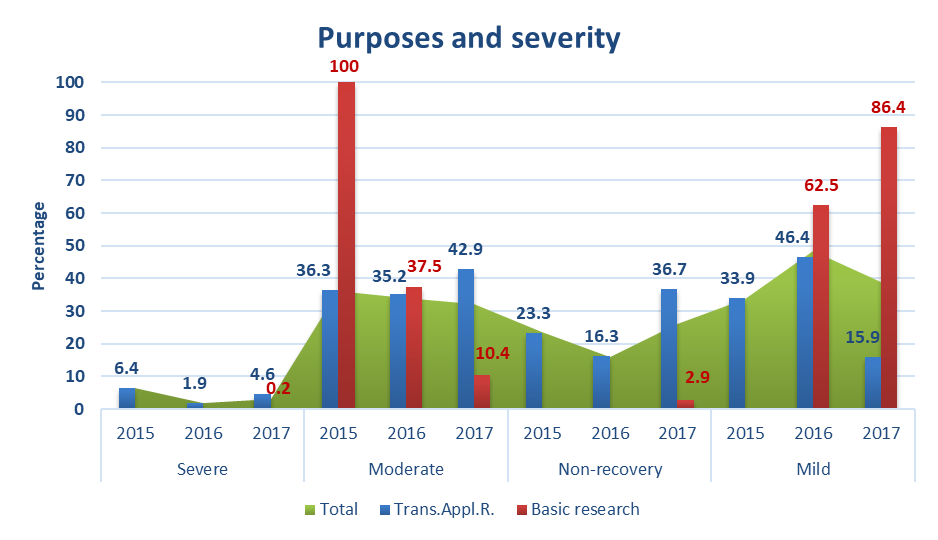
In 2017 1372 (25.94%) animals were used in non-recovery procedures, including 1300 rats for (Trans/Appl Research) Human Cardiovascular Disorders, 50 mice for (Basic Research) Nervous System and 22 pigs for Higher education or training for the acquisition, maintenance or improvement of vocational skills (human and veterinary surgeons training).

In general observation there are evident changes in severity of procedures. Comparing previous years in 2017 increased animal using in severe and non-recovery procedures. That is explained by long lasting projects (5-year projects) that were stopped for one or two year period for various reasons (lack of financing, additional *in vitro* research) but realized in 2017.

The main research purpose is translation and applied research. This is explained with trend between researchers mainly to devote their activities to investigation of new substances with therapeutic effect.

In this research branch for the last two years decreased animal using, especially in harder procedures (see Fig. 4), but in 2017 increased animal using in non-recovery, severe and moderate procedures.

**Figure 4**



Reason for animal amount changes mentioned previous (tendency to decrease animal using in harmful procedures in 2015 and 2016) is a result of scientist more carefully planned work and choosing new less harmful research methods. During the continuous scientific work researchers are looking for new alternative methods and ways to minimize animal using in procedures as well as project evaluation commission suggestions concerning 3RS principles are taken in notice. Moreover, project authors strive to use more *in vitro*, *in silico* and *ex vivo methods* (for example – isolated organs, cells or organelles instead of live animal using), especially for toxicity and effectivity first stage tests. However increasing of animal using in non-recovery, moderate and severe procedures in 2017 is explained with interruption of long lasting projects (5-year lasting projects) and not fully realization during the time of first years authorization because of additional *in vitro* research and/or lack of finances.

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

Authors of scientific projects strive to use *in silico,* *in vitro* and *ex vivo* methods in substance testing processes to detect most effective sample before animal using as well as explore literature and collaborate with other scientists doing research and use other surveys to avoid repeated studies and to use as little as possible animals in procedures. During the project evaluation process competent authority and experts ensures and verifies the project scientific utility and benefits, analyse possibility to replace animals with alternative methods as well as evaluate presented animal amount in procedures and research methods and techniques. Competent authority and experts verifies weather it is possible to achieve the objectives pursued in project according to the project plan. If there are any possibility to decrease animal sufferings or to decrease a total amount of animals in procedures, applicants are strictly obligated to make changes in project before authorization. In addition – during inspections each project is checked according to approved methodology.

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

In 2015, as the project was continued from 2014, 23 pigs were used in non-recovery procedures for higher education purposes (human and veterinary surgeons training), 40 pigs – in 2016 and 22 pigs in 2017. After procedure (surgical intervention) pigs were euthanized. As much as possible manipulations (cuts, trainings of surgical techniques) were done with each animal under anaesthesia and narcosis to decrease a total amount of animals. Decrease of pig using in non-recovery procedure probably is associated with less frequent training requests from surgeons. In 2017 140 bats (*Pipistrellus nathusii*) were used for basic research (animal behaviour and infectious disease) in mild procedures. The procedure involved such a manipulations as blood and skin biopsy sample taking and observation of behaviour after animals were freed.

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

During the year 2017 users have reported two cases were animals did not awake after surgical intervention and narcosis (26 mice) and one case where 34 mice in cancer research where euthanized before the end of procedure because of weight lost more than 25%.

In 2017 users have not asked competent authority to approve procedures where the 'severe' classification is exceeded.

## Latvia: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 3332 | 63% |
| Rats | 1795 | 33.94% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 22 | 0.42% |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 140 | 2.65% |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 5289 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| 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% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 5289 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 1724 | 32.6% |
| Translational and applied research | 3543 | 66.99% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 22 | 0.42% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 5289 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 4 | 0.23% |
| Cardiovascular Blood and Lymphatic System |  |  |
| Nervous System | 1580 | 91.65% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System |  |  |
| Immune System |  |  |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology | 140 | 8.12% |
| Other basic research |  |  |
| Total | 1724 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| 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 Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders | 70 | 1.98% |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders | 0 | 0% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 377 | 10.64% |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 110 | 3.1% |
| Total | 3543 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 5289 | 100% |
| Yes |  |  |
| Total | 5289 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| 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% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 5289 | 100% |
| Yes |  |  |
| Total | 5289 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 5229 | 98.87% |
| Genetically altered without a harmful phenotype | 60 | 1.13% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 5289 | 100.00% |

# Lithuania

## Lithuania: Narrative 2015

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

In 2015, there were 2451 laboratory animals employed for animal studies and other scientific purposes in Lithuania. In comparison to the previous year ~ 1000 less animals were used for the projects. Reduction can be justified due to the expiry date of more than 32 % projects in 2015.

The number of users increased from 8 in 2013 to 12 in 2015, however some establishments finished some projects in 2015.

Increase in use of birds is noticed.

Significant decrease in use of animals for the procedures classified as non-recovery.

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

The total number of animals used in specific areas is affected by many factors (i.e. active projects, funding, international projects ect.)

i. e. increase in use of animals for the purpose „Protection of the natural environment in the interests of the health or welfare of human beings or animals“ was directly related to one project where other birds (*Serinus canaria*) were used.

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

Most part of the animals (~64 %) were used for the procedures classified as mild [up to and including] severity, (~ 32 %) as moderate and (~4 %) as non-recovery.

Only Directive 2010/63/EU contains the requirement that all procedures should be classified, and no analogous to the system used in the Directives was introduced in the national legislation before, so this required additional input from users.

So significant decrease in use of animals for the procedures classified as non-recovery is mostly due to a better understanding of classification and better reporting of the actual severities by the users in 2015.

There was no exceeding of the ‘severe’ classification reported in 2015, because National Committee is encouraging users do not perform projects or organize project in such a way where animals could not be used for procedures classified as severe.

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

Activities undertaken under Article 47 of Directive 2010/63/EU on the protection of animals used for scientific purposes to contribute to the development, validation and promotion of alternative approaches and dissemination of information thereon at the national level for the period 2013–2015 are publically available on the webpage of the European Commission http://ec.europa.eu/environment/chemicals/lab\_animals/3r/pdf/Article\_47\_LT.pdf

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

As regards the category “Other”, only other birds (*Serinus canaria*) were used for one project during the reporting period.

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

No authorisations for projects where the 'severe' classification is exceeded were granted during the reporting period. No exemptions under article 6(4)(a) of the Directive 2010/63/EU were granted in 2015, either

## Lithuania: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1591 | 64.91% |
| Rats | 572 | 23.34% |
| Guinea-Pigs | 85 | 3.47% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 122 | 4.98% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 13 | 0.53% |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds | 64 | 2.61% |
| Reptiles | 4 | 0.16% |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 2451 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 2245 | 91.6% |
| Animals born in the EU but not at a registered breeder | 206 | 8.4% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 2451 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 2041 | 83.27% |
| Translational and applied research | 302 | 12.32% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 64 | 2.61% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 44 | 1.8% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 2451 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 388 | 19.01% |
| Cardiovascular Blood and Lymphatic System | 275 | 13.47% |
| Nervous System | 180 | 8.82% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System | 537 | 26.31% |
| Immune System | 540 | 26.46% |
| Urogenital/Reproductive System | 3 | 0.15% |
| Sensory Organs (skin, eyes and ears) | 30 | 1.47% |
| Endocrine System/Metabolism |  |  |
| Multisystemic | 60 | 2.94% |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research | 28 | 1.37% |
| Total | 2041 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 22 | 7.28% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders | 16 | 5.3% |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 62 | 20.53% |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases | 20 | 6.62% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 182 | 60.26% |
| Total | 302 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 2451 | 100% |
| Yes |  |  |
| Total | 2451 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 96 | 3.92% |
| Mild [up to and including] | 1574 | 64.22% |
| Moderate | 781 | 31.86% |
| Severe |  |  |
| Total | 2451 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 2451 | 100% |
| Yes |  |  |
| Total | 2451 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 2451 | 100% |
| Genetically altered without a harmful phenotype |  |  |
| Genetically altered with a harmful phenotype |  |  |
| Total | 2451 | 100.00% |

## Lithuania: Narrative 2016

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

In 2016, there were 2660 laboratory animals used for scientific or educational purposes in Lithuania. In comparison to the previous year, ~200 more animals were used in the projects.

It was caused by the fact, that more establishments were approved and (or) started performing projects. The number of users increased from 8 in 2013 to 14 in 2016.

The clearest trends in 2016 were increase in the use of farm animals for the purposes “Higher education or training for the acquisition, maintenance or improvement of vocational skills” and “Regulatory use and Routine production“.

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

Almost 4 % of all the animals were used directly for the purpose “Higher education or training for the acquisition, maintenance or improvement of vocational skills” and it was almost twice as many in comparison to the previous year. Increase of animals used for this activity was related to an increased number of hospital type training centers due to active participation in international projects related to surgery training exercises.

The reason for some other changes in use of animals in any of the specific areas is that some approved establishments did not perform any projects in 2016 and other started or continued new projects in the end of the previous year.

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

Increase in use of animals for the purpose “Higher education or training for the acquisition, maintenance or improvement of vocational skills” was partly related to the increased number of animals used for procedures classified as non-recovery.

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

Activities undertaken under Article 47 of Directive 2010/63/EU on the protection of animals used for scientific purposes to contribute to the development, validation and promotion of alternative approaches and dissemination of information thereon at the national level for the period 2013–2015 are publically available on the webpage of the European Commission http://ec.europa.eu/environment/chemicals/lab\_animals/3r/pdf/Article\_47\_LT.pdf

Substantial attention was given to 3R principles in personnel training. Training programmes were amended in terms of 3R theoretical and practical activities related to the search of animal alternatives by the organisers and approved by the competent authority.

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

As regards the category “Other”, no other animals were used during the reporting period.

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

No authorisations for projects where the 'severe' classification is exceeded were granted during the reporting period.

No exemptions under article 6(4)(a) of Directive 2010/63/EU were granted in 2016 as well as in 2015.

## Lithuania: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1759 | 66.13% |
| Rats | 744 | 27.97% |
| Guinea-Pigs | 30 | 1.13% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 51 | 1.92% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 48 | 1.8% |
| Goats |  |  |
| Sheep | 28 | 1.05% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 2660 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 2602 | 97.82% |
| Animals born in the EU but not at a registered breeder | 58 | 2.18% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 2660 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 2212 | 83.16% |
| Translational and applied research | 117 | 4.4% |
| Regulatory use and Routine production | 230 | 8.65% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 101 | 3.8% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 2660 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 567 | 25.63% |
| Cardiovascular Blood and Lymphatic System | 58 | 2.62% |
| Nervous System | 69 | 3.12% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System | 534 | 24.14% |
| Immune System | 248 | 11.21% |
| Urogenital/Reproductive System | 214 | 9.67% |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism | 400 | 18.08% |
| Multisystemic | 122 | 5.52% |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 2212 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders | 18 | 15.38% |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 27 | 23.08% |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 72 | 61.54% |
| Total | 117 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Toxicity and other safety testing including pharmacology | 95 | 41.3% |
| Routine production | 135 | 58.7% |
| Total | 230 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 40 | 42.11% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Target animal safety |  |  |
| Skin sensitisation | 15 | 15.79% |
| Pharmaco-dynamics (incl safety pharmacology) | 40 | 42.11% |
| Total | 95 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 40 | 100% |
| Total | 40 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 135 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 135 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 175 | 76.09% |
| Legislation on medicinal products for veterinary use and their residues | 55 | 23.91% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 230 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 230 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 230 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 2660 | 100% |
| Yes |  |  |
| Total | 2660 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 141 | 5.3% |
| Mild [up to and including] | 1812 | 68.12% |
| Moderate | 707 | 26.58% |
| Severe |  |  |
| Total | 2660 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 2660 | 100% |
| Yes |  |  |
| Total | 2660 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 2660 | 100% |
| Genetically altered without a harmful phenotype | 0 | 0% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 2660 | 100.00% |

## Lithuania: Narrative 2017

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

In 2017, there were 2766 laboratory animals used for scientific or educational purposes in Lithuania. In comparison to the previous year, ~100 more animals were used in the projects.

It was caused by the fact, that more establishments were approved and started performing projects. The number of users increased from 8 in 2013 to 12 in 2015 and to 14 in 2017.

The clearest trends in 2017 were the large increase in the use of fish for research, increase of use of farm animals (pigs) and use of animals for the purposes “Higher education or training for the acquisition, maintenance or improvement of vocational skills” and “Translational and applied research”.

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

The most common primary purpose for using animals was basic research (in Immune System, Oncology, Nervous System) (~ 60 %), then (~ 22 %), for the purpose “Higher education or training for the acquisition, maintenance or improvement of vocational skills” and (~ 18 %) for the purpose “Translational and applied research”.

Increase in use of animals for the purpose “Higher education or training for the acquisition, maintenance or improvement of vocational skills” is noticed from ~ 4 % to ~ 22 %. Increase of animals used for this activity was related to increased number of hospital type training centres due to active participation in international projects related to surgery training exercises.

The reason for some other changes in use of animals in any of the specific areas is that some approved establishments did not perform any projects in 2017 and other started or continued new projects in the end of the previous year.

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

Most part of the animals (~79 %) were used for the procedures classified as mild [up to and including] severity, (~18 %) for the procedures classified as moderate and (~ 3 %) for non-recovery severity.

Decrease in use of animals for the procedures classified as moderate and non-recovery during year 2017-2015 is related to the fact that some establishment did not perform any projects due to reconstruction of premises for some time, so more animals were used for the procedures classified as mild.

There were no exceeding of the ‘severe’ classification reported in 2017 and previous year because National Committee is encouraging users do not perform projects or organize project in such a way where animals could not be used for procedures classified as severe.

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

Activities undertaken under Article 47 of Directive 2010/63/EU on the protection of animals used for scientific purposes to contribute to the development, validation and promotion of alternative approaches and dissemination of information thereon at the national level for the period 2013–2015 are publically available on the webpage of the European Commission http://ec.europa.eu/environment/chemicals/lab\_animals/3r/pdf/Article\_47\_LT.pdf

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

As regards the category “Other”, other birds (~ 1 %) and fish (~ 19 %) were used during the reporting period (~ 20 %) in total comparing to total amount of animals used in 2017.

The clearest trend in 2017 was the large increase in the use of fish for research. The main reason is, that new user was established and started performing projects with specific focus on fish.

Some other birds (Serinus canaria) were used.

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

No authorisations for projects where the 'severe' classification is exceeded were granted during the reporting period.

No exemptions under article 6(4)(a) of Directive 2010/63/EU were granted in 2017.

## Lithuania: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1718 | 62.11% |
| Rats | 391 | 14.14% |
| Guinea-Pigs | 15 | 0.54% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 13 | 0.47% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 68 | 2.46% |
| Goats |  |  |
| Sheep | 15 | 0.54% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds | 26 | 0.94% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish | 520 | 18.8% |
| Cephalopods |  |  |
| Total | 2766 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| 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% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 2766 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 1659 | 59.98% |
| Translational and applied research | 501 | 18.11% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 606 | 21.91% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 2766 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| 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% |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System | 10 | 0.6% |
| Immune System | 873 | 52.62% |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic | 32 | 1.93% |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 1659 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders | 102 | 20.36% |
| Human Cardiovascular Disorders | 8 | 1.6% |
| Human Nervous and Mental Disorders | 107 | 21.36% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 17 | 3.39% |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 267 | 53.29% |
| Total | 501 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 2766 | 100% |
| Yes |  |  |
| Total | 2766 | 100.00% |

### Actual severity of uses

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

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 2766 | 100% |
| Yes |  |  |
| Total | 2766 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 2766 | 100% |
| Genetically altered without a harmful phenotype |  |  |
| Genetically altered with a harmful phenotype |  |  |
| Total | 2766 | 100.00% |

# Luxembourg

## Luxembourg: Narrative 2015

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

In Luxembourg an increase of about 50% of the use of animals was observed. Furthermore comparing the statistic of 2015, in 2015 the species “rat” was used in procedures.

More explanation will be indicated in part 2 of this questionnaire.

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

In Luxembourg the number of uses of animals increased during the last years. This trend will continue when reporting the following year (2016).

In Luxembourg two main institutions lead the laboratories and both modernised and increased their facilities during the last years. For example in 2016 a further facility was authorised, this will have a further impact on the number of animals used due to the fact of the little number of facilities (6 facilities) and the small size of the country.

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

In 2015 the first time the actual severity “severe” was reported. Initially for the concerned project the severity “mild” was prospected and consequently the responsible person stopped this project and they didn’t demanded any authorisation for modification .

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

The particular efforts taken to promote the principle of the Three Rs were notably the enforcement and obligation of the training and the increased impact from the national committee.

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

There is no significant proportion reported.

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

During 2015 there was no case an exceedance of the ‘severe’ classification.

## Luxembourg: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 3078 | 87.34% |
| Rats | 73 | 2.07% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 373 | 10.58% |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 3524 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 3452 | 100% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 3452 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 3484 | 98.86% |
| Translational and applied research | 40 | 1.14% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills |  |  |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 3524 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 764 | 21.93% |
| Cardiovascular Blood and Lymphatic System | 373 | 10.71% |
| Nervous System | 1736 | 49.83% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System |  |  |
| Immune System | 611 | 17.54% |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 3484 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders | 39 | 97.5% |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 1 | 2.5% |
| Total | 40 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 3452 | 97.96% |
| Yes | 72 | 2.04% |
| Total | 3524 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 151 | 4.28% |
| Mild [up to and including] | 1654 | 46.94% |
| Moderate | 1679 | 47.64% |
| Severe | 40 | 1.14% |
| Total | 3524 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 3524 | 100% |
| Yes |  |  |
| Total | 3524 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1721 | 48.84% |
| Genetically altered without a harmful phenotype | 1657 | 47.02% |
| Genetically altered with a harmful phenotype | 146 | 4.14% |
| Total | 3524 | 100.00% |

## Luxembourg: Narrative 2016

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

In Luxembourg there was an increase in the total number of uses from 3.524 in 2015 to 21.472 total uses in 2016. This trend is due to the use of 17.383 zebrafish larvae between day 5-7 post fertilization.

Considering the distribution among the species, a total of 3.660 mammals were used in procedures in 2016. These figures represent an increase of 6% of the total use of mammals from 2015 to 2016.

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

In Luxembourg the number of uses of animals increased significantly from 3.524 uses in 2015 to a total of 21.472 uses in 2016. This trend is due to the use of 17.383 zebrafish larvae between day 5-7 post fertilization.

In Luxembourg, the two main institutions involved in animal testing both modernised and expanded their facilities during the last years. Additionally, a new facility was authorised in 2016.

Due to the small number of parties involved (6 facilities in total), this had a strong impact on the total number of animals used.

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

In 2015 the actual severity “severe” was reported the first time, when 1,14% of the uses were severe. In 2016 0,52% of the actual severities where classified as severe. As to the actual severities, no trend was observed.

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

The particular efforts taken to promote the principle of the Three Rs were:

the focus on the education of the users,

the organisation of a workshop on the severity assessment and reporting

and additional care taken during the project evaluation.

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

The category “other” was not reported.

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

In 2016 there was no case where the ‘severe-classification‘ has been exceeded.

## Luxembourg: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 3493 | 16.27% |
| Rats | 167 | 0.78% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 17812 | 82.95% |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 21472 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 20987 | 98.81% |
| Animals born in the EU but not at a registered breeder | 253 | 1.19% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 21240 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 21017 | 97.88% |
| Translational and applied research | 455 | 2.12% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills |  |  |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 21472 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 946 | 4.5% |
| Cardiovascular Blood and Lymphatic System | 429 | 2.04% |
| Nervous System | 18511 | 88.08% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System |  |  |
| Immune System | 1131 | 5.38% |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 21017 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders | 372 | 81.76% |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 83 | 18.24% |
| Total | 455 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 21240 | 98.92% |
| Yes | 232 | 1.08% |
| Total | 21472 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 341 | 1.59% |
| Mild [up to and including] | 18628 | 86.75% |
| Moderate | 2392 | 11.14% |
| Severe | 111 | 0.52% |
| Total | 21472 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 21472 | 100% |
| Yes |  |  |
| Total | 21472 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 18178 | 84.66% |
| Genetically altered without a harmful phenotype | 1980 | 9.22% |
| Genetically altered with a harmful phenotype | 1314 | 6.12% |
| Total | 21472 | 100.00% |

## Luxembourg: Narrative 2017

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

In Luxembourg there was an increase in the total number of uses from 3.524 total uses in 2015, 21.472 total uses in 2016 to 25.841 total uses in 2017. This trend is due to the use of 19.410 zebrafish larvae between day 5-7 post fertilization.

Considering the distribution among the species, a total number of 5.668 mammals were used in procedures in 2017. These figures represent an increase of 54,86% of the total uses of mammals from 2016 to 2017.

Regarding the purpose of the animal uses, no trends ware observed during the last year. The main category is basic research, followed by translational and applied research, maintenance of colonies and higher education and training.

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

In Luxembourg the number of uses of animals increased significantly from 3.524 uses in 2015, 21.472 uses in 2016 to 25.841 total uses in 2017. This trend is due to the use of 19.410 zebrafish larvae between day 5-7 post fertilization.

In Luxembourg two main institutions are involved in animal testing. Both modernised and expanded their facilities during the last years. Additionally, a new facility was authorised in 2017.

Due to the small number of the parties involved in animal experiments (6 facilities in total), the development of the animal facilities has a strong impact on the total number of animals used. In particular the majority of the animal uses (19.410 zebrafish larvae) represent a few projects.

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

Comparing the actual severities from 2016 to 2017 no trend were observed.

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

The particular efforts taken to promote the principle of the Three Rs have been:

- The focus is put on the education of the users. Notably additional minimum requirements have been adopted for the personal involved in animal experiment,

- A workshop on the severity assessment and reporting took place,

- Refinement of the housing and care of the animals is ensured, inter alia, by modernisation of the animal facilities and by a new animal facility. Another point is the environment enrichment of the cages or aquariums, in particular, providing animals with appropriate housing that allows the expression of species-specific behaviours, such as nesting opportunities for mice.

- During the inspection attention is put on points such as that the staff follows the project protocol and in particularly that the humane endpoints are respected and the score sheets are reviewed. When procedures are conducted which involve pain or invasive procedures, it is verified that these procedures are carried out under general or local anaesthesia and that analgesia or another method is used to ensure that pain, suffering and distress are kept to a minimum.

- Additional care is taken during the project evaluation , inter alia, a review of the referenced literatures, a check of the most up to date references have been considered, a check whether there are alternative methods in place and the statistical calculation is reviewed. Regarding the alternative methods, it is checked if all measures are taken to reduce pain, suffering or lasting harms, if the humane endpoints are appropriate, if the housing, health checks of the animals are appropriate etc.

-Regarding the Reduction the national research institutes are collaborating with other research groups and are sharing data and resources (animals, tissue, organs and equipment) between research groups. Furthermore one institute owns an IRM, which enables longitudinal studies in the same animals and which is put at the disposal of the other institutes

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

The category “other” was not reported.

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

In 2017 there was no case where the severe-classification has been exceeded.

## Luxembourg: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 5572 | 21.56% |
| Rats | 96 | 0.37% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 20173 | 78.07% |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 25841 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 25617 | 100% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 25617 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 24562 | 95.05% |
| Translational and applied research | 888 | 3.44% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 144 | 0.56% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 247 | 0.96% |
| Total | 25841 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 1861 | 7.58% |
| Cardiovascular Blood and Lymphatic System | 374 | 1.52% |
| Nervous System | 20265 | 82.51% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System |  |  |
| Immune System | 2062 | 8.4% |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 24562 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 526 | 59.23% |
| Human Infectious Disorders | 326 | 36.71% |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders | 36 | 4.05% |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 888 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 25617 | 99.13% |
| Yes | 224 | 0.87% |
| Total | 25841 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 519 | 2.01% |
| Mild [up to and including] | 21938 | 84.9% |
| Moderate | 3213 | 12.43% |
| Severe | 171 | 0.66% |
| Total | 25841 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 25764 | 99.7% |
| Yes | 77 | 0.3% |
| Total | 25841 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 22113 | 85.57% |
| Genetically altered without a harmful phenotype | 3660 | 14.16% |
| Genetically altered with a harmful phenotype | 68 | 0.26% |
| Total | 25841 | 100.00% |

# Malta

## Malta: Narrative 2015

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

During this year no changes have been observed in trends noted during the past years. This is due to the complete absence of scientific works involving animals.

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

N/A

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

N/A

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

N/A

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

N/A

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

N/A

## Malta: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 0 |  |
| Rats |  |  |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 0 | 100.00% |

## Malta: Narrative 2016

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

No changes have been noted from the previous year, so no animal experimentation have been carried out.

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

Not applicable

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

No

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

No

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

N/A

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

N/A

## Malta: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 0 |  |
| Rats |  |  |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 0 | 100.00% |

## Malta: Narrative 2017

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

This year an application has been received by the Competent authority and the approval has been granted to carry out research on fish (sea bass).

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

The research program took to an increase in the number of animals used, from 0 to 250 fish.

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

No severe procedures are involved in the study carried out.

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

All the fish had to be been euthanized and incinerated.

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

A significant proportion of animals is not used therefore it is not applicable

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

N/A. This was an host specific parasite study interaction and did not involve severe procedures.

## Malta: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice |  |  |
| Rats |  |  |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish | 250 | 100% |
| Cephalopods |  |  |
| Total | 250 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder |  |  |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe | 250 | 100% |
| Animals born in rest of world |  |  |
| Total | 250 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research |  |  |
| Translational and applied research | 250 | 100% |
| Regulatory use and Routine production |  |  |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills |  |  |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 250 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology |  |  |
| Cardiovascular Blood and Lymphatic System |  |  |
| Nervous System |  |  |
| Respiratory System |  |  |
| Gastrointestinal System including Liver |  |  |
| Musculoskeletal System |  |  |
| Immune System |  |  |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total |  |  |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 250 | 100% |
| Animal Welfare |  |  |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 250 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total |  |  |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total |  |  |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total |  |  |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 250 | 100% |
| Yes |  |  |
| Total | 250 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery |  |  |
| Mild [up to and including] | 250 | 100% |
| Moderate |  |  |
| Severe |  |  |
| Total | 250 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 250 | 100% |
| Yes |  |  |
| Total | 250 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 250 | 100% |
| Genetically altered without a harmful phenotype |  |  |
| Genetically altered with a harmful phenotype |  |  |
| Total | 250 | 100.00% |

# Netherlands

## Netherlands: Narrative 2015

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

In 2014 and 2015, the Dutch collection of statistical information on the use of animals in procedures, was carried out according to the common format of Commission Implementing Decision 2012/707/EU. There are a big differences between the new data categories and the former Dutch data format. This makes it very difficult to compare the statistics of 2014 and 2015 with the data from previous years.

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

In 2015 528.159 animals were used in procedures. This is 92.868 (-14.9%) less than in 2014.

A decrease in numbers of animals has been observed in almost all data categories. Especially the number of mice (-32.701), cattle (-6.646), domestic fowl (-34.289), pigs (-4.777), rhesus monkeys (-47), and cats (-18) was reduced. In 2015 127.813 (26,7%) genetically altered animals were used in procedures, this is 17.574 (-12.1%) animals less than in 2014.

In 2015 animals were 8.514 times reused, which is 2.195 (+34.7%) more than in 2014 (6.319).

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

In 2015 1.971 (+12.9%) more procedures were reported in the severity category ‘severe’, compared to 2014. This increase was especially seen in the categories Translational and applied research (human) (+16.5%), Animal diseases and disorders / animal welfare (+6.3%), Higher education or training for the acquisition, maintenance or improvement of vocational skills (+0.5%), and Testing by legislation/feed legislation including legislation for the safety of target animals, works and environment (+1%).

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

In the Netherlands continuous efforts have been taken to promote the principles of the 3R’s. However, it is not possible to trace back these efforts to specific items in the statistics.

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

In Alures we have provided information on the ‘other’ categories in the required fields. Dutch users were asked to provide more information on the selected category when these information appeared to be insufficient. In some cases the users did realize that they could reclassify the animals uses in the predefined data categories. This is a continuous process of creating awareness to the authorized users.

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

In 2015 exceedance of the severity classification ‘severe’ has not been reported and no exemption was authorised.

## Netherlands: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 244804 | 51.05% |
| Rats | 99602 | 20.77% |
| Guinea-Pigs | 3433 | 0.72% |
| Hamsters (Syrian) | 1518 | 0.32% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 1031 | 0.21% |
| Rabbits | 9899 | 2.06% |
| Cats | 61 | 0.01% |
| Dogs | 750 | 0.16% |
| Ferrets | 396 | 0.08% |
| Other carnivores | 410 | 0.09% |
| Horses, donkeys and cross-breeds | 213 | 0.04% |
| Pigs | 8402 | 1.75% |
| Goats | 239 | 0.05% |
| Sheep | 2126 | 0.44% |
| Cattle | 5240 | 1.09% |
| Prosimians |  |  |
| Marmoset and tamarins | 91 | 0.02% |
| Cynomolgus monkey | 47 | 0.01% |
| Rhesus monkey | 96 | 0.02% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 14 | 0% |
| Domestic fowl | 51386 | 10.71% |
| Other birds | 18248 | 3.8% |
| Reptiles | 851 | 0.18% |
| Rana |  |  |
| Xenopus | 1181 | 0.25% |
| Other Amphibians | 562 | 0.12% |
| Zebra fish | 4909 | 1.02% |
| Other Fish | 24071 | 5.02% |
| Cephalopods |  |  |
| Total | 479580 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 378128 | 80.3% |
| Animals born in the EU but not at a registered breeder | 90414 | 19.2% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 2350 | 0.5% |
| Total | 470892 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 166 | 95.4% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 8 | 4.6% |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 174 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 3 | 1.72% |
| F2 or greater | 8 | 4.6% |
| Self-sustaining colony | 163 | 93.68% |
| Total | 174 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 126592 | 26.4% |
| Translational and applied research | 142675 | 29.75% |
| Regulatory use and Routine production | 137291 | 28.63% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 364 | 0.08% |
| Preservation of species | 1729 | 0.36% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 19628 | 4.09% |
| Forensic enquiries | 42 | 0.01% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 51259 | 10.69% |
| Total | 479580 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 36560 | 28.88% |
| Cardiovascular Blood and Lymphatic System | 12259 | 9.68% |
| Nervous System | 20523 | 16.21% |
| Respiratory System | 1763 | 1.39% |
| Gastrointestinal System including Liver | 3499 | 2.76% |
| Musculoskeletal System | 1890 | 1.49% |
| Immune System | 15280 | 12.07% |
| Urogenital/Reproductive System | 2261 | 1.79% |
| Sensory Organs (skin, eyes and ears) | 234 | 0.18% |
| Endocrine System/Metabolism | 6450 | 5.1% |
| Multisystemic | 3318 | 2.62% |
| Ethology / Animal Behaviour /Animal Biology | 17705 | 13.99% |
| Other basic research | 4850 | 3.83% |
| Total | 126592 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 13203 | 9.25% |
| Human Infectious Disorders | 19623 | 13.75% |
| Human Cardiovascular Disorders | 4985 | 3.49% |
| Human Nervous and Mental Disorders | 11760 | 8.24% |
| Human Respiratory Disorders | 3942 | 2.76% |
| Human Gastrointestinal Disorders including Liver | 2677 | 1.88% |
| Human Musculoskeletal Disorders | 1921 | 1.35% |
| Human Immune Disorders | 3075 | 2.16% |
| Human Urogenital/Reproductive Disorders | 965 | 0.68% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 281 | 0.2% |
| Human Endocrine/Metabolism Disorders | 5034 | 3.53% |
| Other Human Disorders | 882 | 0.62% |
| Animal Diseases and Disorders | 42449 | 29.75% |
| Animal Welfare | 28642 | 20.07% |
| Diagnosis of diseases | 1877 | 1.32% |
| Plant diseases | 436 | 0.31% |
| Non-regulatory toxicology and ecotoxicology | 923 | 0.65% |
| Total | 142675 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 65122 | 47.43% |
| Other efficacy and tolerance testing | 1023 | 0.75% |
| Toxicity and other safety testing including pharmacology | 70723 | 51.51% |
| Routine production | 423 | 0.31% |
| Total | 137291 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 3162 | 4.86% |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 61960 | 95.14% |
| Total | 65122 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 1020 | 1.44% |
| Skin irritation/corrosion | 316 | 0.45% |
| Skin sensitisation | 3777 | 5.34% |
| Eye irritation/corrosion | 85 | 0.12% |
| Repeated dose toxicity | 6928 | 9.8% |
| Carcinogenicity | 1538 | 2.17% |
| Genotoxicity | 733 | 1.04% |
| Reproductive toxicity | 23926 | 33.83% |
| Developmental toxicity | 19323 | 27.32% |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Kinetics | 986 | 1.39% |
| Ecotoxicity | 9292 | 13.14% |
| Safety testing in food and feed area | 960 | 1.36% |
| Target animal safety | 1839 | 2.6% |
| Total | 70723 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 120 | 11.76% |
| Other lethal methods | 425 | 41.67% |
| Non lethal methods | 475 | 46.57% |
| Total | 1020 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 5024 | 72.52% |
| 29 - 90 days | 1904 | 27.48% |
| > 90 days |  |  |
| Total | 6928 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 7821 | 84.17% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity | 720 | 7.75% |
| Bioaccumulation | 751 | 8.08% |
| Other ecotoxicity |  |  |
| Total | 9292 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 294 | 69.5% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 129 | 30.5% |
| Total | 423 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 44052 | 32.09% |
| Legislation on medicinal products for veterinary use and their residues | 33821 | 24.63% |
| Medical devices legislation | 2 | 0% |
| Industrial chemicals legislation | 45992 | 33.5% |
| Plant protection product legislation | 2764 | 2.01% |
| Biocides legislation |  |  |
| Food legislation including food contact material | 740 | 0.54% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 1045 | 0.76% |
| Cosmetics legislation |  |  |
| Other legislation | 8875 | 6.46% |
| Total | 137291 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 127695 | 93.01% |
| Legislation satisfying national requirements only [within EU] | 521 | 0.38% |
| Legislation satisfying Non-EU requirements only | 9075 | 6.61% |
| Total | 137291 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 471066 | 98.22% |
| Yes | 8514 | 1.78% |
| Total | 479580 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 23323 | 4.86% |
| Mild [up to and including] | 346271 | 72.2% |
| Moderate | 92789 | 19.35% |
| Severe | 17197 | 3.59% |
| Total | 479580 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 469439 | 97.89% |
| Yes | 10141 | 2.11% |
| Total | 479580 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 351767 | 73.35% |
| Genetically altered without a harmful phenotype | 63088 | 13.15% |
| Genetically altered with a harmful phenotype | 64725 | 13.5% |
| Total | 479580 | 100.00% |

## Netherlands: Narrative 2016

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

In 2016, the Dutch registered establishments reported 403.370 animals used in procedures. This is 76.210 (-18.9%) less than in 2015. Especially the number of mice (-82.826), sheep (-1688), rabbits (-1320) and cattle (-1167) was reduced.

In 2016 animals were 10.819 times reused, which is which is 2305 more than in 2015 (8.514).

Reuse mainly takes place for the purpose of education and training.

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

In 2016, 78.209 procedures were reported with the use of genetically altered animals. This is a decrease of 49.604 animals compared to 2015. This decrease in use of genetically altered animals can partially be explained with the observation that in the previous years a large numbers of lines of genetically altered animals were established. This after completion of a welfare assessment with a minimum of two generations. For a substantial amount of genetically altered lines, it was concluded in the welfare assessment that they are notexpected to have a harmful phenotype. Therefore, breeding of these lines no longer needs to be reported.

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

The actual severities reported in 2016 (mild 68.7%, moderate 21.7% severe 3.3%, and non-recovery: 6.3%) are generally in line with the actual severities reported in 2015 (non-recovery 4.9%, mild 72.2%, moderate 19.3% and severe 3.6%).

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

In the Netherlands, continuous efforts have been taken to promote the principles of the 3R’s. However, it is not possible to trace back these efforts to specific items in the statistics.

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

Other carnivores (main categories): European pine marten (*Martes martes*), harbour seals (*Phoca vitulina*), European (Russian) minks (*Mustela lutreola*), Toepaja (*Tupaia belan­geri*), and wild boars (*Sus scrofa*).

Other birds (main categories): 4803 (23.8%) *Parus Major* (great tit), 3654 (18.1%) *Anas plathyrynchos* (common mallard), 1572 (7.8%) *Gallus gallus* (red junglefowl), 1363 (6.8%) *Limosa limosa (*black tailed godwit), 1055 (5.2%) *Cyanistes caeruleus* (Eurasian blue tit).

Other fish (main categories): 3087 (23.8%) *Anguilla Anguilla* (European eel), 2909 (22.5%) *Pimephales promelas* (fathead minnow), 2780 (21.5%) *Cyprinus carpio* (common carp)

All procedures (3257) reported in de category ‘other basic research’ were used for cell biology-research.

2756 out of 5008 procedures in the category ‘other efficacy and tolerance testing’ were used for tests concerning the European pharmacopeia.

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

In 2016 exceedance of the severity classification ‘severe’ has not been reported and no exemption was authorised.

## Netherlands: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 148406 | 38.38% |
| Rats | 106876 | 27.64% |
| Guinea-Pigs | 2763 | 0.71% |
| Hamsters (Syrian) | 1443 | 0.37% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 472 | 0.12% |
| Rabbits | 8579 | 2.22% |
| Cats | 89 | 0.02% |
| Dogs | 656 | 0.17% |
| Ferrets | 294 | 0.08% |
| Other carnivores | 216 | 0.06% |
| Horses, donkeys and cross-breeds | 146 | 0.04% |
| Pigs | 10129 | 2.62% |
| Goats | 152 | 0.04% |
| Sheep | 438 | 0.11% |
| Cattle | 4073 | 1.05% |
| Prosimians |  |  |
| Marmoset and tamarins | 16 | 0% |
| Cynomolgus monkey | 34 | 0.01% |
| Rhesus monkey | 70 | 0.02% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 1 | 0% |
| Domestic fowl | 52237 | 13.51% |
| Other birds | 20143 | 5.21% |
| Reptiles | 207 | 0.05% |
| Rana | 20 | 0.01% |
| Xenopus | 431 | 0.11% |
| Other Amphibians | 63 | 0.02% |
| Zebra fish | 15804 | 4.09% |
| Other Fish | 12942 | 3.35% |
| Cephalopods |  |  |
| Total | 386700 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 288771 | 76.84% |
| Animals born in the EU but not at a registered breeder | 82417 | 21.93% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 4612 | 1.23% |
| Total | 375800 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 58 | 71.6% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 23 | 28.4% |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 81 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 25 | 30.86% |
| Self-sustaining colony | 56 | 69.14% |
| Total | 81 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 115211 | 29.79% |
| Translational and applied research | 107466 | 27.79% |
| Regulatory use and Routine production | 142733 | 36.91% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 24 | 0.01% |
| Preservation of species | 4257 | 1.1% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 14714 | 3.81% |
| Forensic enquiries | 677 | 0.18% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 1618 | 0.42% |
| Total | 386700 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 43795 | 38.01% |
| Cardiovascular Blood and Lymphatic System | 7531 | 6.54% |
| Nervous System | 17046 | 14.8% |
| Respiratory System | 1498 | 1.3% |
| Gastrointestinal System including Liver | 3351 | 2.91% |
| Musculoskeletal System | 848 | 0.74% |
| Immune System | 13063 | 11.34% |
| Urogenital/Reproductive System | 1653 | 1.43% |
| Sensory Organs (skin, eyes and ears) | 316 | 0.27% |
| Endocrine System/Metabolism | 3670 | 3.19% |
| Multisystemic | 3598 | 3.12% |
| Ethology / Animal Behaviour /Animal Biology | 15585 | 13.53% |
| Other basic research | 3257 | 2.83% |
| Total | 115211 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 14122 | 13.14% |
| Human Infectious Disorders | 18775 | 17.47% |
| Human Cardiovascular Disorders | 4564 | 4.25% |
| Human Nervous and Mental Disorders | 9646 | 8.98% |
| Human Respiratory Disorders | 2664 | 2.48% |
| Human Gastrointestinal Disorders including Liver | 2186 | 2.03% |
| Human Musculoskeletal Disorders | 917 | 0.85% |
| Human Immune Disorders | 2024 | 1.88% |
| Human Urogenital/Reproductive Disorders | 107 | 0.1% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 430 | 0.4% |
| Human Endocrine/Metabolism Disorders | 2444 | 2.27% |
| Other Human Disorders | 30 | 0.03% |
| Animal Diseases and Disorders | 18186 | 16.92% |
| Animal Welfare | 29363 | 27.32% |
| Diagnosis of diseases | 1339 | 1.25% |
| Plant diseases | 43 | 0.04% |
| Non-regulatory toxicology and ecotoxicology | 626 | 0.58% |
| Total | 107466 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 54947 | 38.5% |
| Other efficacy and tolerance testing | 5008 | 3.51% |
| Toxicity and other safety testing including pharmacology | 82616 | 57.88% |
| Routine production | 162 | 0.11% |
| Total | 142733 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 2603 | 4.74% |
| Pyrogenicity testing |  |  |
| Batch potency testing | 52206 | 95.01% |
| Other quality controls | 138 | 0.25% |
| Total | 54947 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 1903 | 2.3% |
| Skin irritation/corrosion | 124 | 0.15% |
| Skin sensitisation | 4086 | 4.95% |
| Eye irritation/corrosion | 107 | 0.13% |
| Repeated dose toxicity | 6386 | 7.73% |
| Carcinogenicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Genotoxicity | 660 | 0.8% |
| Reproductive toxicity | 25780 | 31.2% |
| Developmental toxicity | 35853 | 43.4% |
| Kinetics | 1001 | 1.21% |
| Ecotoxicity | 4917 | 5.95% |
| Safety testing in food and feed area | 1792 | 2.17% |
| Target animal safety | 7 | 0.01% |
| Total | 82616 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods | 112 | 5.89% |
| Non lethal methods | 1791 | 94.11% |
| Total | 1903 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 2047 | 32.05% |
| 29 - 90 days | 3679 | 57.61% |
| > 90 days | 660 | 10.34% |
| Total | 6386 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 3777 | 76.82% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity | 240 | 4.88% |
| Endocrine activity |  |  |
| Bioaccumulation | 900 | 18.3% |
| Other ecotoxicity |  |  |
| Total | 4917 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 2 | 1.23% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 160 | 98.77% |
| Total | 162 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 38543 | 27% |
| Legislation on medicinal products for veterinary use and their residues | 30184 | 21.15% |
| Medical devices legislation | 62 | 0.04% |
| Industrial chemicals legislation | 68172 | 47.76% |
| Plant protection product legislation | 310 | 0.22% |
| Biocides legislation | 86 | 0.06% |
| Food legislation including food contact material | 438 | 0.31% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 2182 | 1.53% |
| Cosmetics legislation |  |  |
| Other legislation | 2756 | 1.93% |
| Total | 142733 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 140100 | 98.16% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only | 2633 | 1.84% |
| Total | 142733 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 375881 | 97.2% |
| Yes | 10819 | 2.8% |
| Total | 386700 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 8732 | 2.26% |
| Mild [up to and including] | 277205 | 71.68% |
| Moderate | 87429 | 22.61% |
| Severe | 13334 | 3.45% |
| Total | 386700 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 378070 | 97.77% |
| Yes | 8630 | 2.23% |
| Total | 386700 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 308491 | 79.78% |
| Genetically altered without a harmful phenotype | 67451 | 17.44% |
| Genetically altered with a harmful phenotype | 10758 | 2.78% |
| Total | 386700 | 100.00% |

## Netherlands: Narrative 2017

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

In 2017, the Dutch registered establishments reported 477.550 animals used in procedures. This is 74.180 (+18.4%) more than in 2016. Especially the number of mice (+44.015), and zebrafish (+36.220) was increased. The number of rats (-18.052) was reduced.

In 2017 animals were 11.138 times reused, which is 319 animal more than in 2016 (10.819). Reuse mainly takes place for the purpose of education and training.

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

In 2017 more experiments with zebrafish were carried out in the context of intensifying research into new possibilities for the screening of anti-cancer drugs. In addition, more experiments with zebrafish have been carried out as a result of research into hormone-disrupting substances in the context of a larger EU project.

In 2017, 133.365 procedures were reported with the use of genetically altered animals. This is a increase of 55.156 animals compared to 2016. Most animal testing on genetically modified animals have carried out on mice (84,908, 63.7% of the number of animal tests for genetically modified animals animals) and zebrafish (45,941, 34.4%).

After a significant increase in number of animal uses in 2014 and a temporary decrease in 2016, the number of animals uses appears to be stabilizing in 2017 and has reached the same level as in the reporting years 2013 and 2015. These fluctuations seem to be caused mainly by the adaptation of the user community to the new reporting and licensing system, introduced in 2014.

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

The actual severities reported in 2017 (mild 64,9%, moderate 25,5%, severe 3.0%, and non-recovery: 6.6%) are generally in line with the actual severities reported in 2016 (mild 68.7%, moderate 21.7%, severe 3.3%, and non-recovery 6.3%).

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

In the Netherlands, continuous efforts have been taken to promote the principles of the 3R’s. However, it is not possible to trace back these efforts to specific items in the statistics.

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

Other carnivores (main categories): 257 European (Russian) minks (Mustela lutreola), 6 harbour seals (Phoca vitulina), 6 badgers (Meles meles), and 2 European pine marten (Martes martes).

Other birds (main categories): 4618 Parus Major (great tit), 3822 Anas plathyrynchos (common mallard), 3160 Gallus gallus (red junglefowl), 1580 Limosa limosa (black tailed godwit).

Other fish (main categories): 5318 Pleuronectes platessa (European plaice), 4467 Anguilla Anguilla (European eel), 3571 Limanda limanda (common dab).

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

In 2017 exceedance of the severity classification ‘severe’ has not been reported and no exemption was authorised.

## Netherlands: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 205993 | 43.14% |
| Rats | 91537 | 19.17% |
| Guinea-Pigs | 5816 | 1.22% |
| Hamsters (Syrian) | 1035 | 0.22% |
| Hamsters (Chinese) | 12 | 0% |
| Mongolian gerbil |  |  |
| Other Rodents | 736 | 0.15% |
| Rabbits | 9764 | 2.04% |
| Cats | 200 | 0.04% |
| Dogs | 909 | 0.19% |
| Ferrets | 680 | 0.14% |
| Other carnivores | 270 | 0.06% |
| Horses, donkeys and cross-breeds | 173 | 0.04% |
| Pigs | 9738 | 2.04% |
| Goats | 259 | 0.05% |
| Sheep | 558 | 0.12% |
| Cattle | 3833 | 0.8% |
| Prosimians |  |  |
| Marmoset and tamarins | 41 | 0.01% |
| Cynomolgus monkey | 42 | 0.01% |
| Rhesus monkey | 234 | 0.05% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 3315 | 0.69% |
| Domestic fowl | 55371 | 11.59% |
| Other birds | 18322 | 3.84% |
| Reptiles | 294 | 0.06% |
| Rana | 9 | 0% |
| Xenopus | 438 | 0.09% |
| Other Amphibians | 60 | 0.01% |
| Zebra fish | 52024 | 10.89% |
| Other Fish | 15887 | 3.33% |
| Cephalopods |  |  |
| Total | 477550 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 363141 | 77.89% |
| Animals born in the EU but not at a registered breeder | 94773 | 20.33% |
| Animals born in rest of Europe | 44 | 0.01% |
| Animals born in rest of world | 8263 | 1.77% |
| Total | 466221 | 100.00% |

### Source of non-human primates as registered at first use

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

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 2 | 1.05% |
| Self-sustaining colony | 189 | 98.95% |
| Total | 191 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 199245 | 41.72% |
| Translational and applied research | 127385 | 26.67% |
| Regulatory use and Routine production | 122247 | 25.6% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 873 | 0.18% |
| Preservation of species | 3698 | 0.77% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 22074 | 4.62% |
| Forensic enquiries | 361 | 0.08% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 1667 | 0.35% |
| Total | 477550 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 94460 | 47.41% |
| Cardiovascular Blood and Lymphatic System | 6868 | 3.45% |
| Nervous System | 18175 | 9.12% |
| Respiratory System | 758 | 0.38% |
| Gastrointestinal System including Liver | 3203 | 1.61% |
| Musculoskeletal System | 692 | 0.35% |
| Immune System | 16582 | 8.32% |
| Urogenital/Reproductive System | 1199 | 0.6% |
| Sensory Organs (skin, eyes and ears) | 1030 | 0.52% |
| Endocrine System/Metabolism | 4351 | 2.18% |
| Multisystemic | 4115 | 2.07% |
| Ethology / Animal Behaviour /Animal Biology | 20617 | 10.35% |
| Other basic research | 27195 | 13.65% |
| Total | 199245 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 13920 | 10.93% |
| Human Infectious Disorders | 22913 | 17.99% |
| Human Cardiovascular Disorders | 5882 | 4.62% |
| Human Nervous and Mental Disorders | 9692 | 7.61% |
| Human Respiratory Disorders | 2410 | 1.89% |
| Human Gastrointestinal Disorders including Liver | 2555 | 2.01% |
| Human Musculoskeletal Disorders | 1587 | 1.25% |
| Human Immune Disorders | 4179 | 3.28% |
| Human Urogenital/Reproductive Disorders | 814 | 0.64% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 575 | 0.45% |
| Human Endocrine/Metabolism Disorders | 2423 | 1.9% |
| Other Human Disorders | 235 | 0.18% |
| Animal Diseases and Disorders | 31368 | 24.62% |
| Animal Welfare | 22221 | 17.44% |
| Diagnosis of diseases | 1115 | 0.88% |
| Plant diseases | 8 | 0.01% |
| Non-regulatory toxicology and ecotoxicology | 5488 | 4.31% |
| Total | 127385 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 1948 | 3.89% |
| Pyrogenicity testing |  |  |
| Batch potency testing | 47934 | 95.71% |
| Other quality controls | 200 | 0.4% |
| Total | 50082 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Carcinogenicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 1886 | 100% |
| Total | 1886 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of 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 use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 1368 | 33.36% |
| Chronic toxicity | 2329 | 56.79% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation | 404 | 9.85% |
| Other ecotoxicity |  |  |
| Total | 4101 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 6 | 3.39% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 171 | 96.61% |
| Total | 177 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 30227 | 24.73% |
| Legislation on medicinal products for veterinary use and their residues | 31915 | 26.11% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation | 57024 | 46.65% |
| 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 environment | 2164 | 1.77% |
| Cosmetics legislation |  |  |
| Other legislation | 66 | 0.05% |
| Total | 122247 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 119545 | 97.79% |
| Legislation satisfying national requirements only [within EU] | 8 | 0.01% |
| Legislation satisfying Non-EU requirements only | 2694 | 2.2% |
| Total | 122247 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 466412 | 97.67% |
| Yes | 11138 | 2.33% |
| Total | 477550 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 31611 | 6.62% |
| Mild [up to and including] | 310002 | 64.92% |
| Moderate | 121739 | 25.49% |
| Severe | 14198 | 2.97% |
| Total | 477550 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 466582 | 97.7% |
| Yes | 10968 | 2.3% |
| Total | 477550 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 344185 | 72.07% |
| Genetically altered without a harmful phenotype | 123939 | 25.95% |
| Genetically altered with a harmful phenotype | 9426 | 1.97% |
| Total | 477550 | 100.00% |

# Poland

## Poland: Narrative 2015

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

The report is the first submitted under the new rules.

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

The report is the first submitted under the new rules.

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

The report is the first submitted under the new rules.

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

Propagation and awareness of the need for replacement, reduction and refinement (3R) is one of the primary aims Polish National Ethics Committee on Animal Experimentation and is governed by a legal act of the highest importance, the Act on Experiments on Animals of 15 January 2015, in accordance to the Directive 2010/63/EU on the protection of animals used for scientific purposes.

Propagation of list of alternative methods designed to replace some routine animal tests and reduction of number of animals in routine testing is accessible at the webpage of the Committee.

Application of alternative methods to replace animals from routine tests is one of the major criteria in assessment of animal study applications by the Local Ethics Committees in Poland. Description of replacement, reduction and refinement application is also an indispensable part of each application.

The Committee supports the 3R courses for scientists and caretakers, which are obligatory to receive any permission to perform or plan experiments. All these issues are also propagate during the meetings organized with the local committees and disseminate to the bodies on animal welfare, which operate in all breeders, suppliers and users.  At the webpage of the Committee there are documents concerning 3R rules prepared by European Commission and the guides prepared by the Committee describing how to assess the invasiveness procedures and how to make them milder to animals. All these documents are publicly accessible.

In our opinion, it is too early to assess its impacts on statistics.

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

In the 2015 report under the category "other animals" there are:

* Other carnivores (other Carnivora) are Meles meles, Mustela nivalis, Neovison vison, Nyctereutes procyonoides, Ursus arctos, Vulpes vulpes used in the purposes of Ethology / Animal Behaviour /Animal Biology, Protection of the natural environment in the interests of the health or welfare of human beings or animals. They represent 96,24 % of all carnivores.
* Other birds (other Aves) are Acrocephalus schoenobaenus, Actitis hypoleucos, Anas platyrhynchos, Calidris alba, Calidris ferruginea, Calidris canutus, Canistes caerules, Chlidonias hybrida, Chroicocephalus ridibundus, Ciconia ciconia, Cisticola chubbi, Coturnix japonica, Columba livia, Cyanistes caeruleus, Dromaiinae, Emberiza hortulana, Falco peregrinus, Fulica atra, Gerygone flavolateralis, Hirundo rustica, Laniarus atroflavus, Larus canus, Meleagris gallopavo gallopavo var. Domesticus, Passer domesticus, Parus major, Remiz pendulinus, Sternula albiforns, Sterna hirundo, Sylvia communis, Turdus philomelos, Taeniopygia guttata, , Turdus merula used in the purposes of Ethology / Animal Behaviour /Animal Biology, Protection of the natural environment in the interests of the health or welfare of human beings or animals, Higher education or training for the acquisition, maintenance or improvement of vocational skills. They represent 34,31% of all birds.
* Other fish (other Pisces) are Acipenser baeri, Acipenser guldenstaedtii, Acipenser ruthenus, Anguilla anguilla, Babka gymnotrachelus, Carassius carassius, Cobitis taenia, Coregonus lavaretus, Cyprinus carpio, Gasterosteus aculeatus, Leuciscus idus, Neogobius melanostomus, Oncorhynchus mykiss, Perca fluviatilis, Perccottus glenii, Platichthys flesus, Poecilia reticulata, Poecilia sphenops, Proterorhinus semilunaris, Rutilus rutilus, Salmo trutta, Salmonidae, Sander lucioperca, Scardinius erythrophthalmus, Silurus glanis, Tinca tinca used in the purposes of (Regulatory use/Toxicity and../Ecotoxicity) Acute toxicity, (Basic Research) Immune System, (Basic Research) Ethology / Animal Behaviour /Animal Biology, Protection of the natural environment in the interests of the health or welfare of human beings or animals, (Basic Research) Urogenital/Reproductive System, (Trans/Appl Research) Non-regulatory toxicology and ecotoxicology, Higher education or training for the acquisition, maintenance or improvement of vocational skills, Preservation of species, (Basic Research) Multisystemic , (Trans/Appl Research) Animal Welfare. They represent 94,85 % of all fish.
* Other amphibians (other Amphibia) are Bufo bufo, Pelophylax esculentus, Pelophylax lessonae, Pelophylax ridibundus, Slalamandra salamandra, used in the purposes of Basic Research: Urogenital/Reproductive System and Ethology / Animal Behaviour /Animal Biology. They represent 36,7 % of all amphibians.

In Regulatory use / Routine production as „Other” are specified medicinal products and quality controls.

In Regulatory use as „Other efficacy and tolerance testing” are specified study of local tolerance and study of skin sensitization.

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

There are no such cases.

## Poland: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 88776 | 50.16% |
| Rats | 36073 | 20.38% |
| Guinea-Pigs | 5756 | 3.25% |
| Hamsters (Syrian) | 22 | 0.01% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 178 | 0.1% |
| Other Rodents | 8445 | 4.77% |
| Rabbits | 1606 | 0.91% |
| Cats | 8 | 0% |
| Dogs | 24 | 0.01% |
| Ferrets |  |  |
| Other carnivores | 818 | 0.46% |
| Horses, donkeys and cross-breeds | 232 | 0.13% |
| Pigs | 1718 | 0.97% |
| Goats | 8 | 0% |
| Sheep | 566 | 0.32% |
| Cattle | 1637 | 0.92% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 1195 | 0.68% |
| Domestic fowl | 11099 | 6.27% |
| Other birds | 5798 | 3.28% |
| Reptiles | 110 | 0.06% |
| Rana | 224 | 0.13% |
| Xenopus | 102 | 0.06% |
| Other Amphibians | 189 | 0.11% |
| Zebra fish | 639 | 0.36% |
| Other Fish | 11757 | 6.64% |
| Cephalopods |  |  |
| Total | 176980 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 145779 | 83.75% |
| Animals born in the EU but not at a registered breeder | 27864 | 16.01% |
| Animals born in rest of Europe | 21 | 0.01% |
| Animals born in rest of world | 398 | 0.23% |
| Total | 174062 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 126089 | 71.24% |
| Translational and applied research | 14826 | 8.38% |
| Regulatory use and Routine production | 29475 | 16.65% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 3126 | 1.77% |
| Preservation of species | 664 | 0.38% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 2688 | 1.52% |
| Forensic enquiries | 100 | 0.06% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 12 | 0.01% |
| Total | 176980 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 9925 | 7.87% |
| Cardiovascular Blood and Lymphatic System | 7537 | 5.98% |
| Nervous System | 53294 | 42.27% |
| Respiratory System | 236 | 0.19% |
| Gastrointestinal System including Liver | 4076 | 3.23% |
| Musculoskeletal System | 1107 | 0.88% |
| Immune System | 6579 | 5.22% |
| Urogenital/Reproductive System | 5662 | 4.49% |
| Sensory Organs (skin, eyes and ears) | 495 | 0.39% |
| Endocrine System/Metabolism | 3322 | 2.63% |
| Multisystemic | 15835 | 12.56% |
| Ethology / Animal Behaviour /Animal Biology | 6463 | 5.13% |
| Other basic research | 11558 | 9.17% |
| Total | 126089 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 2906 | 19.6% |
| Human Infectious Disorders | 468 | 3.16% |
| Human Cardiovascular Disorders | 207 | 1.4% |
| Human Nervous and Mental Disorders | 2399 | 16.18% |
| Human Respiratory Disorders | 80 | 0.54% |
| Human Gastrointestinal Disorders including Liver | 244 | 1.65% |
| Human Musculoskeletal Disorders | 164 | 1.11% |
| Human Immune Disorders | 338 | 2.28% |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 410 | 2.77% |
| Human Endocrine/Metabolism Disorders | 96 | 0.65% |
| Other Human Disorders | 429 | 2.89% |
| Animal Diseases and Disorders | 1642 | 11.08% |
| Animal Welfare | 2418 | 16.31% |
| Diagnosis of diseases | 577 | 3.89% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 2448 | 16.51% |
| Total | 14826 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 16708 | 56.69% |
| Other efficacy and tolerance testing | 36 | 0.12% |
| Toxicity and other safety testing including pharmacology | 11766 | 39.92% |
| Routine production | 965 | 3.27% |
| Total | 29475 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 4710 | 28.19% |
| Pyrogenicity testing | 234 | 1.4% |
| Batch potency testing | 10089 | 60.38% |
| Other quality controls | 1675 | 10.03% |
| Total | 16708 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 5385 | 45.77% |
| Skin irritation/corrosion | 259 | 2.2% |
| Skin sensitisation | 1284 | 10.91% |
| Eye irritation/corrosion | 50 | 0.42% |
| Repeated dose toxicity | 183 | 1.56% |
| Carcinogenicity | 140 | 1.19% |
| Developmental toxicity |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Phototoxicity |  |  |
| Safety testing in food and feed area |  |  |
| Target animal safety |  |  |
| Reproductive toxicity | 1425 | 12.11% |
| Neurotoxicity | 142 | 1.21% |
| Pharmaco-dynamics (incl safety pharmacology) | 164 | 1.39% |
| Ecotoxicity | 2718 | 23.1% |
| Other toxicity/safety testing | 16 | 0.14% |
| Total | 11766 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 4525 | 84.03% |
| Other lethal methods |  |  |
| Non lethal methods | 860 | 15.97% |
| Total | 5385 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 183 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 183 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 2718 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 2718 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 383 | 39.69% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 582 | 60.31% |
| Total | 965 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 19733 | 66.95% |
| Legislation on medicinal products for veterinary use and their residues | 3025 | 10.26% |
| Medical devices legislation | 867 | 2.94% |
| Industrial chemicals legislation | 2022 | 6.86% |
| Plant protection product legislation | 3150 | 10.69% |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment | 12 | 0.04% |
| Cosmetics legislation |  |  |
| Other legislation | 666 | 2.26% |
| Total | 29475 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 28709 | 97.4% |
| Legislation satisfying national requirements only [within EU] | 607 | 2.06% |
| Legislation satisfying Non-EU requirements only | 159 | 0.54% |
| Total | 29475 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 174062 | 98.35% |
| Yes | 2918 | 1.65% |
| Total | 176980 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 16523 | 9.34% |
| Mild [up to and including] | 67288 | 38.02% |
| Moderate | 64396 | 36.39% |
| Severe | 28773 | 16.26% |
| Total | 176980 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 176187 | 99.55% |
| Yes | 793 | 0.45% |
| Total | 176980 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 166850 | 94.28% |
| Genetically altered without a harmful phenotype | 6489 | 3.67% |
| Genetically altered with a harmful phenotype | 3641 | 2.06% |
| Total | 176980 | 100.00% |

## Poland: Narrative 2016

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

The 2016 report is only the second one made in accordance with the new rules. This makes it impossible to identify real trends in the use of animals for experiments. In addition, the drawing of general conclusions is made difficult by the ongoing transitional period in Poland, during which experiments are being carried out both in accordance with provisions that have already been repealed (up to the end of 2017) and the law currently in force. On the one hand, this has resulted in an increase in the number of animals used, due to rapidly completed ‘old’ experiments. On the other hand, some experiments which are not considered procedures under the new rules continue to take place (and be reported). The reports for 2015 could also contain errors resulting from a misunderstanding of the new rules and reporting rules. Users’ awareness is increasing thanks to numerous training courses held in 2015-2016 and other forms of disseminating information, with the consequence that subsequent reports are correct and more consistent.

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

The observed differences in the number of animals used in each area, as reflected in the 2015 and 2016 reports, may be the consequence of the trends described above. In addition, they seem to be a natural consequence of completing one type of experiment and starting another, in connection with seeking research grants linked to an increase in the popularity of a given field of research or, for example, to seeking orders from external parties.

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

In 2016, a clear decline is observed in the number of mice used in ‘non-recovery’ experiments. This is probably due to an earlier misunderstanding of the concept by users, and also the exhausting of authorisations issued on the basis of the repealed Act. Animals were also likely to be included in this category in 2015 for the sole purpose of the procurement of organs and tissues, since, according to the previous legislation, the consent of the Local Ethics Committee on Animal Experiments (LEC) was also required in the event that an animal was killed for such purposes. Certainty of the accuracy of the data reported was only achieved in the subsequent report for 2016.

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

The statutory objectives of the National Ethics Committee on Animal Experiments (NEC) are action for the three Rs and the promotion of alternative research. The NEC supports training courses for persons planning or carrying out experiments whose programmes incorporate this topic. It also communicates the above information to LECs and welfare teams through direct contacts as well as via its website.

When issuing authorisation for carrying out an experiment, LECs are required to take into account the existence of alternative methods and the application of the three Rs. To this end, the model request for authorisation contains a specific field where the user is required to enter the method of implementation of the three Rs in the experiment. The special welfare teams that users are obliged by law to set up monitor the means of implementing the three Rs in individual units. Their activities are monitored by the NEC, which prepares a comprehensive analysis of users’ reporting in this area on an annual basis.

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

In Poland a large number of nutritional experiments are carried out in which the activities performed fall within the definition of a procedure. However, in the reporting table there is no separate category for nutritional tests in the list of objectives, hence these are placed in the ‘other’ group. A similar situation arises in the case of procedures involving the transfer of embryos. There is also one unit which, under routine manufacturing procedures required by law, employs tests other than those on the list to test medicinal products from material of plant origin (API).

In 2016, the animal species included in the ‘other’ category were:

* ‘Other’ species of carnivore (other Carnivora), namely Mustela nivalis and

Neovison vison. These are used in fundamental research relating to biology and species behaviour and translational research on animal welfare. They account for 18.25% of all carnivorous animal species used in research.

* ‘Other’ bird species (other Aves), namely Acrocephalus arundinaceus, Acrocephalus dumetorum, Acrocephalus palustris, Acrocephalus schoenobaenus, Acrocephalus scirpaceus, Actitis hypoleucos, Anas platyrhynchos, Anser domesticus, Calidris alba, Calidris ferruginea, Canistes caerules, Chlidonias hybrid, Columba livia, Coturnix japonica, Cyanistes caeruleus, Dromaiinae, Ficedula hypoleuca, Fringilla coelebs, Hippolais icterina, Hirundo rustica, Lanius collurio, Larus canus, Locustella fluviatilis, Locustella luscinioides, Locustella naevia, Meleagris gallopavo gallopavo var. domesticus, Passer domesticus, Parus major, Remiz pendulinus, Sterna albifrons, Sterna hirundo, Sylvia borin, Sylvia communis, Sylvia curruca, Sylvia nisoria, Tetrao urogallus, Turdus merula and Turdus philomelos. These are mainly used in fundamental research relating to biology and species behaviour, tests of gastrointestinal systems, including liver and multisystemic tests, and translational research on animal welfare, animal diseases and disorders and the conservation of the species in nature. They account for 66.61% of all bird species used in research.
* ‘Other’ fish species (other Pisces), namely Acipenser baeri, Acipenser ruthenus, Anguilla anguilla, Babka gymnotrachelus, Barbus barbus, Carassius auratus, Carassius carassius, Carassius gibelio, Chondrostoma nasus, Clarias gariepinus, Cobitis taenia, Cobitis elongatoides, Cobitis hybrids, Coregonus albula, Coregonus lavaretus, Cyprinus carpio, Esox lucius, Gasterosteus aculeatus, Gymnocephalus cernua, Neogobius fluviatilis, Neogobius melanostomus, Oncorhynchus mykiss, Perca fluviatilis, Perccottus glenii, Poecilia reticulate, Platichthys flesus, Proterorhinus semilunaris, Rutilus rutilus, Salmo trutta m. trutta, Sander lucioperca, Scardinius erythrophthalmus, Silurus glanis, Squalius cephalus and Tinca tinca. These are mainly used in fundamental research relating to biology and species behaviour, tests of immune systems, reproductive systems and multisystemic tests, translational research on animal welfare, animal diseases and disorders and the conservation of the species in nature, but also in some acute toxicity studies. They account for 97.16% of all fish species used in research.
* ‘Other’ amphibian species (other Amphibia), namely Bufo bufo, Pelophylax esculentus, Pelophylax lessonae, Pelophylax ridibundus and Slalamandra salamandra. These are used in fundamental research relating to biology and species behaviour and reproductive system tests, and translational research on animal diseases and disorders. They account for 97.32% of all amphibian species used in research.

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

No such cases were found. It appears that more complete information in this regard can be provided through retrospective evaluations carried out by local ethics committees**.**

## Poland: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 89105 | 47.22% |
| Rats | 32370 | 17.15% |
| Guinea-Pigs | 6639 | 3.52% |
| Hamsters (Syrian) | 212 | 0.11% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 88 | 0.05% |
| Other Rodents | 1263 | 0.67% |
| Rabbits | 998 | 0.53% |
| Cats | 15 | 0.01% |
| Dogs | 88 | 0.05% |
| Ferrets |  |  |
| Other carnivores | 23 | 0.01% |
| Horses, donkeys and cross-breeds | 220 | 0.12% |
| Pigs | 1068 | 0.57% |
| Goats | 36 | 0.02% |
| Sheep | 1143 | 0.61% |
| Cattle | 492 | 0.26% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 578 | 0.31% |
| Domestic fowl | 3612 | 1.91% |
| Other birds | 7207 | 3.82% |
| Reptiles | 526 | 0.28% |
| Rana | 20 | 0.01% |
| Xenopus |  |  |
| Other Amphibians | 727 | 0.39% |
| Zebra fish | 1203 | 0.64% |
| Other Fish | 41086 | 21.77% |
| Cephalopods |  |  |
| Total | 188719 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 129825 | 69.26% |
| Animals born in the EU but not at a registered breeder | 57519 | 30.69% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 104 | 0.06% |
| Total | 187448 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 142463 | 75.49% |
| Translational and applied research | 17140 | 9.08% |
| Regulatory use and Routine production | 26157 | 13.86% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 321 | 0.17% |
| Preservation of species | 893 | 0.47% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1597 | 0.85% |
| Forensic enquiries | 30 | 0.02% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 118 | 0.06% |
| Total | 188719 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 7378 | 5.18% |
| Cardiovascular Blood and Lymphatic System | 5558 | 3.9% |
| Nervous System | 52700 | 36.99% |
| Respiratory System | 134 | 0.09% |
| Gastrointestinal System including Liver | 5032 | 3.53% |
| Musculoskeletal System | 843 | 0.59% |
| Immune System | 6012 | 4.22% |
| Urogenital/Reproductive System | 3597 | 2.52% |
| Sensory Organs (skin, eyes and ears) | 193 | 0.14% |
| Endocrine System/Metabolism | 7697 | 5.4% |
| Multisystemic | 7232 | 5.08% |
| Ethology / Animal Behaviour /Animal Biology | 40710 | 28.58% |
| Other basic research | 5377 | 3.77% |
| Total | 142463 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 5061 | 29.53% |
| Human Infectious Disorders | 1207 | 7.04% |
| Human Cardiovascular Disorders | 505 | 2.95% |
| Human Nervous and Mental Disorders | 2261 | 13.19% |
| Human Respiratory Disorders | 10 | 0.06% |
| Human Gastrointestinal Disorders including Liver | 160 | 0.93% |
| Human Musculoskeletal Disorders | 70 | 0.41% |
| Human Immune Disorders | 115 | 0.67% |
| Human Urogenital/Reproductive Disorders | 31 | 0.18% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 178 | 1.04% |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders | 30 | 0.18% |
| Animal Diseases and Disorders | 398 | 2.32% |
| Animal Welfare | 3287 | 19.18% |
| Diagnosis of diseases | 3325 | 19.4% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 502 | 2.93% |
| Total | 17140 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 18221 | 69.66% |
| Other efficacy and tolerance testing | 363 | 1.39% |
| Toxicity and other safety testing including pharmacology | 7261 | 27.76% |
| Routine production | 312 | 1.19% |
| Total | 26157 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 3876 | 21.27% |
| Pyrogenicity testing | 202 | 1.11% |
| Batch potency testing | 13177 | 72.32% |
| Other quality controls | 966 | 5.3% |
| Total | 18221 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 1721 | 23.7% |
| Skin irritation/corrosion | 195 | 2.69% |
| Skin sensitisation | 1571 | 21.64% |
| Eye irritation/corrosion | 50 | 0.69% |
| Repeated dose toxicity | 120 | 1.65% |
| Carcinogenicity |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Target animal safety |  |  |
| Developmental toxicity | 164 | 2.26% |
| Kinetics | 40 | 0.55% |
| Pharmaco-dynamics (incl safety pharmacology) | 38 | 0.52% |
| Ecotoxicity | 3338 | 45.97% |
| Other toxicity/safety testing | 24 | 0.33% |
| Total | 7261 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 371 | 21.56% |
| Other lethal methods |  |  |
| Non lethal methods | 1350 | 78.44% |
| Total | 1721 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days | 120 | 100% |
| > 90 days |  |  |
| Total | 120 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 3123 | 93.56% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity | 215 | 6.44% |
| Total | 3338 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 312 | 100% |
| Total | 312 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 18178 | 69.5% |
| Legislation on medicinal products for veterinary use and their residues | 2651 | 10.13% |
| Medical devices legislation | 310 | 1.19% |
| Industrial chemicals legislation | 265 | 1.01% |
| Plant protection product legislation | 4597 | 17.57% |
| Biocides legislation | 122 | 0.47% |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment | 34 | 0.13% |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 26157 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 25604 | 97.89% |
| Legislation satisfying national requirements only [within EU] | 487 | 1.86% |
| Legislation satisfying Non-EU requirements only | 66 | 0.25% |
| Total | 26157 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 187448 | 99.33% |
| Yes | 1271 | 0.67% |
| Total | 188719 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 7963 | 4.22% |
| Mild [up to and including] | 87965 | 46.61% |
| Moderate | 47593 | 25.22% |
| Severe | 45198 | 23.95% |
| Total | 188719 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 188426 | 99.84% |
| Yes | 293 | 0.16% |
| Total | 188719 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 180608 | 95.7% |
| Genetically altered without a harmful phenotype | 5577 | 2.96% |
| Genetically altered with a harmful phenotype | 2534 | 1.34% |
| Total | 188719 | 100.00% |

## Poland: Narrative 2017

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

The drawing of general conclusions is made difficult by the ongoing transitional period in Poland, during which experiments are being carried out both in accordance with provisions that have already been repealed (up to the end of 2017) and the law currently in force. This is the case because some experiments which are not considered procedures under the new rules continue to take place and be reported. Despite this, the number of animals used decreased markedly in 2017. Thanks to the training provided, a better understanding can be seen of the definition of a procedure and the reporting rules, resulting in the more precise identification of animal numbers. One example is that the number of fish other than zebrafish used in 2017 fell significantly.

A steady and significant decrease was also noted in the number of animals reused.

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

The observed variation in the number of animals used of certain species seems to be a natural consequence of completing one type of experiment and starting another, in connection with seeking research grants linked to an increase in the popularity of a given field of research or, for example, to seeking orders from external parties. One good example is the appearance in 2017 of a group of 17 monkeys from Ceboidea and Cercopitecoidea species used in connection with a single experiment on their behaviour in zoo conditions. It is also likely that single experiments on dogs and horses ended in 2017 for this same reason, and the number of dogs and horses used therefore decreased significantly.

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

In 2017, a decrease is observed in the number of rats used in ‘non-recovery’ experiments. This is probably due to an earlier misunderstanding of the concept by users, and also the exhausting of authorisations issued on the basis of the repealed Act. Animals were also likely to be included in this category in 2015 for the sole purpose of the procurement of organs and tissues, since, according to the previous legislation, the consent of the Local Ethics Committee on Animal Experiments (LEC) was also required in the event that an animal was killed for such purposes.

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

The statutory objectives of the National Ethics Committee on Animal Experiments (NEC) are action for the three Rs and the promotion of alternative research. The NEC supports training courses for persons planning or carrying out experiments whose programmes incorporate this topic. It also communicates the above information to LECs and welfare teams through direct contacts as well as via its website, and organises training for LECs once per year.

When issuing authorisation for carrying out an experiment, LECs are required to take into account the existence of alternative methods and the application of the three Rs. To this end, the model request for authorisation contains a specific field where the user is required to enter the method of implementation of the three Rs in the experiment. The special welfare teams that users are obliged to set up by law monitor the means of implementing the three Rs in individual units. Their activities are monitored by the NEC, which prepares a comprehensive analysis of users’ reporting in this area on an annual basis.

In 2017 the NEC also took the initiative to organise a cooperation network between units and bodies involved in the implementation of alternative methods.

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

In Poland a large number of nutritional experiments are carried out in which the activities performed fall within the definition of a procedure. However, in the reporting table there is no separate category for nutritional tests in the list of objectives, hence these are placed in the ‘other’ group. A similar situation arises in the case of procedures involving the transfer of embryos. There is also one unit which, under routine manufacturing procedures required by law, employs tests other than those on the list to test medicinal products from material of plant origin (API).

In 2017, the animal species included in the ‘other’ category were:

* ‘Other’ species of carnivore (other Carnivora), namely Mustela nivalis and Mustela lutreola. These are used mainly in fundamental research relating to biology and species behaviour. They account for 92.86% of all carnivorous animal species used in research.
* ‘Other’ bird species (other Aves), namely Acrocephalus paludicola, Acrocephalus schoenobaenus, Actitis hypoleucos, Anas platyrhynchos, Anser domesticus, Calidris alba, Calidris alpine, Calidris canutus, Calidris falcinellus, Calidris ferruginea, Calidris minuta, Calidris pugnax, Charadrius dubius, Charadrius hiaticula, Chlidonias hybrida, Chroicocephalus ridibundus, Ciconia ciconia, Columba livia, Coturnix japonica, Cyanistes caeruleus, Cygnus olor, Ficedula hypoleuca, Fringilla coelebs, Fulica atra, Gallinago gallinago, Haliaeetus albicilla, Hirundo rustica, Meleagris gallopavo, Motacilla alba, Motacilla flava, Lanius collurio, Larus canus, Parus major, Passer domesticus, Passer montanus, Phasianus colchicus, Serinus canaria, Sterna hirundo, Taeniopygia guttata, Tetrao urogallus, Tringa erythropus, Tringa glareola, Tringa nebularia, Tringa ochropus, Tringa totanus, Turdus merula and Vanellus vanellus. These are mainly used in fundamental research relating to biology and species behaviour, tests of the immune and reproductive systems, and translational research on animal welfare, animal diseases and disorders and the conservation of the species in nature. They account for 56.44% of all bird species used in research.
* ‘Other’ fish species (other Pisces), namely Acipenser baeri, Acipenser gueldenstadtii, Acipenser ruthenus, Babka gymnotrachelus, Coregonus lavaretus, Cottus gobio, Cyprinus carpio, Eudontomyzon mariae, Gobio gobio, Lampetra planeri, Neogobius fluviatilis, Oncorhynchus mykiss, Perca fluviatilis, Poecilia reticulata, Proterorhinus semilunaris, Rutilus rutilus, Sander lucioperca and Scardinius erythrophthalmus. These are mainly used in fundamental research relating to biology and species behaviour, tests of the immune and reproductive systems, and translational research on animal welfare, animal diseases and disorders, and also in some acute toxicity studies. They account for 84.99% of all fish species used in research.
* ‘Other’ amphibian species (other Amphibia), namely Bufotes viridis in the adult and larval stages, Pelophylax esculentus, Pelophylax lessonae, Pelophylax ridibundus. These are mainly used in fundamental research relating to reproductive and metabolism studies, and translational research on animal diseases and disorders, as well as population genetics and phylogeography. They account for 95.8% of all amphibian species used in research.
* ‘Other’ monkey species, namely 17 monkeys from Ceboidea and Cercopithecoidea species used in connection with a single experiment on their behaviour in zoo conditions.

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

No such cases were found. It appears that more complete information in this regard can be provided through retrospective evaluations carried out by local ethics committees.

## Poland: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 89880 | 57.53% |
| Rats | 28982 | 18.55% |
| Guinea-Pigs | 5235 | 3.35% |
| Hamsters (Syrian) | 150 | 0.1% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 120 | 0.08% |
| Other Rodents | 8108 | 5.19% |
| Rabbits | 820 | 0.52% |
| Cats |  |  |
| Dogs | 10 | 0.01% |
| Ferrets |  |  |
| Other carnivores | 130 | 0.08% |
| Horses, donkeys and cross-breeds | 73 | 0.05% |
| Pigs | 1517 | 0.97% |
| Goats | 24 | 0.02% |
| Sheep | 1301 | 0.83% |
| Cattle | 413 | 0.26% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) | 14 | 0.01% |
| Other species of New World Monkeys (Ceboidea) | 3 | 0% |
| Apes |  |  |
| Other Mammals | 700 | 0.45% |
| Domestic fowl | 5067 | 3.24% |
| Other birds | 6566 | 4.2% |
| Reptiles | 314 | 0.2% |
| Rana | 20 | 0.01% |
| Xenopus |  |  |
| Other Amphibians | 456 | 0.29% |
| Zebra fish | 950 | 0.61% |
| Other Fish | 5381 | 3.44% |
| Cephalopods |  |  |
| Total | 156234 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 135878 | 87.43% |
| Animals born in the EU but not at a registered breeder | 18496 | 11.9% |
| Animals born in rest of Europe | 361 | 0.23% |
| Animals born in rest of world | 674 | 0.43% |
| Total | 155409 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 17 | 100% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 17 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 17 | 100% |
| Self-sustaining colony |  |  |
| Total | 17 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 113639 | 72.74% |
| Translational and applied research | 16135 | 10.33% |
| Regulatory use and Routine production | 24762 | 15.85% |
| 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 | 0.72% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 501 | 0.32% |
| Total | 156234 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 8173 | 7.19% |
| Cardiovascular Blood and Lymphatic System | 6727 | 5.92% |
| Nervous System | 52548 | 46.24% |
| Respiratory System | 784 | 0.69% |
| Gastrointestinal System including Liver | 3070 | 2.7% |
| Musculoskeletal System | 673 | 0.59% |
| Immune System | 7755 | 6.82% |
| Urogenital/Reproductive System | 2929 | 2.58% |
| Sensory Organs (skin, eyes and ears) | 225 | 0.2% |
| Endocrine System/Metabolism | 5992 | 5.27% |
| Multisystemic | 5956 | 5.24% |
| Ethology / Animal Behaviour /Animal Biology | 10531 | 9.27% |
| Other basic research | 8276 | 7.28% |
| Total | 113639 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 3081 | 19.1% |
| Human Infectious Disorders | 366 | 2.27% |
| Human Cardiovascular Disorders | 815 | 5.05% |
| Human Nervous and Mental Disorders | 1176 | 7.29% |
| Human Respiratory Disorders | 943 | 5.84% |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 64 | 0.4% |
| Human Immune Disorders | 120 | 0.74% |
| Human Urogenital/Reproductive Disorders | 44 | 0.27% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 20 | 0.12% |
| Human Endocrine/Metabolism Disorders | 316 | 1.96% |
| Other Human Disorders | 35 | 0.22% |
| Animal Diseases and Disorders | 678 | 4.2% |
| Animal Welfare | 3852 | 23.87% |
| Diagnosis of diseases | 3088 | 19.14% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 1537 | 9.53% |
| Total | 16135 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Carcinogenicity |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Safety testing in food and feed area |  |  |
| Target animal safety |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 180 | 17.14% |
| Other lethal methods |  |  |
| Non lethal methods | 870 | 82.86% |
| Total | 1050 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 387 | 47.96% |
| 29 - 90 days | 420 | 52.04% |
| > 90 days |  |  |
| Total | 807 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 2364 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 2364 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 290 | 100% |
| Total | 290 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 16523 | 66.73% |
| Legislation on medicinal products for veterinary use and their residues | 2251 | 9.09% |
| Medical devices legislation | 916 | 3.7% |
| Industrial chemicals legislation | 2652 | 10.71% |
| Plant protection product legislation | 2276 | 9.19% |
| Biocides legislation | 24 | 0.1% |
| Food legislation including food contact material | 120 | 0.48% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 24762 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 24221 | 97.82% |
| Legislation satisfying national requirements only [within EU] | 514 | 2.08% |
| Legislation satisfying Non-EU requirements only | 27 | 0.11% |
| Total | 24762 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 155426 | 99.48% |
| Yes | 808 | 0.52% |
| Total | 156234 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 4791 | 3.07% |
| Mild [up to and including] | 50260 | 32.17% |
| Moderate | 50013 | 32.01% |
| Severe | 51170 | 32.75% |
| Total | 156234 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 155876 | 99.77% |
| Yes | 358 | 0.23% |
| Total | 156234 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 146889 | 94.02% |
| Genetically altered without a harmful phenotype | 5905 | 3.78% |
| Genetically altered with a harmful phenotype | 3440 | 2.2% |
| Total | 156234 | 100.00% |

# Portugal

## Portugal: Narrative 2015 – no narrative submitted

No narrative submitted by the Member State

## Portugal: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 13175 | 63.88% |
| Rats | 2399 | 11.63% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits |  |  |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats | 46 | 0.22% |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 250 | 1.21% |
| Other Fish | 4752 | 23.04% |
| Cephalopods | 1 | 0% |
| Total | 20623 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 16287 | 85.59% |
| Animals born in the EU but not at a registered breeder | 1896 | 9.96% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 847 | 4.45% |
| Total | 19030 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 11853 | 57.47% |
| Translational and applied research | 7288 | 35.34% |
| Regulatory use and Routine production | 1382 | 6.7% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 3 | 0.01% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 97 | 0.47% |
| Total | 20623 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 266 | 2.24% |
| Cardiovascular Blood and Lymphatic System | 576 | 4.86% |
| Nervous System | 1859 | 15.68% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 230 | 1.94% |
| Musculoskeletal System | 330 | 2.78% |
| Immune System | 5965 | 50.32% |
| Urogenital/Reproductive System | 19 | 0.16% |
| Sensory Organs (skin, eyes and ears) | 100 | 0.84% |
| Endocrine System/Metabolism |  |  |
| Multisystemic | 8 | 0.07% |
| Ethology / Animal Behaviour /Animal Biology | 347 | 2.93% |
| Other basic research | 2153 | 18.16% |
| Total | 11853 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 10 | 0.14% |
| Human Infectious Disorders | 1019 | 13.98% |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders | 2002 | 27.47% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 88 | 1.21% |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 350 | 4.8% |
| Human Endocrine/Metabolism Disorders | 89 | 1.22% |
| Other Human Disorders | 230 | 3.16% |
| Animal Diseases and Disorders |  |  |
| Animal Welfare | 3500 | 48.02% |
| Diagnosis of diseases |  |  |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 7288 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 1382 | 100% |
| Total | 1382 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 200 | 14.47% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Ecotoxicity | 750 | 54.27% |
| Safety testing in food and feed area | 432 | 31.26% |
| Total | 1382 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 200 | 100% |
| Total | 200 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity | 750 | 100% |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 750 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation | 750 | 54.27% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 632 | 45.73% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 1382 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements |  |  |
| Legislation satisfying national requirements only [within EU] | 1382 | 100% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 1382 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 19030 | 92.28% |
| Yes | 1593 | 7.72% |
| Total | 20623 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 213 | 1.03% |
| Mild [up to and including] | 11207 | 54.34% |
| Moderate | 6832 | 33.13% |
| Severe | 2371 | 11.5% |
| Total | 20623 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 20573 | 99.76% |
| Yes | 50 | 0.24% |
| Total | 20623 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 15339 | 74.38% |
| Genetically altered without a harmful phenotype | 2116 | 10.26% |
| Genetically altered with a harmful phenotype | 3168 | 15.36% |
| Total | 20623 | 100.00% |

## Portugal: Narrative 2016 - no narrative submitted

No narrative submitted by the Member State

## Portugal: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 28892 | 91.11% |
| Rats | 2251 | 7.1% |
| Guinea-Pigs | 4 | 0.01% |
| Hamsters (Syrian) | 6 | 0.02% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 39 | 0.12% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep |  |  |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl |  |  |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 451 | 1.42% |
| Other Fish | 69 | 0.22% |
| Cephalopods |  |  |
| Total | 31712 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 30784 | 97.64% |
| Animals born in the EU but not at a registered breeder | 623 | 1.98% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 120 | 0.38% |
| Total | 31527 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 14894 | 46.97% |
| Translational and applied research | 9548 | 30.11% |
| Regulatory use and Routine production | 185 | 0.58% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species | 37 | 0.12% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 102 | 0.32% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 6946 | 21.9% |
| Total | 31712 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 680 | 4.57% |
| Cardiovascular Blood and Lymphatic System | 159 | 1.07% |
| Nervous System | 2982 | 20.02% |
| Respiratory System | 95 | 0.64% |
| Gastrointestinal System including Liver | 307 | 2.06% |
| Musculoskeletal System | 240 | 1.61% |
| Immune System | 7543 | 50.64% |
| Urogenital/Reproductive System | 90 | 0.6% |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism | 562 | 3.77% |
| Multisystemic | 92 | 0.62% |
| Ethology / Animal Behaviour /Animal Biology | 1074 | 7.21% |
| Other basic research | 1070 | 7.18% |
| Total | 14894 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 505 | 5.29% |
| Human Infectious Disorders | 5782 | 60.56% |
| Human Cardiovascular Disorders | 300 | 3.14% |
| Human Nervous and Mental Disorders | 477 | 5% |
| Human Respiratory Disorders | 82 | 0.86% |
| Human Gastrointestinal Disorders including Liver | 161 | 1.69% |
| Human Musculoskeletal Disorders | 72 | 0.75% |
| Human Immune Disorders | 784 | 8.21% |
| Human Urogenital/Reproductive Disorders | 10 | 0.1% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 221 | 2.31% |
| Human Endocrine/Metabolism Disorders | 151 | 1.58% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare | 99 | 1.04% |
| Diagnosis of diseases | 904 | 9.47% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 9548 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 185 | 100% |
| Total | 185 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Safety testing in food and feed area | 185 | 100% |
| Total | 185 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 185 | 100% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 185 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 185 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 185 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 31527 | 99.42% |
| Yes | 185 | 0.58% |
| Total | 31712 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 369 | 1.16% |
| Mild [up to and including] | 14043 | 44.28% |
| Moderate | 9487 | 29.92% |
| Severe | 7813 | 24.64% |
| Total | 31712 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 31438 | 99.14% |
| Yes | 274 | 0.86% |
| Total | 31712 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 19723 | 62.19% |
| Genetically altered without a harmful phenotype | 9795 | 30.89% |
| Genetically altered with a harmful phenotype | 2194 | 6.92% |
| Total | 31712 | 100.00% |

## Portugal: Narrative 2017 - no narrative submitted

No narrative submitted by the Member State

## Portugal: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 46107 | 88.04% |
| Rats | 3135 | 5.99% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 140 | 0.27% |
| Rabbits | 36 | 0.07% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 155 | 0.3% |
| Goats |  |  |
| Sheep | 30 | 0.06% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 32 | 0.06% |
| Domestic fowl | 120 | 0.23% |
| Other birds | 56 | 0.11% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish | 1280 | 2.44% |
| Other Fish | 829 | 1.58% |
| Cephalopods | 450 | 0.86% |
| Total | 52370 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 49301 | 96.09% |
| Animals born in the EU but not at a registered breeder | 1678 | 3.27% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 329 | 0.64% |
| Total | 51308 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 36663 | 70.01% |
| Translational and applied research | 5202 | 9.93% |
| Regulatory use and Routine production | 298 | 0.57% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 392 | 0.75% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 9815 | 18.74% |
| Total | 52370 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 3230 | 8.81% |
| Cardiovascular Blood and Lymphatic System | 1205 | 3.29% |
| Nervous System | 4952 | 13.51% |
| Respiratory System | 83 | 0.23% |
| Gastrointestinal System including Liver | 683 | 1.86% |
| Musculoskeletal System | 173 | 0.47% |
| Immune System | 20968 | 57.19% |
| Urogenital/Reproductive System | 36 | 0.1% |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism | 1437 | 3.92% |
| Multisystemic | 153 | 0.42% |
| Ethology / Animal Behaviour /Animal Biology | 1277 | 3.48% |
| Other basic research | 2466 | 6.73% |
| Total | 36663 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 162 | 3.11% |
| Human Infectious Disorders | 403 | 7.75% |
| Human Cardiovascular Disorders | 68 | 1.31% |
| Human Nervous and Mental Disorders | 2058 | 39.56% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver | 102 | 1.96% |
| Human Musculoskeletal Disorders | 127 | 2.44% |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 233 | 4.48% |
| Human Endocrine/Metabolism Disorders | 36 | 0.69% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 3 | 0.06% |
| Animal Welfare | 604 | 11.61% |
| Diagnosis of diseases | 914 | 17.57% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 492 | 9.46% |
| Total | 5202 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Other efficacy and tolerance testing |  |  |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 298 | 100% |
| Total | 298 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Ecotoxicity | 126 | 42.28% |
| Safety testing in food and feed area | 172 | 57.72% |
| Total | 298 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity | 126 | 100% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 126 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use |  |  |
| Legislation on medicinal products for veterinary use and their residues | 126 | 42.28% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 172 | 57.72% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 298 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 298 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 298 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 51308 | 97.97% |
| Yes | 1062 | 2.03% |
| Total | 52370 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 2017 | 3.85% |
| Mild [up to and including] | 27397 | 52.31% |
| Moderate | 12540 | 23.95% |
| Severe | 10416 | 19.89% |
| Total | 52370 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 51836 | 98.98% |
| Yes | 534 | 1.02% |
| Total | 52370 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 30557 | 58.35% |
| Genetically altered without a harmful phenotype | 20466 | 39.08% |
| Genetically altered with a harmful phenotype | 1347 | 2.57% |
| Total | 52370 | 100.00% |

# Romania

## Romania: Narrative 2015

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

Compared to the last report, the one from 2014, there was a decrease in the number of total animals used for scientific purposes, with 0,53%, from 19735 in 2014 to 19632 in 2015.

To the purpose of use has been a decrease in the use of animals for higher education or training and an increased use of animals in research.

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

The difference between 2014 and 2015 is minim, given the fact that is less de 1%.

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

Some changes were observed in severity trend. 26% severe in 2015 vs 0.05% in 2014. 0.59% non- recovery in 2015 vs 17.31% in 2014. 39.27% mild in 2015 vs 62.344 in 2014. 34.14% moderate vs 20.30% in 2014.

The reason is that now, in this year, our colleague learned to done a severity assessment.

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

The competent authorities and scientific organizations in the field through briefings, workshops and trainings have imposed a positive trend of the 3Rs, and the result is decrease in the number of animals used.

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

The animals use under “other" categories are 0.

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

Such a kind of analysis was not made yet.

## Romania: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 10876 | 55.4% |
| Rats | 6322 | 32.2% |
| Guinea-Pigs | 1108 | 5.64% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 380 | 1.94% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 2 | 0.01% |
| Pigs | 10 | 0.05% |
| Goats |  |  |
| Sheep | 167 | 0.85% |
| Cattle | 2 | 0.01% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 565 | 2.88% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana | 200 | 1.02% |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 19632 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 18162 | 94.22% |
| Animals born in the EU but not at a registered breeder | 1115 | 5.78% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 19277 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 7752 | 39.49% |
| Translational and applied research | 3240 | 16.5% |
| Regulatory use and Routine production | 7498 | 38.19% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1142 | 5.82% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 19632 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 3499 | 45.14% |
| Cardiovascular Blood and Lymphatic System | 800 | 10.32% |
| Nervous System | 289 | 3.73% |
| Respiratory System | 200 | 2.58% |
| Gastrointestinal System including Liver | 20 | 0.26% |
| Musculoskeletal System | 188 | 2.43% |
| Immune System | 162 | 2.09% |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic | 84 | 1.08% |
| Ethology / Animal Behaviour /Animal Biology | 50 | 0.64% |
| Other basic research | 2460 | 31.73% |
| Total | 7752 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 32 | 0.99% |
| Human Infectious Disorders | 20 | 0.62% |
| Human Cardiovascular Disorders | 110 | 3.4% |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 85 | 2.62% |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 69 | 2.13% |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders | 30 | 0.93% |
| Animal Diseases and Disorders | 102 | 3.15% |
| Animal Welfare | 66 | 2.04% |
| Diagnosis of diseases | 2726 | 84.14% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 3240 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 6184 | 82.48% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 927 | 12.36% |
| Routine production | 387 | 5.16% |
| Total | 7498 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 5456 | 88.23% |
| Pyrogenicity testing | 58 | 0.94% |
| Batch potency testing | 670 | 10.83% |
| Other quality controls |  |  |
| Total | 6184 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 187 | 20.17% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 740 | 79.83% |
| Total | 927 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 187 | 100% |
| Total | 187 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 740 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 740 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 321 | 82.95% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 66 | 17.05% |
| Total | 387 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 6404 | 85.41% |
| Legislation on medicinal products for veterinary use and their residues | 731 | 9.75% |
| Medical devices legislation | 363 | 4.84% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 7498 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 7438 | 99.2% |
| Legislation satisfying national requirements only [within EU] | 2 | 0.03% |
| Legislation satisfying Non-EU requirements only | 58 | 0.77% |
| Total | 7498 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 19277 | 98.19% |
| Yes | 355 | 1.81% |
| Total | 19632 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 88 | 0.45% |
| Mild [up to and including] | 9958 | 50.72% |
| Moderate | 5550 | 28.27% |
| Severe | 4036 | 20.56% |
| Total | 19632 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 19632 | 100% |
| Yes |  |  |
| Total | 19632 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 19032 | 96.94% |
| Genetically altered without a harmful phenotype | 600 | 3.06% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 19632 | 100.00% |

## Romania: Narrative 2016

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

Compared to the last report, the one from 2015, there was a decrease in the number of total animals used for scientific purposes (around 20.000 in 2015 and around 13.000 in 2016).

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

To the purpose of use has been a decrease in the use of animals for higher education or training and diagnosis of the disease and an increased use of animals in research.

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

Some changes were observed in severity trend. The main category of severity was moderate followed by mild and severe. It have been reduced non - recovery category.

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

The competent authorities and scientific organizations in the field through briefings, workshops and trainings have imposed a positive trend of the 3Rs, and the result is decrease in the number of animals used.

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

The animals use under “other" categories are not in a significant proportion.

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

Such a kind of analysis was not made yet.

## Romania: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 9079 | 64.08% |
| Rats | 2685 | 18.95% |
| Guinea-Pigs | 1076 | 7.59% |
| Hamsters (Syrian) | 146 | 1.03% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 222 | 1.57% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 2 | 0.01% |
| Pigs |  |  |
| Goats |  |  |
| Sheep | 211 | 1.49% |
| Cattle | 2 | 0.01% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 555 | 3.92% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana | 190 | 1.34% |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 14168 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 12592 | 90.95% |
| Animals born in the EU but not at a registered breeder | 1253 | 9.05% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 13845 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 4011 | 28.31% |
| Translational and applied research | 3183 | 22.47% |
| Regulatory use and Routine production | 5402 | 38.13% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1572 | 11.1% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 14168 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 935 | 23.31% |
| Cardiovascular Blood and Lymphatic System | 485 | 12.09% |
| Nervous System | 190 | 4.74% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 261 | 6.51% |
| Musculoskeletal System | 92 | 2.29% |
| Immune System | 334 | 8.33% |
| Urogenital/Reproductive System | 170 | 4.24% |
| Sensory Organs (skin, eyes and ears) | 120 | 2.99% |
| Endocrine System/Metabolism | 70 | 1.75% |
| Multisystemic | 884 | 22.04% |
| Ethology / Animal Behaviour /Animal Biology | 200 | 4.99% |
| Other basic research | 270 | 6.73% |
| Total | 4011 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 15 | 0.47% |
| Human Infectious Disorders | 4 | 0.13% |
| Human Cardiovascular Disorders | 86 | 2.7% |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 277 | 8.7% |
| Animal Welfare |  |  |
| Diagnosis of diseases | 2742 | 86.15% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 59 | 1.85% |
| Total | 3183 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 4913 | 90.95% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 171 | 3.17% |
| Routine production | 318 | 5.89% |
| Total | 5402 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 4260 | 86.71% |
| Pyrogenicity testing | 27 | 0.55% |
| Batch potency testing | 584 | 11.89% |
| Other quality controls | 42 | 0.85% |
| Total | 4913 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 74 | 43.27% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Target animal safety |  |  |
| Skin sensitisation | 97 | 56.73% |
| Total | 171 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 74 | 100% |
| Total | 74 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 303 | 95.28% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 15 | 4.72% |
| Total | 318 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 3992 | 73.9% |
| Legislation on medicinal products for veterinary use and their residues | 1096 | 20.29% |
| Medical devices legislation | 314 | 5.81% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 5402 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 5364 | 99.3% |
| Legislation satisfying national requirements only [within EU] | 11 | 0.2% |
| Legislation satisfying Non-EU requirements only | 27 | 0.5% |
| Total | 5402 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 13845 | 97.72% |
| Yes | 323 | 2.28% |
| Total | 14168 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 169 | 1.19% |
| Mild [up to and including] | 7693 | 54.3% |
| Moderate | 5498 | 38.81% |
| Severe | 808 | 5.7% |
| Total | 14168 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 14168 | 100% |
| Yes |  |  |
| Total | 14168 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 13885 | 98% |
| Genetically altered without a harmful phenotype | 283 | 2% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 14168 | 100.00% |

## Romania: Narrative 2017

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

Since the previous reporting year, there was a slight increase in the number of total animals used for scientific purposes, from 14168 in 2016 to 14642 in 2017.

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

There was a significant decrease in the diagnosis of diseases within the translational and applied research due to the reduced number of samples received.

There was a decrease in regulatory use and routine production, with a significant drop in blood based products and batch safety testing and an increase in batch potency testing. The latter occurred due to an increase in the vaccines production

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

There were some variations in terms of severity, namely a decrease in mild and an increase in non-recovery, according to those who evaluated the projects.

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

There was a joint effort from the competent authority and the scientific organizations to promote the principle of replacement, reduction and refinement through briefings and workshops.

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

No significant proportion of animal use was reported under “other" categories.

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

There were not cases where “severe” classification was exceeded.

## Romania: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 7975 | 54.47% |
| Rats | 4367 | 29.83% |
| Guinea-Pigs | 792 | 5.41% |
| Hamsters (Syrian) | 150 | 1.02% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 504 | 3.44% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 2 | 0.01% |
| Pigs | 58 | 0.4% |
| Goats |  |  |
| Sheep | 209 | 1.43% |
| Cattle | 2 | 0.01% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 330 | 2.25% |
| Other birds | 23 | 0.16% |
| Reptiles |  |  |
| Rana | 230 | 1.57% |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 14642 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| 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% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 14278 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 5381 | 36.75% |
| Translational and applied research | 5500 | 37.56% |
| Regulatory use and Routine production | 2522 | 17.22% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1239 | 8.46% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 14642 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 1525 | 28.34% |
| Cardiovascular Blood and Lymphatic System | 539 | 10.02% |
| Nervous System | 634 | 11.78% |
| Respiratory System |  |  |
| 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% |
| Other basic research |  |  |
| Total | 5381 | 100.00% |

### Translational and applied research

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

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 1789 | 70.94% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 106 | 4.2% |
| Routine production | 627 | 24.86% |
| Total | 2522 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 20 | 18.87% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Ecotoxicity | 86 | 81.13% |
| Total | 106 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 20 | 100% |
| Total | 20 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity | 86 | 100% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 86 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 587 | 93.62% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 40 | 6.38% |
| Total | 627 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 1078 | 42.74% |
| Legislation on medicinal products for veterinary use and their residues | 1253 | 49.68% |
| Medical devices legislation | 170 | 6.74% |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 20 | 0.79% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 1 | 0.04% |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 2522 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 2138 | 84.77% |
| Legislation satisfying national requirements only [within EU] | 2 | 0.08% |
| Legislation satisfying Non-EU requirements only | 382 | 15.15% |
| Total | 2522 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 14278 | 97.51% |
| Yes | 364 | 2.49% |
| Total | 14642 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| 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% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 14642 | 100% |
| Yes |  |  |
| Total | 14642 | 100.00% |

### Uses by genetic status

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

# Slovakia

## Slovakia: Narrative 2015

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

New information on keeping GM (genetically modified) animal lines appeared in the Report from year 2015. In SK the new GM lines were not established, just were kept on the basis of approved Project.

In comparison to the previous year, 3213 less animals were used in the projects. It was caused also by the fact, that more of the approved establishments did not perform any projects in 2015. Some of the establishments informed in advance about the closure of their establishment, because they were not able to assure the compliance with the requirements for placing and treatment of the animals, appointed by the Directive.

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

Red numbers appeared in the column “other birds” of the Report, in particular in Zebra finch (Taeniopygia guttata) species, with the information on consumption of used animals of 13,95 % , which compared to the previous year, is more. It concerns one approved project for one applicant, approved for performance from15.05.2014 to 31.12.2017. Each year, the applicant consumed 36 birds on the average. It is allowed to use 80 male and 15 female animals within this approved project. By the time of duration of the project, 72 animals were already used. In comparison to the previous year, we did not record significant increase in use of the animals of this category in the project. The same number of animals were used in 2015 as in previous year 2014.

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

During year 2015, any significant changes in evaluation of cruelty did not appear in the projects, comparing to the year 2014.

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

Observance of 3R principles is established in our legislation, it is required to observe 3R principles in performance of the projects and breeding and treating of the animals. Great attention is given to 3R principles in trainings of the assigned persons, stated in Article 23 of the Directive.

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

In SK any other more significant animal categories are used, just those already stated in the Report.

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

In SK, there is an Act (No.: 71/67 Coll. on Administrative Order), establishing that the issued decisions are obligatory for the applicant. Any kind of arbitrary change against the project is illegal. This defect, according to the its importance, can be considered as an administrative offence and a penalty can be imposed for it. Each project is classified according to the level of severity, due to the Annex VIII of the Directive. The level of severity of the procedures is stated in the Decision for authorisation of the projects. In SK any situation of arbitrary change of the level of severity towards it increase, cannot appear. It is not possible to use in the projects a different number of animals as those approved, without permission. Within annual reports, CA would see the changes of the levels of severity and the numbers of used animals on the contrary to the Decisions for authorisation of the projects, issued by CA. There is also feed-back in performance of the controls in the approved establishments.

## Slovakia: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 6046 | 44.66% |
| Rats | 5841 | 43.15% |
| Guinea-Pigs | 1026 | 7.58% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 33 | 0.24% |
| Other Rodents |  |  |
| Rabbits | 228 | 1.68% |
| Cats | 29 | 0.21% |
| Dogs | 34 | 0.25% |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 16 | 0.12% |
| Goats |  |  |
| Sheep | 26 | 0.19% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 222 | 1.64% |
| Other birds | 36 | 0.27% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 13537 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 13537 | 100% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 13537 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 9870 | 72.91% |
| Translational and applied research | 788 | 5.82% |
| Regulatory use and Routine production | 2048 | 15.13% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 8 | 0.06% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 823 | 6.08% |
| Total | 13537 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 796 | 8.06% |
| Cardiovascular Blood and Lymphatic System | 1371 | 13.89% |
| Nervous System | 2192 | 22.21% |
| Respiratory System | 992 | 10.05% |
| Gastrointestinal System including Liver | 194 | 1.97% |
| Musculoskeletal System | 106 | 1.07% |
| Immune System | 421 | 4.27% |
| Urogenital/Reproductive System | 2596 | 26.3% |
| Sensory Organs (skin, eyes and ears) | 40 | 0.41% |
| Endocrine System/Metabolism | 496 | 5.03% |
| Multisystemic | 138 | 1.4% |
| Ethology / Animal Behaviour /Animal Biology | 11 | 0.11% |
| Other basic research | 517 | 5.24% |
| Total | 9870 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 134 | 17.01% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders | 79 | 10.03% |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders | 314 | 39.85% |
| Human Urogenital/Reproductive Disorders | 80 | 10.15% |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders | 75 | 9.52% |
| Animal Diseases and Disorders | 62 | 7.87% |
| Animal Welfare |  |  |
| Diagnosis of diseases | 44 | 5.58% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 788 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 1462 | 71.39% |
| Other efficacy and tolerance testing | 6 | 0.29% |
| Toxicity and other safety testing including pharmacology | 580 | 28.32% |
| Routine production |  |  |
| Total | 2048 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 1262 | 86.32% |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 200 | 13.68% |
| Total | 1462 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 253 | 43.62% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Target animal safety |  |  |
| Skin sensitisation | 35 | 6.03% |
| Repeated dose toxicity | 292 | 50.34% |
| Total | 580 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 253 | 100% |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total | 253 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days | 90 | 30.82% |
| > 90 days | 202 | 69.18% |
| Total | 292 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 1385 | 67.63% |
| Legislation on medicinal products for veterinary use and their residues | 126 | 6.15% |
| Medical devices legislation | 90 | 4.39% |
| Industrial chemicals legislation | 245 | 11.96% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 202 | 9.86% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 2048 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 2048 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 2048 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 13537 | 100% |
| Yes |  |  |
| Total | 13537 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 1402 | 10.36% |
| Mild [up to and including] | 8226 | 60.77% |
| Moderate | 3639 | 26.88% |
| Severe | 270 | 1.99% |
| Total | 13537 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 13537 | 100% |
| Yes |  |  |
| Total | 13537 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 12679 | 93.66% |
| Genetically altered without a harmful phenotype | 99 | 0.73% |
| Genetically altered with a harmful phenotype | 759 | 5.61% |
| Total | 13537 | 100.00% |

## Slovakia: Narrative 2016

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

In 2016, in SK 5% less animals were used in the projects than in 2015. From the total number of used animals the most were used rats (46, 6%). There were 40, 9% of mice, 7,4% of guinea-pigs, 2,8% of rabbits, 2% of poultry used. As many as 96% of rodentials were used in the scientific programs. The rest was poultry. On 31 December 2016, the transition period for implementation of the requirements established in Annex III of the Directive 2010/63/EU finished.

Since 2013, in SK re-accreditation of all approved establishments of the users, breeders and suppliers, according to new legislative requirements, was carried out. In 2016, 4 (four) establishments of the users asked the Competent Authority for their withdrawal and discard from the list of approved establishments of the users, for the reason of technical and economical demandingness. 5 (five) users asked for withdrawal of the approval of their establishment for the reason of change of the legal person and the change of address in order to merge into one legal subject. In SK, general reconstruction of several establishments for placement of animals used in the procedures or kept for the reason of their use in the procedures, was carried out. Therefore, the total number of used procedures and subsequently the number of used animals has decreased. In comparison to 2015, the number of approved establishments has changed. In 2015, 54 establishments overall were approved and in 2016, only 40 establishments were approved. Therefore, only 79 projects were approved in 2016 in comparison to 2015, when SVFA SR as the competent authority has issued 102 decisions on the approval of the projects. The most common use of the animals was the basic research (71,3%), subsequently the use in regulated projects with common production (23,4%), then (3,1%) was used in keeping of GMO breeding colonies, and (2,2%) in translation/applied research. In frame of the basic research, mainly nervous system (30%), reproductive system (16%) and immunity system (14%) were declared as the common research areas. 99,67% of used animals were kept/breeded within EU. None of the animals were reused again. 93% of the used animals were without GM and 7% of all used animals were GM.

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

In comparison to 2015, the changes in % are as follows: the number of used mice has decreased by 13% and quinea-pigs by 7%. Increase of the number of used rats has been proved by 2% and rabbits by 59%. In 2016 comparing to the last year, domestic dogs have not been used in any of the procedures. In 2015, 34 dogs were used. The number of used cats decreased from 29 to 11 cats only. In comparison to the last year, the use of other mammals (cattle, pigs, sheep) decreased by 80%. According to withdrawal of the decisions for approval of some of the users establishments and with respect to reduction or stopping of the procedures of some of the users establishments, a significant decrease of the animals used in the procedures namely in mice and quinea-pigs occurred. Decreased number of used mice and quinea-pigs is related to the research procedures of some establishments, which ceased or suspended from their activities by the reason of reconstruction in 2016. The cause is also that minimum 5 users have merged into one legal subject and they had to abolish their establishments. Reconstructions of the establishments had been performed in the establishments using dogs and cats, therefore their number has been reduced or decreased to minimum.

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

In 2016, 52% of projects were classified as “non-recovery” or “,mild”, 46% of the total number were projects classified as ”moderate”, (in 2015, the “moderate” projects were represented only by 27% of all approved establishments), and projects classified as “severe” were represented by 1,2% of the total number of the approved projects. The number of severe projects decreased from 2% in 2015. The reason of increased number of the projects classified as “moderate” can be that the applicants for the approval of projects, performing projects classified as “severe” last year, have refined their procedures, therefore their projects automatically came into category “moderate”.

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

The obligation to comply with 3R principles is established by the legislation. This topics is presented in details at trainings of staff carrying functions referred to in Article 23 of the Directive. During controls of the establishments of the users, breeders and suppliers carried out in a frequency established by the law, a great attention is taken to observance of the 3R principles during performance of the projects and in animal placement and animal care. There is a great space in SK for the performance of “in-vitro” projects, using alternative methods and providing information of 3R principles, also declared in up-dating of the activities in the table due to the Article 47 of the Directive, published on web site of the Competent Authority SVFA SR.

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

In the category „other basic research” a significant increase of the used animals has occurred. The number of 517 animals from 2015 increased to 1875 animals in 2016, which represents almost 20% more animals used in this area. It was found out after the additional control, that some users have incorrectly assigned the objective of the project to the concerned performed type of the project. No significant increase of the number of used animals was recorded in other areas.

In category “other birds” increased number of used animals by 12,45% in comparison to the last year was indicated. 32 pcs of Zebra finch was used in the approved project in 2016. This is not a significant increase whereas the project is approved for the period of 5 (five) years and annualy approximately 30-40 birds are used

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

In the process of authorisation of the project of the user, breeder or supplier in SK, an Authorization Decision is issued. In the Authorization Decision all necessary detailed information, including classification of severity, authorized exemptions within the frame of performance of the project or breeding or animal supplies are specified. According to the seriousness of the infringement it is possible to resolve the infringement of any type of the decision either by issuing veterinary measures in the administrative procedure, or by issuing veterinary measures on site. A penalty on site or financial penalty through administrative procedure can also be imposed. If shortcomings are not eliminated up to the stated deadline, it is possible to increase the penalty, or abolish the decision on authorization of the project or establishment.

Such a case has not happened in SK yet. All establishments are regularly controlled due to the specified frequency. In 2016, altogether 38 controls of the establishments were carried out. Included 2 controls which were follow-up – additional for the purpose of control of elimination of found shortcomings. 29 controls were carried out for the purpose of authorisation of the establishments of the users, breeders or suppliers and 7 controls for the reason of control of the compliance of requirements in the approved establishments. During retrospective assessment, an Advisory Body and the Competent Authority reviewed that each of the projects intended for the reverse control was resent and evaluated. In each “severe” project, several available possibilities for its refinement were used in order to assure that the animals would not feel cruelty/severity. In several projects submitted to the reverse assessment was found out that after their severity was classified as “moderate”. If a pain classified as “severe” occurred, all available possible measures were carried out for its refinement

## Slovakia: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 5263 | 41.01% |
| Rats | 5973 | 46.55% |
| Guinea-Pigs | 955 | 7.44% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 14 | 0.11% |
| Other Rodents |  |  |
| Rabbits | 358 | 2.79% |
| Cats | 11 | 0.09% |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep | 1 | 0.01% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 225 | 1.75% |
| Other birds | 32 | 0.25% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 12832 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 12789 | 99.66% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 43 | 0.34% |
| Total | 12832 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 8366 | 65.2% |
| Translational and applied research | 1085 | 8.46% |
| Regulatory use and Routine production | 2987 | 23.28% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills |  |  |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 394 | 3.07% |
| Total | 12832 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 146 | 1.75% |
| Cardiovascular Blood and Lymphatic System | 808 | 9.66% |
| Nervous System | 2746 | 32.82% |
| Respiratory System | 478 | 5.71% |
| Gastrointestinal System including Liver | 58 | 0.69% |
| Musculoskeletal System | 52 | 0.62% |
| Immune System | 1350 | 16.14% |
| Urogenital/Reproductive System | 1454 | 17.38% |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism | 230 | 2.75% |
| Multisystemic | 23 | 0.27% |
| Ethology / Animal Behaviour /Animal Biology | 40 | 0.48% |
| Other basic research | 981 | 11.73% |
| Total | 8366 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders | 40 | 3.69% |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver | 72 | 6.64% |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders | 103 | 9.49% |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) | 57 | 5.25% |
| Human Endocrine/Metabolism Disorders |  |  |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases | 7 | 0.65% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 806 | 74.29% |
| Total | 1085 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 1533 | 51.32% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 1412 | 47.27% |
| Routine production | 42 | 1.41% |
| Total | 2987 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 1298 | 84.67% |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 235 | 15.33% |
| Total | 1533 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 388 | 27.48% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Target animal safety |  |  |
| Skin sensitisation | 632 | 44.76% |
| Repeated dose toxicity | 392 | 27.76% |
| Total | 1412 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 388 | 100% |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total | 388 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 392 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 392 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 42 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 42 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 1340 | 44.86% |
| Legislation on medicinal products for veterinary use and their residues | 235 | 7.87% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation | 1002 | 33.55% |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material | 410 | 13.73% |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 2987 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 2987 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 2987 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 12832 | 100% |
| Yes |  |  |
| Total | 12832 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 1149 | 8.95% |
| Mild [up to and including] | 5588 | 43.55% |
| Moderate | 5947 | 46.35% |
| Severe | 148 | 1.15% |
| Total | 12832 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 12832 | 100% |
| Yes |  |  |
| Total | 12832 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 11920 | 92.89% |
| Genetically altered without a harmful phenotype | 43 | 0.34% |
| Genetically altered with a harmful phenotype | 869 | 6.77% |
| Total | 12832 | 100.00% |

## Slovakia: Narrative 2017

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

In 2017, the number of animals used in projects increased by 17,66% for the different reasons. The first reason was authorisation of two big establishments of users breeding animals for their own need, offering their establishments for performing projects also for the other users. Thereby, the space for performance of the projects in the Slovak Republic has amplified. The second reason was that by the end of year 2016, all existing establishments of users, breeders, suppliers have finished reconstructions in their establishments and therefore in 2017 they could involve in performing of the projects. In 2016, all existing establishments were newly authorised in compliance with Annex 3 of the Directive 2010/63/EU. Since 2017, scientific activities have fully developed, all authorised establishments have started to perform them. Project Agencies in SK (VEGA, APVV) have allocated financial grants for realisation of several projects authorised by the Competent Authority of SR in the area of protection of animals used for scientific purposes. Increased number of animals used in 2017 is deeply connected with this. After finishing transition period for standards of treating and housing animals until 01.01.2017, performance of the projects in establishments has developed in SK. Purpose of the projects in performance of regulated projects has increased. In comparison to year 2016, in performance of the project with the purpose non-regulatory toxicology and ecotoxicology was not reported in 2017. In the area of regulatory use and routine production a type of regulated project - reproductive toxicity occurred and a test with 29-90 days period of administration was added in the area of repeated dose toxicity. Due to the Act, in vitro methods or alternative methods are used preferentially in the regulated projects. In vivo project shall be carried out only if it is not possible to use an alternative method, if there is any. The reason is that the tested substance e.g. is not dissoluble in the dissolution reagent determined for given alternative method.

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

In 2017, the number of animals used in the projects increased by 17, 66% in comparison to the year 2016. This relates also to the increase of use animals in particular areas or their decrease depending on the area of the research. Significant increase occurred in use of „other birds“, whereas in the approved project No. 2982/17-221 apart from the species Zebra finch the other species Bangalese finch has also started to be used, whereby the number of use animals increased by 7,8%. The number of animals used for maintenance GM animal colonies without their further use in the project increased by 3%. The number of used animals in basic research in the area multisystemic has increased. A project with use of 782 (7,23%) of animals for the purpose of carcinogenicity research was authorised. The project was focused on safety testing of genetically modified plants by means of toxicology methods. The number of animals used in translational and applied research has increased significantly by 50, 48%, whereas in 2016 no project with this purpose had been carried out. The number of used animals in Animal Diseases and Disorders has increased by 36 % relating to increased number of used animals in one year. In 2017, the purpose of regulated projects increased and simultaneously, the number of animals used in regulated projects decreased in general by 5%. At the same time, the number of animals used in the basic research increased by 4 % related to starting research activities of several useres establishments of the Slovak Academy of Science and Universities.

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

In comparison to the year 2016, significant increase occured in classification of severity. The number of animals used in category „mild“ decreased by 10%, whereas the number of animals used in category „moderate“ increased by 11%. This is also related to the purpose of executed projects which have increased significantly in the basic research mainly in the area of „other basic research“, as stated in the table for obligatory report of the Member States. The projects in „other basic reaserch“ had been carried out for the purposes of microbiology, virology and diabetes. By using these methods also the level of severity is increasing.

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

The Slovak Republic annually completes and sends referred templates of the tables for reporting of support and achievements in the area of observing the principles of 3R. The tables are published at the web site of the State Veterinary and Food Administration of SR. Applicants for any kind of authorisation, whether the establishment or the project, in compliance with the Act, are obliged to describe observance of 3R principles. During controls of establishments in the area of observance of legislative requirements, inspectors of animal protection are focused mainly on the area of observance of 3R in keeping and using animals. Several users attend trainings for implementation of in vitro methods in performance of the regulated projects. In 2017, Slovakia organized an International Conference of in vitro methods EUROTOX. The subject of the observance of 3R principles is highly emphasized at the obligational training of specified functions carried out by the staff of authorised establishments of users, breeders and suppliers. Moreover, the members of Animal Welfare Body, which is established in each establishment or its services are used externally, have to supervise the compliance of these principles in the establishments.

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

The number of used animals has changed significantly in basic research in the area „ other basic research“ as listed in the purpose of projects in the table for obligatory report of the Member States. The projects in „other basic research“ were carried out in the area of microbiology, virology and diabetes. Simultaneously, increase of animals category „ other birds“ from 32 in 2016 to 59 in 2017 was notified. It was caused by the use of other bird species, i.e. Bengalese finch (Lonchura striata domestica).

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

The Competent Authority of the Slovak Republic does not register exceed of classification specified as „severe“ in 2017. In the Slovak Republic the projects classified as „severe“ are authorised. The real number of animals that have experienced pain in the projects classified as „severe“ is notified in every obligatory report sent to EU Commission. Exceed is not possible because the establishments are annually controlled by a physical control on site in the establishments by inspectors of animal protection of the District Veterinary and Food Administrations. At the same time, users are obliged to notify real severity caused to animals in the projects according to the submitted template of the tables from EU Commission. The Competent Authority of SR has got all relevant information about the projects and in case of suspicion can impose execution of a targeted control in the establishment of the respective user. Inspector of animal protection shall carry out control focused on observance of severity in the project in comparison to the Decision of authorisation of the project. In case of found incompliances, the veterinary measures or penalties are imposed.

## Slovakia: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 6087 | 39.01% |
| Rats | 7939 | 50.88% |
| Guinea-Pigs | 1036 | 6.64% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 9 | 0.06% |
| Other Rodents |  |  |
| Rabbits | 226 | 1.45% |
| Cats | 11 | 0.07% |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs |  |  |
| Goats |  |  |
| Sheep | 2 | 0.01% |
| Cattle | 1 | 0.01% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 233 | 1.49% |
| Other birds | 59 | 0.38% |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 15603 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 15565 | 100% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 15565 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 10819 | 69.34% |
| Translational and applied research | 1046 | 6.7% |
| Regulatory use and Routine production | 2822 | 18.09% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 56 | 0.36% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 860 | 5.51% |
| Total | 15603 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| 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

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer |  |  |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders | 20 | 1.91% |
| Human Nervous and Mental Disorders | 528 | 50.48% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| 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% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 374 | 35.76% |
| Animal Welfare |  |  |
| Diagnosis of diseases | 6 | 0.57% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 1046 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 1014 | 35.93% |
| Other efficacy and tolerance testing |  |  |
| Toxicity and other safety testing including pharmacology | 1777 | 62.97% |
| Routine production | 31 | 1.1% |
| Total | 2822 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 867 | 85.5% |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 147 | 14.5% |
| Total | 1014 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 653 | 36.75% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Target animal safety |  |  |
| Skin sensitisation | 542 | 30.5% |
| Repeated dose toxicity | 460 | 25.89% |
| Reproductive toxicity | 122 | 6.87% |
| Total | 1777 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 603 | 92.34% |
| Other lethal methods |  |  |
| Non lethal methods | 50 | 7.66% |
| Total | 653 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 280 | 60.87% |
| 29 - 90 days | 180 | 39.13% |
| > 90 days |  |  |
| Total | 460 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 31 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 31 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 1300 | 46.07% |
| Legislation on medicinal products for veterinary use and their residues | 133 | 4.71% |
| Medical devices legislation | 64 | 2.27% |
| Industrial chemicals legislation | 946 | 33.52% |
| Plant protection product legislation | 9 | 0.32% |
| Biocides legislation |  |  |
| Food legislation including food contact material | 190 | 6.73% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 180 | 6.38% |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 2822 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 2822 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 2822 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 15565 | 99.76% |
| Yes | 38 | 0.24% |
| Total | 15603 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 1101 | 7.06% |
| Mild [up to and including] | 5185 | 33.23% |
| Moderate | 8963 | 57.44% |
| Severe | 354 | 2.27% |
| Total | 15603 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 15603 | 100% |
| Yes |  |  |
| Total | 15603 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 14104 | 90.39% |
| Genetically altered without a harmful phenotype | 260 | 1.67% |
| Genetically altered with a harmful phenotype | 1239 | 7.94% |
| Total | 15603 | 100.00% |

# Slovenia

## Slovenia: Narrative 2015

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

Number of animals used for scientific purposes in 2015 is slightly lower in comparison with numbers reported in 2014. In 2014, approximately 12.000 animals were used and in 2015, the number of animals used for scientific purposes is slightly over 9.000.

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

More than 95% of all used animals in 2015 are rodents and rabbits. Mice is the most commonly used species (95%), following rats (2%) and rabbits (1, 4%). 477 animals (rodents) were reported as GA animals, 58 of them with a harmful phenotype (39 mice and 19 rats). Animals were used in basic research (endocrine system/metabolism and cardiovascular/lymphatic system).

No cats, dogs and non-human primates were used for scientific purposes in 2015.

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

The majority of all animals (74,17%) were used for the purpose of regulatory use and routine production. Out of this percentage, over 40% of animals (mice and rabbits) were re-used for quality control (including batch potency testing and pyrogenicity testing). The severity of each of these tests were carried out on parameters such as pain at the application and/or blood sampling, handling and equipment used in procedure and also on evaluation of the results gathered in last 10 years. It was decided that the both tests (pyrogenicity test and potency test) are classified as mild.

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

The principle of replacement, reduction and refinement was well considered in the use of animals in procedures for the purpose of regulatory - quality control, as prescribed and validated parameters were achieved with re-use of mice and rabbits, which in the end result in lower number of used mice and rabbits. Re-use is possible precisely because the tests are mild and non-harmful for animals. As this are standardized procedures and the testing is done only for generic products and at therapeutic dose, the procedures are classified as “mild”.

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

In 2015, 57 fish (*Onchorhynchus mykiss*) were used in higher education or training for the acquisition, maintenance or improvement of vocational skills. Severity of procedures was classified as non-recovery or mild.

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

No information submitted.

## Slovenia: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 8621 | 95.63% |
| Rats | 184 | 2.04% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 127 | 1.41% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 2 | 0.02% |
| Pigs | 8 | 0.09% |
| Goats |  |  |
| Sheep | 3 | 0.03% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 13 | 0.14% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish | 57 | 0.63% |
| Cephalopods |  |  |
| Total | 9015 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 5400 | 98.58% |
| Animals born in the EU but not at a registered breeder | 78 | 1.42% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 5478 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 963 | 10.68% |
| Translational and applied research | 1177 | 13.06% |
| Regulatory use and Routine production | 6757 | 74.95% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 118 | 1.31% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 9015 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 125 | 12.98% |
| Cardiovascular Blood and Lymphatic System | 68 | 7.06% |
| Nervous System |  |  |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 15 | 1.56% |
| Musculoskeletal System | 35 | 3.63% |
| Immune System | 174 | 18.07% |
| Urogenital/Reproductive System | 74 | 7.68% |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism | 472 | 49.01% |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research |  |  |
| Total | 963 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 1002 | 85.13% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders | 24 | 2.04% |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders | 112 | 9.52% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases | 39 | 3.31% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 1177 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 6717 | 99.41% |
| Other efficacy and tolerance testing |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 40 | 0.59% |
| Total | 6757 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 175 | 2.61% |
| Pyrogenicity testing | 111 | 1.65% |
| Batch potency testing | 6431 | 95.74% |
| Other quality controls |  |  |
| Total | 6717 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Kinetics | 40 | 100% |
| Total | 40 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 6757 | 100% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 6757 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 6757 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 6757 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 5478 | 60.77% |
| Yes | 3537 | 39.23% |
| Total | 9015 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 105 | 1.16% |
| Mild [up to and including] | 8559 | 94.94% |
| Moderate | 351 | 3.89% |
| Severe |  |  |
| Total | 9015 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 9015 | 100% |
| Yes |  |  |
| Total | 9015 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 8538 | 94.71% |
| Genetically altered without a harmful phenotype | 419 | 4.65% |
| Genetically altered with a harmful phenotype | 58 | 0.64% |
| Total | 9015 | 100.00% |

## Slovenia: Narrative 2016

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

Number of animals used for scientific purposes in 2016 has dropped significantly in comparison with numbers reported in 2015. In 2015, approximately 9.000 animals were used and in 2016, the number of animals used for scientific purposes is around 6.800. The highest drop in the number of used animals was in regulatory use and routine production.

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

As every year, more than 95% of all used animals are rodents and rabbits. Mice is the most commonly used species (95%), following rats (1, 36 %) and rabbits (less than 1%).

66 animals (rodents) were reported as GA animals, all without a harmful phenotype (50 mice and 16 rats). Those animals were used in basic research (oncology and cardiovascular blood and lymphatic system). No cats, dogs and non-human primates were used for scientific purposes in 2016.

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

Almost 86 % off all animals were used for the purpose of regulatory use and routine production. Out of this percentage, around 26 % of animals (mice and rabbits) were re-used for quality control (including batch potency testing and pyrogenicity testing). The severity of each of these tests were carried out on parameters such as pain at the application and/or blood sampling, handling and equipment used in procedure and also on evaluation of the results gathered in last 10 years. It was decided that the both tests (pyrogenicity test and potency test) are classified as mild.

1,54 % of all uses were classified as non – recovery (animals used for the purpose of translational and applied research and higher education). Almost 91% of all uses were mild, 4,5 % moderate and 3 % were classified as severe, where all uses were for the purpose of basic research (mice used for immune system research).

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

The principle of replacement, reduction and refinement was well considered in the use of animals in procedures for the purpose of regulatory - quality control, as prescribed and validated parameters were achieved with re-use of mice and rabbits, which in the end result in lower number of used mice and rabbits. Re-use is possible precisely because the tests are mild and non-harmful for animals. As this are standardized procedures and the testing is done only for generic products and at therapeutic dose, the procedures are classified as “mild”.

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

No information submitted.

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

No information submitted.

## Slovenia: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 6542 | 97.28% |
| Rats | 93 | 1.38% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 45 | 0.67% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds |  |  |
| Pigs | 32 | 0.48% |
| Goats |  |  |
| Sheep | 3 | 0.04% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 10 | 0.15% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish |  |  |
| Cephalopods |  |  |
| Total | 6725 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 4920 | 99.8% |
| Animals born in the EU but not at a registered breeder | 10 | 0.2% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 4930 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 419 | 6.23% |
| Translational and applied research | 1762 | 26.2% |
| Regulatory use and Routine production | 4491 | 66.78% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals |  |  |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 53 | 0.79% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 6725 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 50 | 11.93% |
| Cardiovascular Blood and Lymphatic System | 16 | 3.82% |
| Nervous System |  |  |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 24 | 5.73% |
| Musculoskeletal System | 32 | 7.64% |
| Immune System | 224 | 53.46% |
| Urogenital/Reproductive System | 49 | 11.69% |
| Sensory Organs (skin, eyes and ears) |  |  |
| Endocrine System/Metabolism |  |  |
| Multisystemic |  |  |
| Ethology / Animal Behaviour /Animal Biology |  |  |
| Other basic research | 24 | 5.73% |
| Total | 419 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 1603 | 90.98% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders | 17 | 0.96% |
| Human Urogenital/Reproductive Disorders | 10 | 0.57% |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders | 122 | 6.92% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases | 10 | 0.57% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 1762 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 4491 | 100% |
| Other efficacy and tolerance testing |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology |  |  |
| Total | 4491 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 70 | 1.56% |
| Pyrogenicity testing | 40 | 0.89% |
| Batch potency testing | 4381 | 97.55% |
| Other quality controls |  |  |
| Total | 4491 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Kinetics |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 4491 | 100% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 4491 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 4491 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 4491 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 4930 | 73.31% |
| Yes | 1795 | 26.69% |
| Total | 6725 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 16 | 0.24% |
| Mild [up to and including] | 6183 | 91.94% |
| Moderate | 318 | 4.73% |
| Severe | 208 | 3.09% |
| Total | 6725 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 6725 | 100% |
| Yes |  |  |
| Total | 6725 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 6659 | 99.02% |
| Genetically altered without a harmful phenotype | 66 | 0.98% |
| Genetically altered with a harmful phenotype |  |  |
| Total | 6725 | 100.00% |

## Slovenia: Narrative 2017

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

In 2017, the number of animals used for scientific purposes has been reduced in comparison with numbers reported in previous years. The number is around 5.000 animals. The highest drop in the number of used animals was in regulatory use and routine production, where almost 50% less animals were used compared to previous years. The reason is the replacement of in vivo methods, which follows the 3R principle of replacement. Further more, the reason can be found in the termination of certain projects for certain markets, which leads in reduction of use of animals for regulatory purposes. Not negligible is also the fact, that the principle of reduction is followed as much as possible and animals are being re-used.

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

As every year, more than 95% of all used animals are rodents (mice and rats) and rabbits. Mice is the most commonly used species (88%), following rats (4, 40 %) and rabbits (less than 2,63%).

There is an increase of animals used in basic research where, in comparison with previous year almost 1.000 rodents (mice in rats) were used. The number was less than 400 rodents (mice and rats) in 2016. Animals were mainly used in research for the purpose of oncology, endocrine system, immune system and gastrointestinal system including liver. The highest number of rodents was used for the research of endocrine system.

A slight increase can be observed also in the use of GA animals. While there were 66 animals reported as GA in 2016, 351 GA animals were reported in 2017. This number represent 6,70 % of all used animals in Slovenia in 2017. Out of this 351 GA animals, 288 mice were reported as GA without a harmful phenotype and 63 mice with harmful phenotype. In 2016 no GA animal with harmful phenotype was reported.

Pyrogenicity testing is still used on rabbits for the purpose of quality control including batch safety and potency testing, but only when the alternative method (in vitro method) gives doubtful results.

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

Majority of procedures in Slovenia are still classified as mild (over 85%), around 12% are moderate and less than 2% severe, where all uses were for basic research for the purpose of immune system research.

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

The principle of replacement, reduction and refinement was well considered in the use of animals in procedures for the purpose of regulatory use - quality control, as prescribed and validated parameters were achieved with the re-use of mice and rabbits, which in the end result in lower number of used mice and rabbits. Re-use is possible precisely because the tests are mild and non-harmful for animals. As this are standardized procedures and the testing is done only for generic products and at therapeutic dose, the procedures are classified as “mild”.

No cats, dogs and non-human primates were used in procedures in 2017.

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

No information submitted.

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

No information submitted.

## Slovenia: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 4563 | 88.74% |
| Rats | 226 | 4.4% |
| Guinea-Pigs |  |  |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 135 | 2.63% |
| Cats |  |  |
| Dogs |  |  |
| Ferrets |  |  |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 2 | 0.04% |
| Pigs | 80 | 1.56% |
| Goats |  |  |
| Sheep | 28 | 0.54% |
| Cattle |  |  |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey |  |  |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals |  |  |
| Domestic fowl | 10 | 0.19% |
| Other birds |  |  |
| Reptiles |  |  |
| Rana |  |  |
| Xenopus |  |  |
| Other Amphibians |  |  |
| Zebra fish |  |  |
| Other Fish | 98 | 1.91% |
| Cephalopods |  |  |
| Total | 5142 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 4569 | 100% |
| Animals born in the EU but not at a registered breeder |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world |  |  |
| Total | 4569 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia |  |  |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total |  |  |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater |  |  |
| Self-sustaining colony |  |  |
| Total |  |  |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 1035 | 20.13% |
| Translational and applied research | 1786 | 34.73% |
| Regulatory use and Routine production | 2183 | 42.45% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 16 | 0.31% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 122 | 2.37% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures |  |  |
| Total | 5142 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 149 | 14.4% |
| Cardiovascular Blood and Lymphatic System |  |  |
| Nervous System | 70 | 6.76% |
| Respiratory System |  |  |
| Gastrointestinal System including Liver | 150 | 14.49% |
| Musculoskeletal System | 34 | 3.29% |
| Immune System | 102 | 9.86% |
| Urogenital/Reproductive System |  |  |
| Sensory Organs (skin, eyes and ears) |  |  |
| 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

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 1552 | 86.9% |
| Human Infectious Disorders |  |  |
| Human Cardiovascular Disorders |  |  |
| Human Nervous and Mental Disorders |  |  |
| Human Respiratory Disorders |  |  |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders |  |  |
| Human Immune Disorders |  |  |
| Human Urogenital/Reproductive Disorders |  |  |
| Human Sensory Organ Disorders (skin, eyes and ears) |  |  |
| Human Endocrine/Metabolism Disorders | 65 | 3.64% |
| Other Human Disorders | 55 | 3.08% |
| Animal Diseases and Disorders |  |  |
| Animal Welfare |  |  |
| Diagnosis of diseases | 114 | 6.38% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology |  |  |
| Total | 1786 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 2101 | 96.24% |
| Other efficacy and tolerance testing |  |  |
| Routine production |  |  |
| Toxicity and other safety testing including pharmacology | 82 | 3.76% |
| Total | 2183 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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% |
| Other quality controls |  |  |
| Total | 2101 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Kinetics | 82 | 100% |
| Total | 82 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 2183 | 100% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 2183 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 2183 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 2183 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 4569 | 88.86% |
| Yes | 573 | 11.14% |
| Total | 5142 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 44 | 0.86% |
| Mild [up to and including] | 4372 | 85.03% |
| Moderate | 637 | 12.39% |
| Severe | 89 | 1.73% |
| Total | 5142 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 5087 | 98.93% |
| Yes | 55 | 1.07% |
| Total | 5142 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 4791 | 93.17% |
| Genetically altered without a harmful phenotype | 288 | 5.6% |
| Genetically altered with a harmful phenotype | 63 | 1.23% |
| Total | 5142 | 100.00% |

# Spain

## Spain: Narrative 2015

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

The Ministry of Agriculture, Fisheries, Food and the Environment (MAGRAMA) designed an IT application which was used for the first time this past year. Its purpose is to facilitate the collection, control and transmission of data from user centres that use animals to the European Commission’s IT application. The information is provided by the authorised centres, which input the reports from each centre in the system. The authorised centres are overseen by the competent authorities of the various Autonomous Communities which report to MAGRAMA. The latter sends the communications to the European Commission.

Both the information to be collected and the system for collecting represented significant changes. It was therefore necessary to adapt both the tools used and the organisation and assignment of the various uses to the various categories used for organising the information. This affects how the information about uses in 2014 compare with the same information in 2015. This problem should be resolved with the experience gained as future reports are created. This means that comparisons between years will be more reliable, and it will be possible to evaluate the trends which, for the moment, cannot be evaluated.

In 2015, there was a significant effort to improve the classification of uses under the corresponding headings and, as far as possible, to avoid using ‘others’.

In addition, analysis of the data showed that the severity classification ‘non-recovery’ had at times been interpreted incorrectly. For this reason, there is a change in the proportions of the various severity classifications, which is largely due to better understanding of the meaning of each category. It is also partly due to the generally accepted practice of applying the precautionary principle. As a result, where there is uncertainty between two levels of severity, the higher level of actual severity is assigned to a use.

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

In the report on uses in 2015, there were uses of new species not used in 2014. Nevertheless, this is not considered highly significant as such uses are associated with projects that use such species on an occasional basis (for example, frogs).

The proportion of ‘other animal species’ is high as there are several registered users that work with wildlife.

In 2015, several lines of research associated with zootechnics were developed. This can be seen in the use of ‘production animals’, although it is partially obscured by the reduction in the use of sheep.

In addition, a new user conducting research in the field of animal nutrition has been using relatively large groups of animals. This is because the user is working in commercial conditions, which significantly increases the figures reported.

The field of aquaculture, and the development of technologies to extend the practice, requires the use of ‘non-habitual’ species of fish, such as cephalopods, in significant numbers. The main species used are sea-bream, sea-bass, turbot and trout. The notable increase in the use of cephalopods has the same [...].

The increase in genetically altered mice is notable: this is a global trend on account of the wide range of options offered by the use of such animals.

Finally, with regard to the purposes for which animals are used, there is a notable decrease in uses in basic research in parallel with the increase in applied research. A reduction is apparent in the use of animals for regulatory purposes. This is partly due to better classification of the purposes for which animals are used. The significant increase in maintaining genetically altered lines is due to the increase in altered lines and, largely, to the fact that genotyping by invasive methods was considered a procedure. The emphasis placed on the need for thorough education and training in new surgical techniques was reflected in the increase in animals intended for training and teaching.

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

In Spain, assignment of severity to the procedures is one of the most significant new features of the Directive. It was done for the first time following the application of the Directive.

Furthermore, assignment of severity is a complex process. On the one hand, it is necessary to be aware of a broad range of circumstances, and on the other hand those responsible for assigning severity need to be widely experienced. In these circumstances, and given the, as yet, brief existence of the requirement, a process of adaptation is under way. For example, some guidelines are needed to clarify certain questions that decide the final severity classification of a specific procedure.

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

It is understood that promoting the principles of the three ‘Rs’ must be done in a combined form by the users, through the various bodies responsible for animal welfare - which, in Spain, in the user centres, are known as ‘ethics committees for animal experimentation’ - [and] by the assessment bodies, which in Spain are termed ‘empowered bodies’ authorised by the competent authorities for this purpose, along with the competent authorities themselves. Given the uniqueness of the composition of the empowered bodies, the competent authorities consider it vital to concentrate on optimising that composition.

Several competent authorities have created consultative committees that conduct a supplementary assessment of ‘sensitive’ projects, especially those involving severe procedures. The purpose is a more thorough assessment of the possibilities of reducing the number of animals, and of refining the techniques in order to minimise the number of animals that come under this classification.

The points on which the greatest effort is being made are: disseminating reference tools and databases; establishing sample size correctly; encouraging pilot studies; and establishing end-point criteria with both quantitative and qualitative indicators.

One of the areas in which the greatest effort was apparent was in teaching with the increasing use of virtual simulators, artificial models, work with organs of animals not bred especially for this purpose, cadavers etc., and finally with animals for which the severity of the procedures must not exceed the classification of ‘mild’. However, this situation is not apparent in the statistics because of the increase in the number of projects authorised and conducted for the purposes of higher education or training for the acquisition, maintenance or improvement of professional skills.

1. **Further breakdown on the use of ‘other’ categories if a significant proportion of animal use is reported under this category.**

In the category ‘other animals’, the majority corresponds to ‘other fishes’, for two main reasons. The first is that the range of options for this group is limited to two options. This means that ‘other fishes’ in reality represents ‘fishes other than zebrafish’. Secondly, in Spain there are several centres dedicated to researching the biology and needs of fish in aquaculture, for example trout, sea-bream, sea-bass, turbot etc. These represent a significant number of animals.

Furthermore, there are centres that work with wildlife, also for the purpose of thoroughly understanding their biology and behaviour.

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

This situation has not arisen in Spain.

## Spain: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 483689 | 57.65% |
| Rats | 57616 | 6.87% |
| Guinea-Pigs | 7760 | 0.92% |
| Hamsters (Syrian) | 665 | 0.08% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 193 | 0.02% |
| Rabbits | 30408 | 3.62% |
| Cats | 361 | 0.04% |
| Dogs | 860 | 0.1% |
| Ferrets | 94 | 0.01% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 210 | 0.03% |
| Pigs | 9262 | 1.1% |
| Goats | 389 | 0.05% |
| Sheep | 1980 | 0.24% |
| Cattle | 519 | 0.06% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey | 289 | 0.03% |
| Rhesus monkey | 4 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons | 18 | 0% |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 607 | 0.07% |
| Domestic fowl | 98444 | 11.73% |
| Other birds | 4585 | 0.55% |
| Reptiles | 302 | 0.04% |
| Rana | 14 | 0% |
| Xenopus | 1304 | 0.16% |
| Other Amphibians | 2267 | 0.27% |
| Zebra fish | 44543 | 5.31% |
| Other Fish | 76709 | 9.14% |
| Cephalopods | 15848 | 1.89% |
| Total | 838940 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 744953 | 90.26% |
| Animals born in the EU but not at a registered breeder | 76558 | 9.28% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 3802 | 0.46% |
| Total | 825313 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 21 | 8.61% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 78 | 31.97% |
| Animals born in America |  |  |
| Animals born in Africa | 145 | 59.43% |
| Animals born elsewhere |  |  |
| Total | 244 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 9 | 3.69% |
| F2 or greater | 185 | 75.82% |
| Self-sustaining colony | 50 | 20.49% |
| Total | 244 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 433171 | 51.63% |
| Translational and applied research | 217468 | 25.92% |
| Regulatory use and Routine production | 133876 | 15.96% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 17306 | 2.06% |
| Preservation of species | 13 | 0% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 13922 | 1.66% |
| Forensic enquiries | 1 | 0% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 23183 | 2.76% |
| Total | 838940 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 46399 | 10.71% |
| Cardiovascular Blood and Lymphatic System | 35069 | 8.1% |
| Nervous System | 83966 | 19.38% |
| Respiratory System | 2755 | 0.64% |
| Gastrointestinal System including Liver | 49205 | 11.36% |
| Musculoskeletal System | 13259 | 3.06% |
| Immune System | 24368 | 5.63% |
| Urogenital/Reproductive System | 6680 | 1.54% |
| Sensory Organs (skin, eyes and ears) | 7809 | 1.8% |
| Endocrine System/Metabolism | 29287 | 6.76% |
| Multisystemic | 41201 | 9.51% |
| Ethology / Animal Behaviour /Animal Biology | 18301 | 4.22% |
| Other basic research | 74872 | 17.28% |
| Total | 433171 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 62970 | 28.96% |
| Human Infectious Disorders | 22693 | 10.44% |
| Human Cardiovascular Disorders | 5317 | 2.44% |
| Human Nervous and Mental Disorders | 17719 | 8.15% |
| Human Respiratory Disorders | 5243 | 2.41% |
| Human Gastrointestinal Disorders including Liver | 2286 | 1.05% |
| Human Musculoskeletal Disorders | 3072 | 1.41% |
| Human Immune Disorders | 3342 | 1.54% |
| Human Urogenital/Reproductive Disorders | 1563 | 0.72% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 13873 | 6.38% |
| Human Endocrine/Metabolism Disorders | 16953 | 7.8% |
| Other Human Disorders | 1048 | 0.48% |
| Animal Diseases and Disorders | 35315 | 16.24% |
| Animal Welfare | 18539 | 8.52% |
| Diagnosis of diseases | 5540 | 2.55% |
| Plant diseases | 14 | 0.01% |
| Non-regulatory toxicology and ecotoxicology | 1981 | 0.91% |
| Total | 217468 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 71438 | 53.36% |
| Other efficacy and tolerance testing | 288 | 0.22% |
| Toxicity and other safety testing including pharmacology | 59672 | 44.57% |
| Routine production | 2478 | 1.85% |
| Total | 133876 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 16585 | 23.22% |
| Pyrogenicity testing | 9960 | 13.94% |
| Batch potency testing | 41617 | 58.26% |
| Other quality controls | 3276 | 4.59% |
| Total | 71438 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 16447 | 27.56% |
| Skin irritation/corrosion | 103 | 0.17% |
| Skin sensitisation | 630 | 1.06% |
| Eye irritation/corrosion | 39 | 0.07% |
| Repeated dose toxicity | 5172 | 8.67% |
| Carcinogenicity |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Genotoxicity | 60 | 0.1% |
| Developmental toxicity | 90 | 0.15% |
| Neurotoxicity | 8400 | 14.08% |
| Kinetics | 2069 | 3.47% |
| Pharmaco-dynamics (incl safety pharmacology) | 3849 | 6.45% |
| Ecotoxicity | 133 | 0.22% |
| Safety testing in food and feed area | 19301 | 32.35% |
| Target animal safety | 3331 | 5.58% |
| Other toxicity/safety testing | 48 | 0.08% |
| Total | 59672 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 14047 | 85.41% |
| Other lethal methods | 75 | 0.46% |
| Non lethal methods | 2325 | 14.14% |
| Total | 16447 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 3244 | 62.72% |
| 29 - 90 days | 1129 | 21.83% |
| > 90 days | 799 | 15.45% |
| Total | 5172 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 57 | 42.86% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation | 76 | 57.14% |
| Other ecotoxicity |  |  |
| Total | 133 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 1759 | 70.98% |
| Monoclonal antibody by mouse ascites method | 719 | 29.02% |
| Other product types |  |  |
| Total | 2478 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 33313 | 24.88% |
| Legislation on medicinal products for veterinary use and their residues | 65403 | 48.85% |
| Medical devices legislation | 501 | 0.37% |
| Industrial chemicals legislation | 510 | 0.38% |
| Plant protection product legislation | 10 | 0.01% |
| Biocides legislation |  |  |
| Food legislation including food contact material | 21626 | 16.15% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 2368 | 1.77% |
| Cosmetics legislation |  |  |
| Other legislation | 10145 | 7.58% |
| Total | 133876 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 112896 | 84.33% |
| Legislation satisfying national requirements only [within EU] | 3371 | 2.52% |
| Legislation satisfying Non-EU requirements only | 17609 | 13.15% |
| Total | 133876 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 825557 | 98.4% |
| Yes | 13383 | 1.6% |
| Total | 838940 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 72630 | 8.66% |
| Mild [up to and including] | 382421 | 45.58% |
| Moderate | 325697 | 38.82% |
| Severe | 58192 | 6.94% |
| Total | 838940 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 814686 | 97.11% |
| Yes | 24254 | 2.89% |
| Total | 838940 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 573795 | 68.4% |
| Genetically altered without a harmful phenotype | 234380 | 27.94% |
| Genetically altered with a harmful phenotype | 30765 | 3.67% |
| Total | 838940 | 100.00% |

## Spain: Narrative 2016

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

The Ministry of Agriculture and Fisheries, Food and the Environment (MAPAMA) designed an IT application which, since 2014, has made it possible to facilitate the collection, control and transmission of data from user centres that use animals to the European Commission’s IT application. The user centres input their reports in the system. They are overseen by the respective competent authorities of the various Autonomous Communities which report to MAPAMA. The latter sends the communications to the European Commission.

Both the information to be collected and the system for collecting represented significant changes. There has therefore been a process of adapting both the tools used and the organisation and assignment of the various uses to the various categories used for organising the information. This meant that one action could be classified differently throughout the reporting periods.

This can affect data patterns. We therefore believe that it is too early to draw conclusions regarding trends.

In 2016, efforts were maintained to improve the classification of uses under the corresponding headings, with the identification and correction of errors in the assignment of uses to the various categories available in the data collection form and, as far as possible, avoidance of using the heading ‘others’.

In assessing the figures on uses, it must be taken into account that projects in the field of animal nutrition are undertaken in commercial production conditions. For this reason, relatively large groups of animals are used, which significantly increases the figures.

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

The report on uses in 2016 includes species which are new, while others that appeared in previous reports have disappeared. Nevertheless, it is understood that these variations are not significant as they are associated with the implementation or completion of projects that use such species on an occasional basis.

The trend in increased use of genetically modified mice continues as the ability to design them to order makes them ideal experimental models for a multitude of studies.

The number of uses of fish continues to increase. This is due in part to the adaptation of the models that use zebrafish, which are being developed in an increasing number of fields, and in part to research concerning fish in aquaculture in Spain.

The proportion of ‘other animal species’ is high as there are several registered users that work with wildlife. Furthermore, as stated in the previous paragraph, the field of aquaculture, and the development of technologies to extend the practice, requires the use of ‘non-habitual’ species of fish, such as cephalopods, in significant numbers. The main species used are sole, sea-bream, sea-bass, turbot and trout.

The increase in ‘maintaining genetically modified lines’ continues. This is due both to the greater presence of the genetically modified lines themselves, and to the fact that, as of this report, genotyping by invasive methods was considered a procedure.

The need for thorough education and training in new surgical techniques was reflected in an increase in animals intended for training and teaching, making it possible to refine post-research activity.

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

As stated in previous reports, in Spain assigning severity to uses of animals is one of the most significant new aspects of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes. It was done for the first time when the Directive was applied: in the year 2013 with the report issued in 2014.

Furthermore, assignment of severity is a complex process. On the one hand, it is necessary to be aware of a broad range of circumstances, and on the other hand those responsible for assigning severity need to be widely experienced in recognising the elements and their weighting in order to assign specific categories of severity. It is understood that, where there is uncertainty about an assignment, preference is given to assessments that are more sensitive to the suffering of the animals involved. This means that assignment tends towards the levels that are more [...]

In these circumstances, and given the, as yet, brief existence of the requirement, a process of adaptation is under way. For example, some guidelines are needed to clarify certain questions that decide the final severity classification of a specific use.

The apparent fall in the proportion of ‘non-recovery’ uses continues. However this variation can be attributed to correct information as a result of the concept of ‘non-recovery use’ being clarified rather than to any real variation in the type of procedures carried out.

Uses classified as severe, while increasing in absolute figures, remain unchanged (8% of uses) in comparison with last year when their relative importance is compared with the total uses.

The greatest severities can be seen to be associated with uses required by European Union legislation, in the category ‘regulatory use’, and to a lesser extent in studies on animal diseases.

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

It is understood that promoting the principles of the three ‘Rs’ must be done in a combined form by the competent authorities, the users, through the various bodies responsible for animal welfare - which, in Spain, in the user centres, are known as ‘ethics committees for animal experimentation’ - and by the assessment bodies, which in Spain are termed ‘empowered bodies’ authorised by the competent authorities for this purpose. Given the uniqueness of the composition of the empowered bodies, the competent authorities consider it vital to concentrate on optimising that composition.

Several competent authorities have created consultative committees that conduct a supplementary assessment of ‘sensitive’ projects, especially those involving severe procedures. The purpose is a more thorough assessment of the possibilities of reducing the number of animals, and of refining the techniques in order to minimise the number of animals that come under this classification.

Bearing in mind that the staff who work with the animals are one of the key aspects, more thorough and up-to-date training results not only in knowledge of more tools but also in greater motivation to use them.

The points on which the greatest effort is being made are: dissemination of reference tools and databases; establishing sample size correctly; encouraging pilot studies; and establishing end-point criteria with both quantitative and qualitative indicators.

One of the areas in which the greatest effort was apparent was in teaching with the increasing use of virtual simulators, artificial models, work with organs of animals not bred especially for this purpose, and cadavers.

Improvements in training and in the instruments available enable progress in refining procedures.

However, this situation is obscured in the overall statistical figures by the significant increase of those... [text unclear] not apparent in the statistics because of the increased number of projects authorised and conducted for the purposes of higher education or training for the acquisition, maintenance or improvement of professional skills.

1. **Further breakdown on the use of ‘other’ categories if a significant proportion of animal use is reported under this category.**

In the ‘other animals’ section, a significant number of uses refer to ‘other birds’. These are limited to centres working to gain detailed knowledge of the biology and behaviour of wildlife. Almost all of these uses (96%) have been classified as ‘mild’.

However, the vast majority (95% of uses under ‘other species’) corresponds to fish other than zebrafish. In this case, it mainly concerns uses of fish species from aquaculture in order to understand their needs. Such fish include sole, trout, sea-bream, sea-bass and turbot.

A significant effort was made to avoid the classification of ‘others’ for the purposes of the uses of animals. As a result, the number fell dramatically.

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

This situation has not arisen.

## Spain: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 539959 | 61% |
| Rats | 54910 | 6.2% |
| Guinea-Pigs | 7223 | 0.82% |
| Hamsters (Syrian) | 734 | 0.08% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 322 | 0.04% |
| Rabbits | 28035 | 3.17% |
| Cats | 358 | 0.04% |
| Dogs | 1083 | 0.12% |
| Ferrets | 74 | 0.01% |
| Other carnivores |  |  |
| Horses, donkeys and cross-breeds | 91 | 0.01% |
| Pigs | 9434 | 1.07% |
| Goats | 269 | 0.03% |
| Sheep | 2695 | 0.3% |
| Cattle | 888 | 0.1% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey | 272 | 0.03% |
| Rhesus monkey | 2 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 383 | 0.04% |
| Domestic fowl | 89795 | 10.14% |
| Other birds | 2400 | 0.27% |
| Reptiles | 684 | 0.08% |
| Rana | 30 | 0% |
| Xenopus | 1091 | 0.12% |
| Other Amphibians | 110 | 0.01% |
| Zebra fish | 68562 | 7.75% |
| Other Fish | 67324 | 7.61% |
| Cephalopods | 8444 | 0.95% |
| Total | 885172 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 840339 | 95.88% |
| Animals born in the EU but not at a registered breeder | 34299 | 3.91% |
| Animals born in rest of Europe |  |  |
| Animals born in rest of world | 1804 | 0.21% |
| Total | 876442 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 115 | 66.47% |
| Animals born in America |  |  |
| Animals born in Africa | 58 | 33.53% |
| Animals born elsewhere |  |  |
| Total | 173 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 1 | 0.58% |
| F2 or greater | 172 | 99.42% |
| Self-sustaining colony |  |  |
| Total | 173 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 442337 | 49.97% |
| Translational and applied research | 256090 | 28.93% |
| Regulatory use and Routine production | 132505 | 14.97% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 8115 | 0.92% |
| Preservation of species | 137 | 0.02% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 12261 | 1.39% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 33727 | 3.81% |
| Total | 885172 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 50747 | 11.47% |
| Cardiovascular Blood and Lymphatic System | 52032 | 11.76% |
| Nervous System | 82046 | 18.55% |
| Respiratory System | 2184 | 0.49% |
| Gastrointestinal System including Liver | 10033 | 2.27% |
| Musculoskeletal System | 11870 | 2.68% |
| Immune System | 28232 | 6.38% |
| Urogenital/Reproductive System | 11156 | 2.52% |
| Sensory Organs (skin, eyes and ears) | 9328 | 2.11% |
| Endocrine System/Metabolism | 16138 | 3.65% |
| Multisystemic | 86591 | 19.58% |
| Ethology / Animal Behaviour /Animal Biology | 77993 | 17.63% |
| Other basic research | 3987 | 0.9% |
| Total | 442337 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 98730 | 38.55% |
| Human Infectious Disorders | 14506 | 5.66% |
| Human Cardiovascular Disorders | 4516 | 1.76% |
| Human Nervous and Mental Disorders | 23096 | 9.02% |
| Human Respiratory Disorders | 3141 | 1.23% |
| Human Gastrointestinal Disorders including Liver | 5094 | 1.99% |
| Human Musculoskeletal Disorders | 3317 | 1.3% |
| Human Immune Disorders | 4513 | 1.76% |
| Human Urogenital/Reproductive Disorders | 3142 | 1.23% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 16927 | 6.61% |
| Human Endocrine/Metabolism Disorders | 19038 | 7.43% |
| Other Human Disorders |  |  |
| Animal Diseases and Disorders | 39324 | 15.36% |
| Animal Welfare | 11045 | 4.31% |
| Diagnosis of diseases | 8568 | 3.35% |
| Plant diseases | 10 | 0% |
| Non-regulatory toxicology and ecotoxicology | 1123 | 0.44% |
| Total | 256090 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 74344 | 56.11% |
| Other efficacy and tolerance testing | 7999 | 6.04% |
| Toxicity and other safety testing including pharmacology | 49667 | 37.48% |
| Routine production | 495 | 0.37% |
| Total | 132505 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 20368 | 27.4% |
| Pyrogenicity testing | 9878 | 13.29% |
| Batch potency testing | 39956 | 53.74% |
| Other quality controls | 4142 | 5.57% |
| Total | 74344 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 12920 | 26.01% |
| Skin irritation/corrosion | 99 | 0.2% |
| Skin sensitisation | 794 | 1.6% |
| Eye irritation/corrosion | 39 | 0.08% |
| Repeated dose toxicity | 2032 | 4.09% |
| Carcinogenicity | 146 | 0.29% |
| Genotoxicity | 50 | 0.1% |
| Reproductive toxicity | 530 | 1.07% |
| Developmental toxicity | 166 | 0.33% |
| Neurotoxicity | 2406 | 4.84% |
| Kinetics | 2739 | 5.51% |
| Pharmaco-dynamics (incl safety pharmacology) | 3679 | 7.41% |
| Phototoxicity |  |  |
| Ecotoxicity | 104 | 0.21% |
| Safety testing in food and feed area | 18437 | 37.12% |
| Target animal safety | 5523 | 11.12% |
| Other toxicity/safety testing | 3 | 0.01% |
| Total | 49667 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 10946 | 84.72% |
| Other lethal methods | 56 | 0.43% |
| Non lethal methods | 1918 | 14.85% |
| Total | 12920 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 791 | 38.93% |
| 29 - 90 days | 437 | 21.51% |
| > 90 days | 804 | 39.57% |
| Total | 2032 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 104 | 100% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 104 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 140 | 28.28% |
| Monoclonal antibody by mouse ascites method | 309 | 62.42% |
| Other product types | 46 | 9.29% |
| Total | 495 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 35421 | 26.73% |
| Legislation on medicinal products for veterinary use and their residues | 67169 | 50.69% |
| Medical devices legislation | 376 | 0.28% |
| Industrial chemicals legislation | 3374 | 2.55% |
| Plant protection product legislation | 1172 | 0.88% |
| Biocides legislation | 264 | 0.2% |
| Food legislation including food contact material | 20105 | 15.17% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 4599 | 3.47% |
| Cosmetics legislation |  |  |
| Other legislation | 25 | 0.02% |
| Total | 132505 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 111915 | 84.46% |
| Legislation satisfying national requirements only [within EU] | 4092 | 3.09% |
| Legislation satisfying Non-EU requirements only | 16498 | 12.45% |
| Total | 132505 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 876615 | 99.03% |
| Yes | 8557 | 0.97% |
| Total | 885172 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 50237 | 5.68% |
| Mild [up to and including] | 471092 | 53.22% |
| Moderate | 300645 | 33.96% |
| Severe | 63198 | 7.14% |
| Total | 885172 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 855372 | 96.63% |
| Yes | 29800 | 3.37% |
| Total | 885172 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 520719 | 58.83% |
| Genetically altered without a harmful phenotype | 319969 | 36.15% |
| Genetically altered with a harmful phenotype | 44484 | 5.03% |
| Total | 885172 | 100.00% |

## Spain: Narrative 2017

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

The Ministry of Agriculture and Fisheries, Food and the Environment (MAPAMA) designed an IT application which, since 2014, has made it possible to facilitate the collection, control and transmission of data from user centres that use animals to the European Commission’s IT application. The user centres input their reports in the system. They are overseen by the respective competent authorities of the various Autonomous Communities which report to MAPAMA. The latter sends the communications to the European Commission.

Both the information to be collected and the system for collecting represented significant changes. There has therefore been a process of adapting both the tools used and the organisation and assignment of the various uses to the various categories used for organising the information. This meant that one action could be classified differently in the reports from different periods.

This can affect data patterns and make it difficult to interpret possible trends in animal use.

In assessing the figures on uses, it must be taken into account that projects in the field of animal nutrition are undertaken in commercial production conditions. For this reason, relatively large groups of animals are used, which significantly increases the figures for uses of animals.

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

In 2017, the number of uses of animals for scientific purposes fell among all species except rats, carnivores, goats and cattle, reptiles and ‘other amphibians’.

In the case of rats, the greatest increase was in the area of applied research in relation to research on the gastro-intestinal system, the nervous system and the sensory organs.

Use of carnivores increased by around 45% in comparison with 2016, especially in diagnosis of diseases but also in regulatory use (mainly in kinetics and efficiency controls).

There was an increase in the use of species of farm animals for studies on diseases in such animals as target species for such diseases.

As in previous years, reptiles are mainly used in biology and ethology studies.

The common badger was used for the first time, in a study of animal diseases, as was the common spadefoot toad in studies of animal biology.

In assessing the figures on uses, it must be taken into account that there are users conducting research in the field of animal nutrition. They use relatively large groups of animals because they are working in conditions similar to commercial conditions. This significantly increases the figures reported, as can be seen in the studies carried out in the area of nutrition in chickens for fattening. This is also the reason for the significant reduction in the use of cephalopods given that, in 2017, this type of study was no longer being conducted.

The overall use of mice fell significantly, however their use increased in applied research in cancer, respiratory diseases and diseases of the nervous system.

The number of uses of fish fell by almost 40%. Nevertheless, there was a significant increase in the number of uses of genetically modified fish with a harmful phenotype, also partly due to a better understanding of the behaviour and biology of the fish, making it possible to identify the signs of the aforementioned harmful phenotype.

The proportion of ‘other animal species’ remains high as there are several registered users that work with wildlife, in particular mammals and birds. Furthermore, the field of aquaculture, and the development of technologies to extend the practice, requires the use of ‘non-habitual’ species of fish in significant numbers. The main species used are sea-bream, sea-bass, turbot, salmon and trout.

In 2017, an increase was apparent in the reuse of animals although it is difficult to evaluate the actual trend as the concept of ‘reuse’ has not always been interpreted consistently by reporters. The increase is especially clear in the reuse of dogs, cats and primates.

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

As stated in previous reports, in Spain assigning severity to uses of animals is one of the most significant new aspects of Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes. It was done for the first time when the Directive was applied: in the year 2013 with the report issued in 2014.

Furthermore, assignment of severity is a complex process. On the one hand, it is necessary to be aware of a broad range of circumstances, and on the other hand those responsible for assigning severity need to be widely experienced in recognising the elements and their weighting in order to assign specific categories of severity. It is understood that, where there is uncertainty about an assignment, preference is given to assessments that are more sensitive to the suffering of the animals involved. This means that assignment tends towards the levels that are more [...]

In 2017, as in previous years, the apparent fall in the proportion of ‘non-recovery’ uses continues. However this variation can be attributed to an improvement in the quality of the information as a result of the concept of ‘non-recovery’ use being clarified rather than to changes in the characteristics of the studies.

In 2017, an increase is apparent in the severity observed, especially in the procedures carried out with fish. This is due not only to the characteristics of the projects, but also to more training in identifying welfare indicators in this group of animals.

Nevertheless, the relative increase continues in uses with ‘mild’ severity with a corresponding decrease in ‘moderate’. This is presumably due to the application of measures to refine procedures.

As in previous years, the greatest severities are associated with regulatory uses of animals required by European Union legislation. To a lesser extent, to studies on animal diseases [...]

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

It is understood that promoting the principles of the three ‘Rs’ must be done in a combined form by the competent authorities, the users, through the various bodies responsible for animal welfare - which, in Spain, in the user centres, are known as ‘ethics committees for animal experimentation’ - and by the assessment bodies, which in Spain are termed ‘empowered bodies’ authorised by the competent authorities for this purpose. Given the uniqueness of the composition of the empowered bodies, the competent authorities consider it vital to concentrate on optimising that composition.

The consultative committees established by some competent authorities conduct a supplementary assessment of ‘sensitive’ projects, especially those involving severe procedures. The purpose is a more thorough assessment of the possibilities of reducing the number of animals, and of refining the techniques in order to minimise the number of animals that undergo this level of suffering.

Staff training involves both initial skills training in order to be able to work with animals and ongoing training. It is a basic tool for correctly applying the alternative strategies to the use of live animals in research and teaching. Proper training confers not only knowledge of the techniques, approaches and tools that can be useful, but also greater motivation for using them.

The user centres are working to optimise the sharing of animal models, and of the animals themselves, especially their cadavers in order to avoid the unnecessary killing of animals.

In order to reduce the number of animals and adapt the project designs, pilot studies are being carried out to enable research to be directed to much more specific procedures.

One of the areas in which the greatest effort is being made is in dissemination of reference tools and databases, along with access to articles, publications and guides related to the application of the three ‘Rs’, using emails to centres and sector organisations.

As in previous years, efforts continue in the field of teaching with increasing use of virtual simulators, artificial models, work with organs of animals not bred especially for this purpose, and cadavers.

The inclusion of statistical experts in the teams represents an improvement in the design of procedures, making it possible to reduce the number of animals used.

Furthermore in their applications for project authorisation, project managers are required to provide increasingly detailed information with regard to strategies for applying the three ‘Rs’.

In tissue sampling, this involves improving or substituting certain techniques, for example avoiding genotyping by tail-docking.

1. **Further breakdown on the use of ‘other’ categories if a significant proportion of animal use is reported under this category.**

As in previous years, the number of uses of ‘other species’ is very high, totalling almost 50,000 uses.

The vast majority (90% of uses under ‘other species’) corresponds to fish other than zebrafish. As in previous years, it mainly concerns uses of fish species from aquaculture in order to understand their needs. Such fish include sea-bream, sea-bass, turbot, salmon and trout.

Of these ‘other animals’, 5% are birds used in the study of biology, behaviour and pathologies in wild birds.

In the case of ‘other purposes’, in basic research the majority are concerned with the field of animal nutrition, and of aquaculture, and in toxicology other quality controls, especially in conducting checks for absence of external viruses, duration of immunity and categorisation of active principles.

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

This situation has not arisen in Spain.

## Spain: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 523467 | 65.19% |
| Rats | 56036 | 6.98% |
| Guinea-Pigs | 6747 | 0.84% |
| Hamsters (Syrian) | 599 | 0.07% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 141 | 0.02% |
| Rabbits | 25931 | 3.23% |
| Cats | 531 | 0.07% |
| Dogs | 1476 | 0.18% |
| Ferrets | 164 | 0.02% |
| Other carnivores | 25 | 0% |
| Horses, donkeys and cross-breeds | 61 | 0.01% |
| Pigs | 8656 | 1.08% |
| Goats | 369 | 0.05% |
| Sheep | 1953 | 0.24% |
| Cattle | 1700 | 0.21% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey | 451 | 0.06% |
| Rhesus monkey |  |  |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 99 | 0.01% |
| Domestic fowl | 82107 | 10.23% |
| Other birds | 2535 | 0.32% |
| Reptiles | 1003 | 0.12% |
| Rana | 18 | 0% |
| Xenopus | 1204 | 0.15% |
| Other Amphibians | 1996 | 0.25% |
| Zebra fish | 41020 | 5.11% |
| Other Fish | 44667 | 5.56% |
| Cephalopods | 20 | 0% |
| Total | 802976 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 745928 | 94.13% |
| Animals born in the EU but not at a registered breeder | 45911 | 5.79% |
| Animals born in rest of Europe | 33 | 0% |
| Animals born in rest of world | 606 | 0.08% |
| Total | 792478 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 104 | 42.28% |
| Animals born in America |  |  |
| Animals born in Africa | 142 | 57.72% |
| Animals born elsewhere |  |  |
| Total | 246 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 2 | 0.81% |
| F2 or greater | 244 | 99.19% |
| Self-sustaining colony |  |  |
| Total | 246 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 329508 | 41.04% |
| Translational and applied research | 281870 | 35.1% |
| Regulatory use and Routine production | 120192 | 14.97% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 6048 | 0.75% |
| Preservation of species | 371 | 0.05% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 11785 | 1.47% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 53202 | 6.63% |
| Total | 802976 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 28417 | 8.62% |
| Cardiovascular Blood and Lymphatic System | 26264 | 7.97% |
| Nervous System | 78970 | 23.97% |
| Respiratory System | 2457 | 0.75% |
| Gastrointestinal System including Liver | 8885 | 2.7% |
| Musculoskeletal System | 6997 | 2.12% |
| Immune System | 24659 | 7.48% |
| Urogenital/Reproductive System | 6548 | 1.99% |
| Sensory Organs (skin, eyes and ears) | 10283 | 3.12% |
| Endocrine System/Metabolism | 22634 | 6.87% |
| Multisystemic | 37812 | 11.48% |
| Ethology / Animal Behaviour /Animal Biology | 73215 | 22.22% |
| Other basic research | 2367 | 0.72% |
| Total | 329508 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 116597 | 41.37% |
| Human Infectious Disorders | 13579 | 4.82% |
| Human Cardiovascular Disorders | 6440 | 2.28% |
| Human Nervous and Mental Disorders | 21394 | 7.59% |
| Human Respiratory Disorders | 2713 | 0.96% |
| Human Gastrointestinal Disorders including Liver | 8755 | 3.11% |
| Human Musculoskeletal Disorders | 2052 | 0.73% |
| Human Immune Disorders | 5093 | 1.81% |
| Human Urogenital/Reproductive Disorders | 1160 | 0.41% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 15801 | 5.61% |
| Human Endocrine/Metabolism Disorders | 15652 | 5.55% |
| Other Human Disorders | 1651 | 0.59% |
| Animal Diseases and Disorders | 50632 | 17.96% |
| Animal Welfare | 8413 | 2.98% |
| Diagnosis of diseases | 9848 | 3.49% |
| Plant diseases | 10 | 0% |
| Non-regulatory toxicology and ecotoxicology | 2080 | 0.74% |
| Total | 281870 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 10180 | 91.97% |
| Other lethal methods |  |  |
| Non lethal methods | 889 | 8.03% |
| Total | 11069 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of 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 use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 124 | 79.49% |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity | 32 | 20.51% |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 156 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | 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 to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 32566 | 27.09% |
| Legislation on medicinal products for veterinary use and their residues | 62289 | 51.82% |
| Medical devices legislation | 138 | 0.11% |
| Industrial chemicals legislation | 3194 | 2.66% |
| Plant protection product legislation | 28 | 0.02% |
| Biocides legislation | 56 | 0.05% |
| Food legislation including food contact material | 21850 | 18.18% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 68 | 0.06% |
| Cosmetics legislation |  |  |
| Other legislation | 3 | 0% |
| Total | 120192 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 107209 | 89.2% |
| Legislation satisfying national requirements only [within EU] | 4112 | 3.42% |
| Legislation satisfying Non-EU requirements only | 8871 | 7.38% |
| Total | 120192 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 792724 | 98.72% |
| Yes | 10252 | 1.28% |
| Total | 802976 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 41203 | 5.13% |
| Mild [up to and including] | 415094 | 51.69% |
| Moderate | 280781 | 34.97% |
| Severe | 65898 | 8.21% |
| Total | 802976 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 779035 | 97.02% |
| Yes | 23941 | 2.98% |
| Total | 802976 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 512735 | 63.85% |
| Genetically altered without a harmful phenotype | 243856 | 30.37% |
| Genetically altered with a harmful phenotype | 46385 | 5.78% |
| Total | 802976 | 100.00% |

# Sweden

## Sweden: Narrative 2015

**Adjustments in 2018**

The European Commission noticed some irregularities in the Swedish statistic for 2015. After being in contact with four users, we have adjusted their reports. In total for 2015 (after the adjustments), 254,789 animal uses were reported, of which 235,961 animal uses were reported as first time use. We have not updated the text below. For updated numbers for 2015 and 2016, see the narrative for 2017.

**1. General information on any changes in trends observed since the previous reporting period.**  
  
**1.1 Number of animals**   
In 2015 SE 224,979 animals are reported in first time use, compared to 278,885 in 2014. The total figure encompassing reuse is 258,403 for 2015 and 284,170 for 2014.

The most used animal species are mice, followed by fish (mainly zebra fish) and rats. These categories topped the usage also in 2014. The figure for mice is lower compared to 2014, as is the figure for rats and other fish, while the use of zebra fish has increased.

The major part of animals are used within *Basic Research* (78 %), followed by *Translational and applied research* (17 %).   
  
**1.2 More detailed data through the new statistics**

Directive 2010/63/EU and Commission implementing decision 2012/707/EU contain several new objects to be collected in the statistics, for example a more detailed division of research areas. A reason for doing so is to enable identification of more areas within which animals are used, and not ending up aggregating them in an unidentifiable ‘*Other’* group.

Earlier reports from both the EU as a whole and SE showed a large proportion of animals being reported under more undefined areas of ‘*Other…*’ for example *Other human diseases*. The new more elaborate categories in 2012/707/EU resulted in the 2014 report in a diminishing of the amount of animals being categorised as ‘*others*’. This is repeated in the 2015 data. To illustrate, the figures from *Basic research* and *Translational and applied research* are shown below. Figures in red are the new topics that were introduced through 2012/707/EU.

1. **Basic Research (first use and re-use); number of uses 200,580**   
   Oncology 7 %  
   Cardiovascular Blood and Lymphatic System 14 %  
   Nervous System 22 %Respiratory System 1 %  
   Gastrointestinal System including Liver 2 %   
   Musculoskeletal System 2 %   
   Immune System 15 %  
   Urogenital/Reproductive System 1 %   
   Sensory Organs (skin, eyes and ears) 2 %   
   Endocrine System/Metabolism 9 %   
   Multisystemic 9 %   
   Ethology / Animal Behaviour /Animal Biology 10 %   
   Other 6 %   
     
   Thus, for 2015, 51 % of basic research could be closer identified thanks to the new division of topics compared to the statistics collected using the former directive. The total use in category *Other basic research* is 6 % in 2015 compared to 8 % in 2014.
2. **Translational and applied research (first use and re-use); number of uses 43,441**   
   Human Cancer 27 %   
   Human Infectious Disorders 2%   
   Human Cardiovascular Disorders 17 %   
   Human Nervous and Mental Disorders 6 %   
   Human Respiratory Disorders 15 %   
   Human Gastrointestinal Disorders including Liver 1 %   
   Human Musculoskeletal Disorders 1 %  
   Human Immune Disorders 5 %   
   Human Urogenital/Reproductive Disorders <1 %   
   Human Sensory Organ Disorders (skin, eyes and ears) <1 %   
   Human Endocrine/Metabolism Disorders 7 %  
   Other Human Disorders 4 %   
   Animal Diseases and Disorders 10 %   
   Animal Welfare < 1%   
   Diagnosis of diseases 1 %   
   Plant diseases 0%  
   Non-regulatory toxicology and ecotoxicology 5 %

Thus, for 2015, only 4 % of the translational and applied research was specified into more detailed human disorders instead of ending up in *Other human disorders*, compared to 20 %  
in 2014. These have been identified as pharmacokinetic studies, pharmacological analysis of new formulations of already approved pharmaceuticals, pharmacological studies of candidate drugs, research on hemorrhagic chock, skin and transplantation research, hematology, skeleton and cartilage diseases, development of models for sepsis and treatment of severe infections affecting organs and circulation, and development of pharmaceuticals against preeclampsia.

1. **Genetic status**

Results show that most uses are animals that are genetically altered without a harmful phenotype (49%), followed by not genetically altered (44 %), and finally genetically altered with a harmful phenotype (7 %). This is a slight shift from 2014, where the main use was not genetically altered (51 %), followed by genetically altered without a harmful phenotype (46%), and genetically altered with a harmful phenotype (3%).

1. **Creation of a genetically modified line**  
   The amount of uses in the creation of genetically modified line has increased from 1 % in 2014 to 10 % in 2015.
2. **Regulatory use and routine production; number of uses 2,188**

SE has a low figure in regulatory use during 2015, in line with previous reports. Most of the animals have been used in *toxicity and other safety testing including pharmacology* (93 %), mainly used in *ecotoxicity* (62 %) followed by *pharmaco-dynamics* (26 %), *kinetics* (7 %), *repeated dose toxicity* (4 %) and *other toxicity/safety testing* (1 %). The remaining 7% under regulatory use and routine production falls under *Other efficacy and tolerance testing*.

There is a drop in the figures from 2014; from 12,175 uses to 2,188 uses in 2015. This is due to an erroneous reporting in 2014 of regulatory use of roosters (9,664 uses), for more details see 2.ii. These uses were wrongly reported as EU statistics, when they should have been reported in the national statistics only. The error was detected in time for this report, and is thus not repeated for 2015.

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

**i. Total number of uses**

There is a decrease in the total number of uses. There is, however, no clear reason for the decrease which can be due to normal fluctuations in research efforts and/or financing.

**ii. Species**

We see a slight decrease in the percentage of mice being used; 175,962 compared to 197,491 in 2014. During the last years the figure has been approximately the same although slightly decreasing compared to earlier years.

The use of rats decreased from 26,762 in 2014 to 21,907 in 2015. This is in line with the last years where the use has been decreasing.

The use of zebrafish more than doubled from 8,171 in 2014 to 20,519 in 2015. A major reason for this was a significant increase in the use of zebrafish in *Basic Research/Multisystemic* between the years, from 3,174 uses in 2014 to 16,233 uses in 2015.

The use of other fish has decreased by a third from 21,697 in 2014 to 14,355 in 2015. This is partly explained by a large feeding regime study constituting ca 25 % of the total uses in 2014, as well as one user having a significant decrease in use in 2015. However, there are many users and many different projects, especially during 2014, and the analysis is complex.

The use of domestic fowl decreased from 10,899 in 2014 to 5,266 in 2015. However, what seems like a decrease is in fact an increase – in 2014, SE reported 9,664 domestic fowl, more specifically roosters, used for the production and harvesting of hyaluronic acid from their combs, as EU statistics. In 2015 roosters have been used for the same purpose, however, after due consideration this use has been categorized as non-EU purpose. The roosters used in 2014 were thus erroneously reported as EU statistics. The use in 2015 is now mostly derived from two major studies at one user; one on welfare indicators and one on ecologically produced chicken.

There was a rise in the use of cattle, from 129 in 2014 to 2,097 in 2015. The major part was under 2015 used in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* – but there was also a specific project on raw milk during the year causing the figures to increase.

Other rodents decreased slightly from 5,296 in 2014 to 3,323 in 2015. The decrease was almost in total due to a lower use by the same user and at least in part due a misreporting of insectivores under Other rodents, instead of reporting these under Other mammals. This was corrected in the 2015 report leading to a higher amount in this area; Other mammals doubled from 1,128 in 2014 to 2,104 in 2015.   
  
Under 2015 57 uses of ferrets were reported whereas none was reported for 2014. The ferrets were used in a study under *Basic research/Nervous system*.

The use of horses, donkeys and cross-breads increased from 58 in 2014 to 275 in 2015. The increase is to the major part due to a large study on *Translational and applied research/Animal Diseases and Disorders.*  
  
The use of pigs has increased from 585 in 2014 to 1,625 in 2015.This change is in part due to studies performed by users who did not use pigs in 2014, and also partly to an increase in the use of pigs for *Higher education or training for the acquisition, maintenance or improvement of vocational skills* by 420 uses.   
  
The use of reptiles increased from 9 uses in 2014 to 50 in 2015. Both years the use took place in individual studies under *Basic Research/ Ethology/Animal Behaviour/Animal Biology*; one on European grass snake (*Natrix natrix*) (2014)and the other on the common European adder (*Vipera berus*) (2015).  
  
Under 2015 600 uses of *Rana* were reported whereas none was reported for 2014. The *Rana* were used in a study for *Protection of the natural environment in the interests of the health or welfare of human beings or animals.*

The use of *Xenopus* decreased from 1,598 in 2014 to 574 in 2015. In 2014 more users performed studies on *Xenopus*, and there were also larger studies in *Translational and applied research/ Non-regulatory toxicology and ecotoxicology* as well as studies of the ability of the nervous system and the locomotion to heal themselves and gene function under *Basic Research/Other.*

The use of Other amphibians decreased from 2,857 uses in 2014 to 1,894 in 2015. In 2014 there was a large study of pH-changes in aquaria under *Basic Research/Ethology/Animal Behaviour /Animal Biology* with 2,080 uses, but the smaller decrease in 2015 does not reflect this entirely. A further explanation is that more animals were used in studies of the ability of the nervous system and the locomotion to heal themselves and gene function under *Basic Research/Other* in 2015 compared to 2014.

**iii. Use in specific areas**

The major part of animals are used within *Basic Research* (78 %), followed by *Translational and applied research* (17 %), *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (2 %), *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (1 %), *Regulatory use and Routine production* (1 %), *Preservation of species* (<1 %), and finally *Maintenance of colonies of established genetically altered animals, not used in other procedures* (<1 %). This is in close correlation with figures from 2014, with the exception of *Preservation of species* which had decreased from 3 % to less than 1 % in 2015.The figures concerning *Regulatory use and Routine production* show a decrease from 4 % to 1 % in 2015, however, the 2014 figure is too high due to an erroneous report (for explanation see 1.2.v. and 2.ii.), therefore it is not a true decrease.

A comparison of specific areas under *Basic research* 2015 and 2014 shows many areas exhibit close correlation between the two years. There is a slight decrease in   
*Cardiovascular Blood and Lymphatic System* (14 % vs 19 %), Nervous System (22 % vs 30 %), *Urogenital/Reproductive System* (1 % vs 2 %) and *Other basic research* (6 % vs 8%). There is a slight increase in *Gastrointestinal System including Liver* (2 % vs 1 %), *Immune System* (15 % vs 12%), *Sensory Organs (skin, eyes and ears)* (2 % vs 1%) *Multisystemic* (9 % vs 7%), and *Ethology/Animal Behaviour/Animal Biology* (10 % vs 4 %). However, it is too early to tell if these changes are trends or simply normal fluctuations in research.

Furthermore, a comparison of specific areas under *Translational and applied research* 2015 and 2014 also shows close correlation between the two years. There is a slight decrease in *Human Nervous and Mental Disorders* (6 % vs 7 %), *Human Respiratory Disorders* (15 % vs 16 %), *Other Human Disorders* (4 % vs 20 %), *Animal Diseases and Disorders* (10 % vs 11 %), *Diagnosis of diseases* (1 % vs 2 %), and *Non-regulatory toxicology and ecotoxicology* (5 % vs 8 %). There is a slight increase in *Human Cancer* (27 % vs 19 %), *Human Infectious Disorders* (2 % vs 1 %), *Human Cardiovascular Disorders* (17 % vs 12 %), *Human Immune Disorders* (5 % vs 3 %), and *Human Endocrine/Metabolism Disorders* (7 % vs 0 %). As for *Basic research* it is too early to tell if these changes are trends or simply normal fluctuations in research.

**iv. Reuse**

Reuse is 13 % in 2015 compared to 2 % in 2014. The higher figure could indeed to some extent be due to a higher reuse, however, analysis of data has clarified that it is at least in part due to a misconception of the definition of reuse with some users, leading to animals erroneously being recorded as reuse when they should not have been. Where it has been possible to correct the figures this has been done, but this was not possible in all cases. Information work has been initiated to clear this misunderstanding in future reporting.

**3. Information on any changes in trends in actual severities and analysis of the reasons thereof.**  
  
The results for 2015 show that (51 %) procedures are moderate followed by mild [up to and including] (36 %), non-recovery (6 %) and finally severe (7 %). It follows rather closely the figures from 2014, where (56 %) procedures were moderate followed by mild [up to and including] (28 %), non-recovery (9 %) and finally severe (7 %). No conclusions can be drawn from the material at this stage.

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

The Swedish Board of Agriculture is since 2015 building a competence centre for the 3Rs. The Swedish National Committee will act as the steering group for the centre, which will be in place late 2017.

The purpose of the 3Rs centre is to promote and coordinate the work on alternative methods to animal experiments together with stakeholders, such as regional ethics committees, authorities, researchers and animal welfare organizations. The 3Rs centre shall obtain, provide and actively disseminate information on the 3Rs. The Swedish Board of Agriculture considers that the national work with the 3Rs, including the project evaluation process will be considerably strengthened through the establishment of the 3Rs centre.

Under 2016, the Swedish National Committee for the protection of animals used for scientific purposes held two courses for the members of the regional ethics committees together with the Swedish Board of Agriculture. The National Committee also held a meeting with the animal welfare bodies. These efforts were made towards increasing the consciousness of the 3Rs.

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

**5.1 Other animals**

**i. Fish**

41 % of the reported fish constitutes of *Other fish*. Many different species are used, e.g. three-spined stickleback (*Gasterosteus aculeatus*), perch (*Perca fluviatilis*), eel (*Anguilla anguilla*), brown trout (*Salmo trutta*), rainbow trout (*Oncorhynchus mykiss*), *Cyclostomata*, salmon (*Salmo salar*), pike (*Esox lucius*) and burbot (*Lota lota*).

These were used mainly for *Basic research/Ethology/Animal behaviour/animal biology*, but also in f e *Protection of the natural environment in the interests of the health or welfare of human beings or animals and* Preservation of species. In translational and applied research fish were used in *Non-regulatory toxicology and ecotoxicology*.

**ii. Amphibians**

More than half, 62 %, of the amphibians are registered as *Other amphibians*. These are Iberian ribbed newt (*Pleurodeles waltl*), eastern newt (*Notophthalmus viridescens*), European green toad (*Bufotes viridis*) and natterjack toad (*Epidalea calamita*).

Iberian ribbed newt and eastern newt have been used in *Other basic research*, more specifically studies of the ability of the nervous system and the locomotion to heal themselves and gene function. European green toad and natterjack toad have been used in *Basic Research/Ethology /Animal Behaviour /Animal Biology.*

**iii. Birds**

A large percentage, 55 %, among the birds constitutes of *Other birds.* These are Old World flycatchers (*Muscicapidae*), collared flycatcher (*Ficedula albicollis*), Eurasian blue tit (*Cyanistes caeruleus*), great tit (*Parus major*), mallard (*Anas platyrhyncos*), northern wheatear (*Oenanthe oenanthe*), Eurasian teal (*Anas crecca*), bean goose (*Anser fabalis),* willow warbler (*Phylloscopus trochilus*), golden eagle (*Aquila chrysaetos*), Eurasian wryneck (*Jynx torquilla*), Eurasian skylark (*Alauda arvensis*), carrion crow (*Corvus [corone] corone*), hooded crow (*Corvus [corone] cornix)*, common crane (*Grus grus*), Eurasian wigeon (*Anas penelope*), tufted duck (*Aythya fuligula*), common pochard (*Aythya ferina*), and northern pintail (*Anas acuta*)*.*

Approximately half of these birds have been used in *Basic research/Other*, more specifically for blood sampling for gene analyses and prevalence of malaria, infections in wild animals, or behavioural studies without restraining equipment. The remaining half has been used in *Basic Research/ Ethology / Animal Behaviour /Animal Biology*.

**iv. Carnivores**

Among the carnivores SE had a large percentage (38 %) of *Other carnivores*. These are raccoon dog (*Nyctereutes procyonoides*), fox (*Vulpes vulpes*), American mink (*Neovison vison*), Eurasian lynx (*Lynx lynx*), wolf (*Canis lupus*) and wolverine (*Gulo gulo*).

They have all been used in *Basic research/Ethology/Animal behaviour/animal biology*, apart from the racoon dogs, which have been used in *Translational and applied research/Animal Welfare.*

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

There has been no such case in SE up to this date.

## Sweden: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 175904 | 69.04% |
| Rats | 21907 | 8.6% |
| Guinea-Pigs | 482 | 0.19% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents |  |  |
| Rabbits | 446 | 0.18% |
| Cats | 23 | 0.01% |
| Dogs | 115 | 0.05% |
| Ferrets | 57 | 0.02% |
| Other carnivores | 118 | 0.05% |
| Horses, donkeys and cross-breeds | 275 | 0.11% |
| Pigs | 1625 | 0.64% |
| Goats |  |  |
| Sheep | 52 | 0.02% |
| Cattle | 2097 | 0.82% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey | 7 | 0% |
| Rhesus monkey | 1 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 1871 | 0.73% |
| Domestic fowl | 5266 | 2.07% |
| Other birds | 6551 | 2.57% |
| Reptiles | 50 | 0.02% |
| Rana | 600 | 0.24% |
| Xenopus | 574 | 0.23% |
| Other Amphibians | 1894 | 0.74% |
| Zebra fish | 20519 | 8.05% |
| Other Fish | 14355 | 5.63% |
| Cephalopods |  |  |
| Total | 254789 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 190472 | 80.72% |
| Animals born in the EU but not at a registered breeder | 39960 | 16.94% |
| Animals born in rest of Europe | 249 | 0.11% |
| Animals born in rest of world | 5277 | 2.24% |
| Total | 235958 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 3 | 100% |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 3 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 3 | 100% |
| Self-sustaining colony |  |  |
| Total | 3 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 202450 | 79.46% |
| Translational and applied research | 39885 | 15.65% |
| Regulatory use and Routine production | 2188 | 0.86% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 6280 | 2.46% |
| Preservation of species | 500 | 0.2% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 3331 | 1.31% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 155 | 0.06% |
| Total | 254789 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 13825 | 6.83% |
| Cardiovascular Blood and Lymphatic System | 28833 | 14.24% |
| Nervous System | 44616 | 22.04% |
| Respiratory System | 1652 | 0.82% |
| Gastrointestinal System including Liver | 3971 | 1.96% |
| Musculoskeletal System | 4597 | 2.27% |
| Immune System | 29358 | 14.5% |
| Urogenital/Reproductive System | 2892 | 1.43% |
| Sensory Organs (skin, eyes and ears) | 3495 | 1.73% |
| Endocrine System/Metabolism | 18578 | 9.18% |
| Multisystemic | 18073 | 8.93% |
| Ethology / Animal Behaviour /Animal Biology | 19510 | 9.64% |
| Other basic research | 13050 | 6.45% |
| Total | 202450 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 11929 | 29.91% |
| Human Infectious Disorders | 883 | 2.21% |
| Human Cardiovascular Disorders | 7234 | 18.14% |
| Human Nervous and Mental Disorders | 2777 | 6.96% |
| Human Respiratory Disorders | 6436 | 16.14% |
| Human Gastrointestinal Disorders including Liver | 386 | 0.97% |
| Human Musculoskeletal Disorders | 263 | 0.66% |
| Human Immune Disorders | 2053 | 5.15% |
| Human Urogenital/Reproductive Disorders | 117 | 0.29% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 109 | 0.27% |
| Human Endocrine/Metabolism Disorders | 2914 | 7.31% |
| Other Human Disorders | 1636 | 4.1% |
| Animal Diseases and Disorders | 728 | 1.83% |
| Animal Welfare | 18 | 0.05% |
| Diagnosis of diseases | 239 | 0.6% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 2163 | 5.42% |
| Total | 39885 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) |  |  |
| Routine production |  |  |
| Other efficacy and tolerance testing | 144 | 6.58% |
| Toxicity and other safety testing including pharmacology | 2044 | 93.42% |
| Total | 2188 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch potency testing |  |  |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 80 | 3.91% |
| Kinetics | 145 | 7.09% |
| Pharmaco-dynamics (incl safety pharmacology) | 535 | 26.17% |
| Ecotoxicity | 1260 | 61.64% |
| Other toxicity/safety testing | 24 | 1.17% |
| Total | 2044 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days | 80 | 100% |
| Total | 80 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity | 1260 | 100% |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total | 1260 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 928 | 42.41% |
| Legislation on medicinal products for veterinary use and their residues |  |  |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment | 1260 | 57.59% |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 2188 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 928 | 42.41% |
| Legislation satisfying national requirements only [within EU] | 1260 | 57.59% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 2188 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 235961 | 92.61% |
| Yes | 18828 | 7.39% |
| Total | 254789 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 11034 | 4.33% |
| Mild [up to and including] | 92991 | 36.5% |
| Moderate | 132628 | 52.05% |
| Severe | 18136 | 7.12% |
| Total | 254789 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 228629 | 89.73% |
| Yes | 26160 | 10.27% |
| Total | 254789 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 109855 | 43.12% |
| Genetically altered without a harmful phenotype | 126664 | 49.71% |
| Genetically altered with a harmful phenotype | 18270 | 7.17% |
| Total | 254789 | 100.00% |

## Sweden: Narrative 2016

**Adjustments in 2018**

The European Commission noticed some irregularities in the Swedish statistic for 2016. After being in contact with four users, we have adjusted their reports. In total for 2016 (after the adjustments), 345,433 animal uses were reported, of which 339,299 animal uses were reported as first time use. We have not updated the text below. For updated numbers for 2015 and 2016, see the narrative for 2017.

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

For 2016, 344,255 uses were reported as first time use, compared to 224,979 in 2015. The total figure encompassing re-use was 258,403 for 2015 and 350,664 for 2016. The large part of the increase (93 %) constitutes of mice – 85,885 more mice used in 2016 compared to 2015 (first time use and re-use).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Re-Use** | **2015** | | **2016** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| No | *224,979* | *87* | *344,255* | *98* |
| Yes | *33,424* | *13* | *6,409* | *2* |
| **Totally** | ***258,403*** | ***100*** | ***350,664*** | ***100*** |

The most used animal species were mice, followed by zebra fish, rats and other fish. These four categories topped the usage also in 2015. The uses of mice, zebra fish and other fish increased numerically compared to 2015 (mice: 175,962 vs 261,847, zebrafish: 20,519 vs 24,607, and other fish: 14,355 vs 18,024). The use of rats was similar in 2015 and 2016 (21,907 vs 21,218). For the first time more uses of zebra fish than rats were reported (24,607 compared to 21,218). The major part of animals are used within *Basic Research* (81 %), followed by *Translational and applied research* (14 %).   
  
**1.2 More detailed data through the new statistics**

Directive 2010/63/EU and Commission implementing decision 2012/707/EU contain several new objects to be collected in the statistics, for example a more detailed division of research areas. A reason for doing so is to enable identification of more areas within which animals are used, and not ending up aggregating them in an unidentifiable ‘*Other’* group.

Earlier reports from both the EU as a whole and SE showed a large proportion of animals being reported under more undefined areas of ‘*Other…*’ for example *Other human diseases*. The new more elaborate categories in 2012/707/EU resulted in the 2014 report in a diminishing of the amount of animals being categorised as ‘*others*’. This pattern is repeated in the 2015 as well as the 2016 data. To illustrate, the figures from *Basic research* and *Translational and applied research* are shown below. Figures in red are the new topics that were introduced through 2012/707/EU.

1. **Basic Research (first use and re-use)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Basic research** | **2015** | | **2016** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Oncology | 13,825 | *7* | 28,930 | *10* |
| Cardiovascular Blood and Lymphatic System | 28,833 | *14* | 39,229 | *14* |
| Nervous System | 44,616 | *22* | 51,837 | *18* |
| Respiratory System | 1,652 | *1* | 2,732 | *1* |
| Gastrointestinal System including Liver | 3,971 | *2* | 6,256 | *2* |
| Musculoskeletal System | 4,597 | *2* | 7,120 | *3* |
| Immune System | 29,358 | *15* | 42,537 | *15* |
| Urogenital/Reproductive System | 2,892 | *1* | 2,658 | *1* |
| Sensory Organs (skin, eyes and ears) | 3,495 | *2* | 4,523 | *2* |
| Endocrine System/Metabolism | 18,578 | *9* | 25,651 | *9* |
| Multisystemic | 18,073 | *9* | 31,111 | *11* |
| Ethology / Animal Behaviour /Animal Biology | 19,510 | *10* | 16,487 | *6* |
| Other basic research | 13,050 | *6* | 24,836 | *9* |
| **Totally** | ***202,450*** | ***100*** | ***283,907*** | ***100*** |

Thus, for 2016, 49 % of basic research could be closer identified thanks to the new division of topics compared to the statistics collected using the former directive. The total use in category *Other basic research* was 9 % in 2016 compared to 6 % in 2015.

1. **Translational and applied research (first use and re-use)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Translational and applied research** | **2015** | | **2016** | |
| ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Human Cancer | 11,929 | *27* | 14,014 | *28* |
| Human Infectious Disorders | 883 | *2* | 973 | *2* |
| Human Cardiovascular Disorders | 7,234 | *17* | 5,606 | *11* |
| Human Nervous and Mental Disorders | 2,777 | *6* | 4,523 | *9* |
| Human Respiratory Disorders | 6,436 | *15* | 5,806 | *11* |
| Human Gastrointestinal Disorders including Liver | 386 | *1* | 279 | *1* |
| Human Musculoskeletal Disorders | 263 | *1* | 246 | *<1* |
| Human Immune Disorders | 2,053 | *5* | 1,441 | *3* |
| Human Urogenital/Reproductive Disorders | 117 | *<1* | 75 | *<1* |
| Human Sensory Organ Disorders (skin, eyes and ears) | 109 | *<1* | 292 | *1* |
| Human Endocrine/Metabolism Disorders | 2,914 | *7* | 3,288 | *7* |
| Other Human Disorders | 1,636 | *4* | 3,802 | *8* |
| Animal Diseases and Disorders | 4,284 | *10* | 1,160 | *2* |
| Animal Welfare | 18 | *<1* | 6,578 | *13* |
| Diagnosis of diseases | 239 | *1* | 530 | *1* |
| Plant diseases | 0 | *0* | 0 | *0* |
| Non-regulatory toxicology and ecotoxicology | 2,163 | *5* | 1,955 | *4* |
| **Totally** | ***43, 441*** | ***100*** | ***50,568*** | ***100*** |

For 2016, 38 % of the translational and applied research could be closer identified thanks to the new division of topics compared to the statistics collected using the former directive. For 2016, 8% were classified as *Other human disorders*, compared to 4% in 2015.

These have been identified among others as the following: Studies on anti-bacterial therapies against wound infections, research and development of products or devices in human medicine, understanding of growth mechanisms to treat children with growth abnormalities, creation of cartilage and skin in animal models, skeleton and cartilage diseases, studies on pharmaceuticals for patients with disturbed skin barriers e.g. psoriasis and eczema, research on haematology, recreation of human organs using tissue therapy for transplantation, creating individually designed blood vessels using tissue therapy for transplantation, test of substances to prevent rejection of transplanted organs, and pharmacokinetic studies of new formulations of registered pharmaceuticals.

1. **Genetic status**For 2016 most uses were of animals that were genetically altered without a harmful phenotype (52%), followed by not genetically altered (42 %), and finally genetically altered with a harmful phenotype (6 %). The figures are similar to the distribution in 2015.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Genetic Status** | **2015** | | **2016** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Not genetically altered | 113,411 | *44* | 146,110 | *42* |
| Genetically altered without a harmful phenotype | 126,722 | *49* | 182,261 | *52* |
| Genetically altered with a harmful phenotype | 18,270 | *7* | 22,293 | *6* |
| **Totally** | **258,403** | ***100*** | **350,664** | ***100*** |

1. **Creation of a genetically modified line**  
   The amount of uses for the creation of genetically modified lines were 7 % for 2016 compared to 10 % in 2015.
2. **Regulatory use and routine production**

SE had a low figure in regulatory use during 2016 as in 2015. Most of the animals have been used in *Toxicity and other safety testing including pharmacology* (55 %), and *Quality control (incl batch safety and potency testing)* (40 %).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Regulatory use and routine production** | **2015** | | **2016** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Quality control (incl batch safety and potency testing) | 0 | *0* | 1,048 | *40* |
| Other efficacy and tolerance testing | 144 | *7* | 120 | *5* |
| Toxicity and other safety testing including pharmacology | 2,044 | *93* | 1,426 | *55* |
| Routine production | 0 | *0* | 5 | *<1* |
| **Totally** | **2,188** | ***100*** | **2,599** | ***100*** |

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

**i. Total number of uses**

There is an increase in the total number of uses reported, 350,664 uses in 2016 compared to 258,403 uses in 2015. The absolutely largest part of the increase (93 %) constitutes of mice – 85,885 more mice used in 2016 compared to 2015 (first time use and re-use).

**ii. Species**

There are increases as well as decreases in the number of uses in many of the species, however some of the species remain on the same level as the previous year. It is, however, difficult in most cases to determine the reasons behind the changes and also too early into the new reporting in accordance with Commission decision 2012/707/EU to tell if either increases or decreases are true significant differences that will prevail over time. We present data from 2014 to 2016 to illustrate the fluctuations over the past three year.

As discussed above, there was a large increase in number of mice uses being reported for 2016 (261,847 uses, 75 %) compared to 2015 (175,962 uses, 68 %). Much of this increase is due to a few users reporting considerably higher numbers for 2016 compared to 2015. In one case there is an increase of approximately 30,000 uses, and in another around 25,000 uses. The reason for this is unknown, but could be due to increased research funding, but also a mere consequence of the continuously rising use of mice in research that has been observed for the last decades.

Other rodents decreased from 3,323 uses in 2015 to 63 in 2016. All uses in 2016 were reported as *Basic Research* while all uses in 2015 was reported from one single user as *Translational and Applied Research*, more specifically as *Animal Diseases and Disorders*.

Cats increased from 23 uses in 2015 (all in *Basic Research/Musculoskeletal System*) to 94 uses in 2016 (54 uses in *Basic Research/Musculoskeletal System* and 40 uses in *Translational and applied research/Animal Diseases and Disorders*).

Dogs increased from 115 uses in 2015 to 204 uses in 2016. For both years most uses were reported as *Translational and applied research*. More specifically, in 2015, *Human Endocrine/ Metabolism Disorders* (83 uses), *Human Respiratory Disorders* (7 uses), *Non-regulatory toxicology and ecotoxicology* (14 uses), *Human Cardiovascular Disorders* (5 uses), and *Diagnosis of diseases* (2 uses). More specifically, in 2016,*Animal Diseases and Disorders* (128 uses), *Diagnosis of diseases* (21 uses), *Human Infectious Disorders* (6 uses), *Human Cardiovascular Disorders* (5 uses) and *Non-regulatory toxicology and ecotoxicology* (4 uses). The remaining uses in 2015 were reported in *Basic Research/Cardiovascular Blood and Lymphatic System* (5 uses), and in 2016 in *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (24 uses), *Basic Research/Other* (12 uses), and *Regulatory use and Routine production/Toxicity and other safety testing including pharmacology/Kinetics* (4 uses). The wide distribution between many different categories makes it difficult to find clear reasons for the increase.

Other mammals decreased from 2,104 uses in 2015 to 427 uses in 2016*.* The main difference depends on the 1,500 uses of reindeer in 2015, and none in 2016. *Ethology/Animal Behaviour/Animal Biology* was the most common purpose in both years; 1,871 uses in 2015 and 416 uses in 2016.

Rabbits increased from 446 uses in 2015 to 1,447 uses in 2016. Most uses of rabbits in 2016 concerned *Basic Research* (1,391 uses), more specifically *Other basic research* (885 uses) and *Respiratory System* (409 uses).

Horses/donkeys increased from 275 uses in 2015 to 824 uses in 2016. Most uses of horses/donkeys 2016 was reported as *Translational and Applied Research* (741 uses), more specifically as *Animal Diseases and Disorders*.

Domestic fowls decreased from 5,266 in 2015 to 971 in 2016. In 2016 most uses were reported in *Translational and applied research* (586 uses), whereas 385 uses were reported in *Basic research*. The more specific areas were diverse. Under *Basic research*; *Sensory Organs (skin, eyes and ears)* (144 uses), *Ethology / Animal Behaviour /Animal Biology* (105 uses), *Cardiovascular Blood and Lymphatic System* (84 uses), *Other basic research* (polyclonal antibodies) (37 uses), and *Endocrine System/ Metabolism* (15 uses). Under *Translational*: *Human Gastrointestinal Disorders including Liver* (240 uses), *Non-regulatory toxicology and ecotoxicology* (105 uses), *Human Respiratory Disorders* (90 uses), *Animal Diseases and Disorders* (90 uses) and *Diagnosis of diseases* (61 uses). In 2015 most uses were reported under *Basic research*, more specifically *Ethology / Animal Behaviour /Animal Biology* (4,140 uses, of which 3,240 uses are reported in a study on welfare indicators and 600 uses on ecologically produced chicken) and *Nervous System* (120 uses). Remaining uses were reported under *Translational and applied research*; *Animal Diseases and Disorders* (475 uses), *Non-regulatory toxicology and ecotoxicology* (351 uses) and *Diagnosis of diseases* (180 uses).

Other birds increased from 6,551 in 2015 to 11,583 in 2016. Almost all uses were reported as *Basic research*. In 2015, 3,008 uses were reported in *Ethology/Animal Behaviour/Animal Biology,* and 3,543 uses in *Other Basic Research* (blood sampling for gene analyses and prevalence of malaria, 2,969 uses; infections on wild animals, 553 uses; behavioural studies, 21 uses). In 2016, 4,570 uses were reported in *Ethology/Animal Behaviour/Animal Biology.* The large increase for 2016 is found under *Other Basic Research* with 6,940 uses reported(blood sampling for genetical analyses, 3,486; blood sampling, 3,072 uses; infections on wild animals, 365 uses; and behavioural studies, 17 uses). Remaining uses were reported under *Musculoskeletal System* (8 uses), *Sensory organs* (4 uses)and *Translational and applied research, Animal Diseases and Disorders* (61 uses).

Reptiles increased from 50 in 2015 to 380 in 2016. All were used in *Basic research*, more specifically, in 2015 in *Ethology / Animal Behaviour /Animal Biology*, and in 2016 in the *Other* category; 300 uses in evolutionary biology and 80 uses for blood sampling and marking.

The use of Other amphibians increased from 1,894 in 2015 to 3,923 in 2016. All were reported under Basic research. In 2015, 1,236 uses were reported for studies of the ability of the nervous system and the locomotion to heal themselves and gene function compared to 1,624 in 2016. In 2016, 1,320 uses of moor frog (*Rana arvalis*) were reported in *Basic Research/Ethology/Animal Behaviour/Animal Biology*, and another study in 2016 reported 553 uses for how the chytrid fungus *Batrachochytrium dendrobatidis* affects Swedish amphibians. Remaining uses were reported in the *Other* category for 2016 (426 uses, 130 of these for marking) and in *Ethology/Animal Behaviour/Animal Biology* for 2015 (658 uses).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Animal group** | **Animal species** | **2014** | **2015** | **2016** |
| Rodents | Mice | 197,491 | 175,962 | 261,847 |
|  | Rats | 26,762 | 21,907 | 21,218 |
|  | Guinea-Pigs | 663 | 482 | 422 |
|  | Hamsters (Syrian) | 0 | 0 | 0 |
|  | Hamsters (Chinese) | 0 | 0 | 0 |
|  | Mongolian gerbil | 0 | 0 | 0 |
|  | Other rodents | 5,296 | 3,323 | 63 |
| Lagomorphs | Rabbits | 571 | 446 | 1,447 |
| Carnivores | Cats | 28 | 23 | 94 |
|  | Dogs | 111 | 115 | 204 |
|  | Ferrets | 0 | 57 | 0 |
|  | Other carnivores | 91 | 118 | 167 |
| Ungulates | Horses, donkeys and cross-breeds | 58 | 275 | 824 |
|  | Pigs | 585 | 1,625 | 1,840 |
|  | Goats | 0 | 0 | 58 |
|  | Sheep | 51 | 52 | 27 |
|  | Cattle | 129 | 2,097 | 1,436 |
| Primates | Prosimians | 0 | 0 | 0 |
|  | Marmosets and tamarins | 0 | 0 | 0 |
|  | Cynomolgus monkey | 3 | 7 | 10 |
|  | Rhesus monkey | 0 | 1 | 28 |
|  | Vervets (Chlorocebus spp.) | 0 | 0 | 0 |
|  | Baboons | 0 | 0 | 0 |
|  | Squirrel monkey | 0 | 0 | 0 |
|  | Other species of New World Monkeys (Ceboidea) | 0 | 0 | 0 |
|  | Other species of Old World Monkeys (Cercopithecoidea) | 0 | 0 | 0 |
|  | Other species of non-human primates | 0 | 0 | 0 |
|  | Apes | 0 | 0 | 0 |
| Other mammals | Other mammals | 1,128 | 2,104 | 427 |
| Birds | Domestic fowl | 10,899 | 5,266 | 971 |
|  | Other birds | 5,972 | 6,551 | 11,583 |
| Reptiles | Reptiles | 9 | 50 | 380 |
| Amphibians | Rana | 0 | 600 | 623 |
|  | Xenopus | 1,598 | 574 | 441 |
|  | Other amphibians | 2,857 | 1,894 | 3,923 |
| Fish | Zebra fish | 8,171 | 20,519 | 24,607 |
|  | Other fish | 21,697 | 14,355 | 18,024 |
| Cephalopods | Cephalopods | 0 | 0 | 0 |
|  | **Total uses** | **284,170** | **258,403** | **350,664** |

**iii. Use in specific areas**

The uses in overall, in percentages, were similar in 2015 and 2016, but the percentages of two of the less frequent reported categories have changed between 2015 and 2016. The category *Protection of the natural environment in the interests of the health or welfare of human beings or animals* has dropped from2.4 % (6,280 uses) to 0.7 % (2,759 uses). *Maintenance of colonies of established genetically altered animals, not used in other procedures* has increased from 0.1 % (213 uses) to 1.6 % (5,676 uses).

The percentages for the specific areas under both *Basic research* and *Translational and applied research* 2015 and 2016 are similar. The most notable differences are for *Animal Diseases and Disorders* which were reported for 10 % (4,284 uses) in 2015 and 2 % (1,160 uses) in 2016 and *Animal Welfare* which increased from <1 % (18 uses) in 2015 to 13 % (6,578 uses) in 2016.

It is too early to tell if these changes are trends or simply normal fluctuations in research.

**iv. Re-use**

Re-use were reported for 2 % of the uses in 2016. For 2015, that number was 13 %; that higher figure could indeed to some extent be due to a higher re-use, however, analysis of data has clarified that it is at least in part due to a misconception of the definition of re-use with some users, leading to animals erroneously being recorded as re-used when they should not have been. Figures were corrected where it was possible, which was unfortunately not always the case. In order to improve the future quality of the reporting, information efforts were initiated, that are believed to have led to a more accurate reporting on re-use in the 2016 statistics.

**3. Information on any changes in trends in actual severities and analysis of the reasons thereof.**  
  
The proportion of moderate severity has increased from 51 % in 2015 to 58 % in 2016, while the proportions of *Mild* and *Non-recovery* have decreased. No conclusions can be drawn from the material at this stage.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Severity** | **2015** | | **2016** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Non-recovery | 14,648 | *6* | 6,427 | *2* |
| Mild (up to and including) | 92,991 | *36* | 112,034 | *32* |
| Moderate | 132,628 | *51* | 202,626 | *58* |
| Severe | 18,136 | *7* | 29,577 | *8* |
| **Totally** | **258,403** | ***100*** | **350,664** | ***100*** |

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

The Swedish parliament decided in late 2016 to finance a competence centre for the 3Rs, placed at the Swedish Board of Agriculture. The Swedish National Committee will act as the steering group for the centre. The centre will have its official opening on the 21th of November 2017.

The purpose of the 3Rs centre is to promote and coordinate the work on alternative methods to animal experiments together with stakeholders, such as regional ethics committees, authorities, researchers and animal welfare organizations. The 3Rs centre shall obtain, provide and actively disseminate information on the 3Rs. The Swedish Board of Agriculture considers that the national work with the 3Rs, including the project evaluation process will be considerably strengthened through the establishment of the 3Rs centre.

Under 2017, the Swedish National Committee for the protection of animals used for scientific purposes held one course for the members of the regional ethics committees together with the Swedish Board of Agriculture. The National Committee also held a meeting with the animal welfare bodies. These efforts were made towards increasing the consciousness of the 3Rs.

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

**5.1 Other animals**

**i. Fish**

42 % of the reported fish constitutes of *Other fish*. Of the 18,024 uses of *Other fish* most are reported as three-spined stickleback (*Gasterosteus aculeatus*, 4,339 uses), brown trout (*Salmo trutta,* 3,983 uses), salmon (*Salmo salar,* 3,417 uses), perch (*Perca fluviatilis,* 1,443 uses) and common roach (*Rutilus rutilus*, 1,358 uses).

The fish in this category were used mainly for *Basic research/Ethology/Animal behaviour/animal biology (8,303 uses)* and in *Translational and applied research/Animal Welfare* (6,566 uses), but also in *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (2,159 uses).Remaining uses are reported in *Basic research* (*Gastrointestinal System including Liver,* 294 uses*; Nervous system,* 66 uses*;* and *Cardiovascular Blood and Lymphatic System*, 29 uses); *Translational and applied research (Diagnosis of disease,* 154 uses; and *Non-regulatory toxicology and ecotoxicology*, 70 uses) and *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (13 uses).

**ii. Amphibians**

79 %, of the amphibians are registered as *Other amphibians*. The category (3,923 uses) consists mostly of moor frog (*Rana arvalis*, 1,614 uses), Iberian ribbed newt (*Pleurodeles waltl,* 1,570 uses), but also common toad (*Bufo bufo*, 500 uses), natterjack toad (*Epidalea calamita,* 143 uses), eastern newt (*Notophthalmus viridescens*, 54 uses), European green toad (*Bufotes virides*, 36 uses) and edible frog (*Pelophylax kl esculentus*, 6 uses).

Most other amphibians have been used in *Other basic research*. Iberian ribbed newt and eastern newt have been used in studies of the ability of the nervous system and the locomotion to heal themselves and gene function. Furthermore, the common toad, moor frog, European green toad, natterjack toad and edible frog have been used to understand how the chytrid fungus *Batrachochytrium dendrobatidis* affects Swedish amphibians. 1,320 uses of moor frog were categorised as *Basic Research/Ethology /Animal Behaviour /Animal Biology.*

**iii. Birds**

A large percentage, 92 %, among the birds constitutes of *Other birds.* These (11,583 uses) consist mostly of Old World flycatchers (*Muscicapidae,* 3,486 uses), followed by collared flycatcher (*Ficedula albicollis*, 1,750 uses), Eurasian blue tit (*Cyanistes caeruleus*, 1,962 uses), European pied flycatcher (*Ficedula hypoleuca*, 766 uses) and marsh tit (*Poecile palustris*, 641 uses).

60 % of these birds have been used in *Basic research/Other*, more specifically for blood sampling for gene analyses, infections in wild animals, or behavioural studies without restraining equipment. The remaining birds have been used in *Basic Research: Ethology / Animal Behaviour /Animal Biology* (4,570 uses), *Musculoskeletal System* (8 uses) and *Sensory Organs* (4 uses); and in *Translational and applied research/Animal Diseases and Disorders* (61 uses).

**iv. Carnivores**  
Among the carnivores SE had a large percentage (36 %) of *Other carnivores*. These (167 uses) are mainly brown bear (*Ursus arctos*, 68 uses) and raccoon dog (*Nyctereutes procyonoides*,60 uses), but also fox (*Vulpes vulpes*, 17 uses), American mink (*Neovison vison*, 12 uses), wolf (*Canis lupus,* 6 uses), and wolverine (*Gulo gulo*, 4 uses).

They have all been used in *Basic research/Ethology/Animal behaviour/animal biology*, apart from the American mink, used in *Translational and applied research/Animal Welfare.*

**5.2 Other legislation**

14 % of the uses in *Testing by legislation* are reported under *Other legislation*. These constitute 320 uses of rainbow trout (*Oncorhyncus mykiss*) and 50 uses of three-spined stickleback (*Gasterosteus aculeatus*) in *Regulatory use and Routine production /Toxicity and other safety testing including pharmacology/Acute and sub-acute/Non lethal methods, Legislation satisfying EU requirements.* The user has identified this legislation as concerning biotoxicity.

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

There has been no such case in SE up to this date.

## Sweden: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 255949 | 74.24% |
| Rats | 21218 | 6.15% |
| Guinea-Pigs | 422 | 0.12% |
| Hamsters (Syrian) |  |  |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 63 | 0.02% |
| Rabbits | 1447 | 0.42% |
| Cats | 94 | 0.03% |
| Dogs | 204 | 0.06% |
| Ferrets |  |  |
| Other carnivores | 167 | 0.05% |
| Horses, donkeys and cross-breeds | 824 | 0.24% |
| Pigs | 1840 | 0.53% |
| Goats | 58 | 0.02% |
| Sheep | 27 | 0.01% |
| Cattle | 1436 | 0.42% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey | 10 | 0% |
| Rhesus monkey | 28 | 0.01% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 427 | 0.12% |
| Domestic fowl | 971 | 0.28% |
| Other birds | 11583 | 3.36% |
| Reptiles | 380 | 0.11% |
| Rana | 623 | 0.18% |
| Xenopus | 441 | 0.13% |
| Other Amphibians | 3923 | 1.14% |
| Zebra fish | 24607 | 7.14% |
| Other Fish | 18024 | 5.23% |
| Cephalopods |  |  |
| Total | 344766 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 261665 | 77.28% |
| Animals born in the EU but not at a registered breeder | 67459 | 19.92% |
| Animals born in rest of Europe | 5884 | 1.74% |
| Animals born in rest of world | 3586 | 1.06% |
| Total | 338594 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 38 | 100% |
| Animals born in America |  |  |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 38 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 38 | 100% |
| Self-sustaining colony |  |  |
| Total | 38 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 283240 | 82.15% |
| Translational and applied research | 50568 | 14.67% |
| Regulatory use and Routine production | 2599 | 0.75% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 2759 | 0.8% |
| Preservation of species |  |  |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 5155 | 1.5% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 445 | 0.13% |
| Total | 344766 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 28930 | 10.21% |
| Cardiovascular Blood and Lymphatic System | 39229 | 13.85% |
| Nervous System | 51837 | 18.3% |
| Respiratory System | 2732 | 0.96% |
| Gastrointestinal System including Liver | 6256 | 2.21% |
| Musculoskeletal System | 7120 | 2.51% |
| Immune System | 41870 | 14.78% |
| Urogenital/Reproductive System | 2658 | 0.94% |
| Sensory Organs (skin, eyes and ears) | 4523 | 1.6% |
| Endocrine System/Metabolism | 25651 | 9.06% |
| Multisystemic | 31111 | 10.98% |
| Ethology / Animal Behaviour /Animal Biology | 16487 | 5.82% |
| Other basic research | 24836 | 8.77% |
| Total | 283240 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 14014 | 27.71% |
| Human Infectious Disorders | 973 | 1.92% |
| Human Cardiovascular Disorders | 5606 | 11.09% |
| Human Nervous and Mental Disorders | 4523 | 8.94% |
| Human Respiratory Disorders | 5806 | 11.48% |
| Human Gastrointestinal Disorders including Liver | 279 | 0.55% |
| Human Musculoskeletal Disorders | 246 | 0.49% |
| Human Immune Disorders | 1441 | 2.85% |
| Human Urogenital/Reproductive Disorders | 75 | 0.15% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 292 | 0.58% |
| Human Endocrine/Metabolism Disorders | 3288 | 6.5% |
| Other Human Disorders | 3802 | 7.52% |
| Animal Diseases and Disorders | 1160 | 2.29% |
| Animal Welfare | 6578 | 13.01% |
| Diagnosis of diseases | 530 | 1.05% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 1955 | 3.87% |
| Total | 50568 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 1048 | 40.32% |
| Other efficacy and tolerance testing | 120 | 4.62% |
| Toxicity and other safety testing including pharmacology | 1426 | 54.87% |
| Routine production | 5 | 0.19% |
| Total | 2599 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 36 | 3.44% |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 1012 | 96.56% |
| Total | 1048 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 370 | 25.95% |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Repeated dose toxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Neurotoxicity | 119 | 8.35% |
| Kinetics | 937 | 65.71% |
| Total | 1426 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods | 370 | 100% |
| Total | 370 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days |  |  |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total |  |  |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 5 | 100% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total | 5 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 1093 | 42.05% |
| Legislation on medicinal products for veterinary use and their residues | 1136 | 43.71% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation | 370 | 14.24% |
| Total | 2599 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 2594 | 99.81% |
| Legislation satisfying national requirements only [within EU] | 5 | 0.19% |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 2599 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 338632 | 98.22% |
| Yes | 6134 | 1.78% |
| Total | 344766 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 6427 | 1.86% |
| Mild [up to and including] | 111460 | 32.33% |
| Moderate | 197302 | 57.23% |
| Severe | 29577 | 8.58% |
| Total | 344766 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 318807 | 92.47% |
| Yes | 25959 | 7.53% |
| Total | 344766 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 145476 | 42.2% |
| Genetically altered without a harmful phenotype | 176997 | 51.34% |
| Genetically altered with a harmful phenotype | 22293 | 6.47% |
| Total | 344766 | 100.00% |

## Sweden: Narrative 2017

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

*Total number of uses*

There was a decrease in the total number of uses reported for 2017 (325,838 uses) compared to 2016 (345,433 uses), but more were used than in 2015 (254,789 uses).

*Genetic status*

The use of genetically altered animals with a harmful phenotype has gradually increased since 2015; with twice as many uses reported in 2017 (36,929 uses, 11%) compared to 2015 (18,270 uses, 7%).

*Place of birth*

A minority of the animal uses in 2017 were with animals born in rest of the world (2,714 uses, 1%), and the numbers have decreased compared to 2016 (3,586 uses, 1%) and 2015 (5,277 uses, 2%).

*Non-human Primate Source*

Most uses of non-human primates in 2017 (19 uses, 76%) were of primates born in America. This is in contrast to both 2016 and 2015 were all were born in Asia (2016: 38 uses, 2015: 3 uses).

*Species*

Hamsters (Syrian) increased to 34 uses in 2017, while none was reported for 2016 and 2015. Most (31 uses) of the uses in 2017 were reported as *Translational and Applied Research*,mainly *Human Endocrine/Metobolism Studies* (26 uses). Other rodents decreased to 5 uses in 2017 compared to 63 uses in 2016; none was reported for 2015. All uses in 2017 of other rodents were reported as *Preservation of species.*

Dogs had 386 uses in 2017, which is an increase compared to 2016 (204 uses) and 2015 (115 uses). For all three years, most uses were reported as *Translational and applied research* (for 2017 it was 330 uses, 85%). More specifically in 2017: *Animal Diseases and Disorders* (251 uses), *Human Cardiovascular Disorders* (45 uses), *Human Respiratory Disorders* (15 uses), *Diagnosis of diseases* (10 uses), *Human Endocrine/Metobolism Studies* (5 uses) and *Non-regulatory toxicology and ecotoxicology* (4 uses). Also for 2016 *Animal Diseases and Disorders* were the most reportedcategory in *Translational and applied research* (785 in 2016, 765 in 2017).

Horses, donkeys and cross-breeds had 41 uses in 2017 which is a large decrease compared to 2016 (824 uses) and 2015 (275 uses). The uses in 2017 was reported as *Higher education or training for the acquisition, maintenance or improvement of vocational skills* (26 uses) and *Basic research* (15 uses, of which 8 were for *Other basic research* and 7 for *Respiratory System*). A main difference from 2016 is that one user in 2016 reported 741 uses (90%) as *Translational and Applied Research* (more specifically as *Animal Diseases and Disorders*).

Goats had 30 uses in 2017, which is about half as many as in 2016 (58 uses); none was reported for 2015. In 2017 most uses were reported in *Translational and applied research,* more precisely *Diagnosis of diseases* (20 uses), whereas 10 uses were reported in *Basic research*. The uses was similar in 2016 except that 24 uses were reported as *Higher education or training for the acquisition, maintenance or improvement of vocational skills* in 2016*.*

Domestic fowls had 1,452 uses in 2017, which is an increase compared to 2016 (971 uses), but a decrease compared to 2015 (5,266 uses). In 2017 most uses were reported in *Translational and applied research* (1,125 uses), more specifically *Non-regulatory toxicology and ecotoxicology* (653 uses),followed by *Animal Diseases and Disorders* (130 uses), *Human Infectious Disorders* (128 uses), and *Human Respiratory Disorders* (118 uses). Of the reported domestic fowls 327 uses were reported in *Basic research*, mainly in *Cardiovascular Blood and Lymphatic System* (200 uses) and *Oncology* (76 uses). Also in 2016 most fowl uses were reported as *Translational and applied research* (586 uses), followed by *Basic research* (385 uses). The more specific areas were diverse in 2016 as well.

No reptiles was reported for 2017, which is a decrease compared to 2016 (380 uses) and 2015 (50 uses). In 2016 all uses were reported as *Other basic research*, more specifically: evolutionary biology (300 uses) and blood sampling and marking (80 uses).

Rana (a genus of frogs) had 308 uses in 2017, which is about half as many compared to 2016 (623 uses) and 2015 (600 uses). In 2017, the uses were reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (200 uses), and *Translational and applied research,* more specifically *Non-regulatory toxicology and ecotoxicology* (108 uses). For 2015 and 2016 all or almost all (100% respectively 96%) uses were reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals.*

Xenopus (a genus of frogs) had 261 uses in 2017, and has had a gradual decrease from 2015 to 2017 (2016: 441 uses and 2015: 574 uses). For 2017 the uses were reported as *Basic research* (145 uses, all under *Nervous System*)and *Translational and applied research* (116 uses, all under *Non-regulatory toxicology and ecotoxicology*). Both these categories had uses reported in 2015 and 2016 as well.

Other amphibians had 2,694 uses in 2017, which is a decrease compared to 2016 (3,923 uses), but an increase compared to 2015 (1,894 uses). For 2017 most uses were reported as *Basic Research* (2,574 uses), more specifically *Nervous System* (1,022 uses), *Ethology/Animal Behaviour/Animal Biology* (843 uses) and *Other basic research* (709 uses; all to study how the chytrid fungus *Batrachochytrium dendrobatidis* affects Swedish amphibians). For 2017 an additional 60 uses were reported as *Preservation of species* and 60 uses as *Translational and applied research*, more specifically *Non-regulatory toxicology and ecotoxicology*. For both 2015 and 2016 all uses were reported under Basic research (*Ethology/Animal Behaviour/Animal Biology* and *Other basic research*).

Zebra fish has gradually increased since 2015. For 2017 was 29,158 uses reported, compared to 24,607 uses in 2016 and 20,519 uses in 2015. The uses in 2017 were reported as *Basic Research* (19,057 uses, mainly *Cardiovascular Blood and Lymphatic System* [7,282 uses] and *Multisystemic* [7,399 uses]) and *Translational and applied research* (10,101 uses, mainly

*Human Nervous and Mental Disorders* [7,000 uses] and *Human Endocrine/Metabolism Disorders* [300 uses]).

Other fish has gradually increased since 2015. For 2017 was 33,940 uses reported, compared to 18,024 uses in 2016 and 14,355 uses in 2015. For 2017 most uses was reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (27,302 uses) and *Basic Research* (5,827 uses, of which 2,900 was in the category *Ethology/Animal Behaviour/Animal Biology*).

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

The uses in overall are similar 2015-2017. A change is that the category *Protection of the natural environment in the interests of the health or welfare of human beings or animals* has increased to 27,916 in 2017 compared to 2,759 uses in 2016 and 6,280 uses in 2015. In 2017, 98% of these uses were other fish. Another change is that *Maintenance of colonies of established genetically altered animals, not used in other procedures* has increased to 1,679 uses in 2017 compared to 445 uses in 2016 and 155 uses in 2015. In 2017, 99% of these uses were mice and all were classified as mild severity.

The number of uses for many of the categories under *Basic research* are either similar to 2016 or to 2015. A change is that *Respiratory System* increased to 7,362 uses in 2017 compared to 2,732 uses in 2016 and 1,652 uses in 2015. *Gastrointestinal System including Liver* has decreased to 1,531 uses from 6,256 uses in 2016 and 3,971 uses in 2015. In addition, the *Immune System* has decreased; 23,611 uses in 2017 compared to 42,537 uses in 2016.

The number of uses for many of the categories under *Translational and applied research* are either similar to 2016 or to 2015.A change is that *Human Nervous and Mental Disorders* increased to 9,737 uses in 2017 compared to 4,523 uses in 2016 and 2,777 uses in 2015. In addition, *Human Immune Disorders* increased to 9,271 uses in 2017 compared to 1,441 uses in 2016 and 2,053 uses in 2015; and *Human Endocrine/Metabolism Disorders* increased to 5,687 uses in 2017 compared to 3,288 uses in 2016 and 2,914 uses in 2015.

It is unclear what the changes depends on.

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

The uses with severe severity has gradually increased since 2015, reaching 41,475 uses (13%) in 2017, which is more than twice as many as in 2015 (18,136 uses, 7%). Most uses classified as severe in 2017 were reported as *Basic research* (79%). Of those, *Oncology*, *Nervous system*, *Respiratory system* and *Musculoskeletal System* are purpose categories that has increased 2015-2017. *Oncology* increased from 516 uses in 2015 to 4,854 uses in 2017,  *Nervous system* from 8,375 uses in 2015 to 12,466 uses in 2017, *Respiratory system* from 0 uses in 2015 to 979 uses in 2017, and *Musculoskeletal System* from 732 uses in 2015 to 1,895 uses in 2017.

Of the uses classified as severe in 2017 under *Translational and applied research* (21%), *Human Immune disorders* increased most (2015: 50 uses; 2017: 7,191 uses) and *Human Cancer* decreased most (2015: 853 uses; 2017: 33 uses).

25% of the uses reported as severe in 2017 comes from two purposes in two user reports. One of the report has 6,869 uses within *Human Immune disorders* and the other has 3,316 uses within *Nervous System* (*Basic research*).

It is unclear what the changes depends on.

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

Sweden established a 3Rs center for the promotion of the 3Rs. The Swedish 3Rs Center had its official opening on the 21st of November 2017. The 3Rs Center is the executive body of the Swedish National Committee for the Protection of Animals Used for Scientific Purposes. As such, the 3Rs Center assists the Committee in carrying out its tasks by e.g. developing advice on alternative methods, disseminating information on the 3Rs, and supporting the local animal welfare bodies, the regional ethics committees and authorities concerned with animal experiments.

During 2017, two working groups were appointed by the National Committee to develop advice for marking and tagging of fish, and group housing of male mice. While the fish project is entirely based on existing literature, the mice project also includes workshops and a questionnaire targeting animal technicians and researchers.

On 14 June 2017, the Swedish 3Rs Center together with the Users’ Committee and the Ethics and Education Committee held a meeting with Sweden’s animal welfare bodies.

The purpose of the meeting was to establish contact and develop efficient cooperation methods between the animal welfare bodies and the 3Rs Center as the committee’s executive body. The meeting provided an opportunity for the participants to make new contacts, gather new knowledge and acquire new tools to carry out their assignments effectively.

On 17–19 October 2017, the Committee on ethics and education of the National Committee together with the Swedish Centre for Animal Welfare (SCAW) arranged the annual education in ethical evaluation for members of the regional ethics committees. The Swedish 3Rs Center participated with a lecture.

In November 2017, the 3Rs Centre used a quantitative questionnaire to learn more about researchers´ thoughts and implementation of the 3Rs, but also to increase their awareness of the 3Rs and the Swedish 3Rs Centre. The results from the survey shall serve as base for the development of further strategies to promote the 3Rs. The results were presented at the scientific conference Scand-LAS in 2018, and will be published in a report.

The Swedish Government has suggested that the Swedish 3Rs Center support six authorities in their 3Rs work by, for example, compiling and reviewing the authorities’ 3R-related activities and the establishing of 3R-strategies. During 2017, the centre begun working on compiling and analysing these authorities’ 3R-strategies.

The Swedish 3Rs Center created a website during 2017. This is an important channel for disseminating information on the 3Rs. It is accessible via the Swedish Board of Agriculture’s website with its home page: www.jordbruksverket.se/3R. During the development of the website, the focus was on putting together pages with information on what the 3Rs are and why it is important to work with the 3Rs. The website also contains information on the centre’s history, vision, mission and objectives as well as the National Committees and 3Rs centers organisational structure. During 2017 the 3Rs Center started also working on developing more specialised pages with information on, for example, animal welfare bodies, how to apply for research funding for projects linked to the 3Rs as well as links to other organisations that work with animal welfare and 3R-related issues. Those pages were published early in 2018. The 3Rs Center also publishes news and information on its website regarding courses and conferences related to the 3Rs.

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

*Other fish*

54% of the reported fish constitutes of other fish. Of the 33,940 uses of other fish most are reported as goldsinny wrasse (*Ctenolabrus rupestris*, 8,518 uses), corkwing wrasse (S*ymphodus melops*, 6,127 uses), and Atlantic cod (*Gadus morhua,* 5,224 uses). As mentioned above (section 1), most uses of other fish was reported as *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (27,302 uses) and *Basic Research* (5,827 uses, of which 2,900 was in *Ethology/Animal Behaviour/Animal Biology*).

*Other amphibians*

83% of the amphibians are registered as other amphibians. This category (2,787 uses) consists mostly of moor frog (*Rana arvalis*, 1,132 uses), Iberian ribbed newt (*Pleurodeles waltl,* 956 uses) and common toad (*Bufo bufo*, 388 uses). As mentioned above (section 1), most uses of other amphibians were reported as *Basic Research* (2,574 uses), more specifically *Nervous System* (1,022 uses), *Ethology/Animal Behaviour/Animal Biology* (843 uses) and *Other basic research* (709 uses).

*Other birds*

89% of the birds are reported as other birds*.* These 11,269 uses consist mostly of European pied flycatcher (*Ficedula hypoleuca,* 3,511 uses), followed by Eurasian blue tit (*Cyanistes caeruleus*, 1,882 uses), collared flycatcher (*Ficedula albicollis*, 1,800 uses), great tit (*Parus major*, 978 uses), mallard (*anas platyrhynchos*, 663 uses), and marsh tit (*Poecile palustris*, 558 uses). Most uses of other birdswas reported as *Basic research* (10,744 uses, of which 10,072 was specified as *Ethology/Animal Behaviour/Animal Biology*).

*Other carnivores*

22% of the carnivores was recorded as other carnivores. These 140 uses consist of *Arctic fox* (*Vulpes lagopus*, 66 uses), raccoon dog (*Nyctereutes procyonoides*,39 uses), red fox (*Vulpes vulpes*, 22 uses), wolverine (*Gulo gulo*, 7 uses) and wolf (*Canis lupus,* 6 uses). The uses of other carnivoreswas reported as *Preservation of species* (73 uses), *Protection of the natural environment in the interests of the health or welfare of human beings or animals* (369 uses), and *Basic research* (28 uses).

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

There has been no such case in SE up to this date.

**Appendix**

The European Commission noticed some irregularities in the Swedish statistic for 2015 and 2016. After being in contact with those users, we have adjusted their reports. We have used the updated numbers for 2015 and 2016 in the present narrative.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Animal group** | **Animal species** | **2015** | **2016** | **2017** |
| Rodents | Mice | 175,904 | 256,616 | 221,232 |
|  | Rats | 21,907 | 21,218 | 19,437 |
|  | Guinea-Pigs | 482 | 422 | 409 |
|  | Hamsters (Syrian) | 0 | 0 | 34 |
|  | Hamsters (Chinese) | 0 | 0 | 0 |
|  | Mongolian gerbil | 0 | 0 | 0 |
|  | Other rodents | 0 | 63 | 5 |
| Lagomorphs | Rabbits | 446 | 1,447 | 1,574 |
| Carnivores | Cats | 23 | 94 | 104 |
|  | Dogs | 115 | 204 | 386 |
|  | Ferrets | 57 | 0 | 0 |
|  | Other carnivores | 118 | 167 | 140 |
| Ungulates | Horses, donkeys and cross-breeds | 275 | 824 | 41 |
|  | Pigs | 1,625 | 1,840 | 1,557 |
|  | Goats | 0 | 58 | 30 |
|  | Sheep | 52 | 27 | 35 |
|  | Cattle | 2,097 | 1,436 | 1,420 |
| Primates | Prosimians | 0 | 0 | 0 |
|  | Marmosets and tamarins | 0 | 0 | 0 |
|  | Cynomolgus monkey | 7 | 10 | 2 |
|  | Rhesus monkey | 1 | 28 | 23 |
|  | Vervets (Chlorocebus spp.) | 0 | 0 | 0 |
|  | Baboons | 0 | 0 | 0 |
|  | Squirrel monkey | 0 | 0 | 0 |
|  | Other species of New World Monkeys (Ceboidea) | 0 | 0 | 0 |
|  | Other species of Old World Monkeys (Cercopithecoidea) | 0 | 0 | 0 |
|  | Other species of non-human primates | 0 | 0 | 0 |
|  | Apes | 0 | 0 | 0 |
| Other mammals | Other mammals | 1,871 | 427 | 327 |
| Birds | Domestic fowl | 5,266 | 971 | 1,452 |
|  | Other birds | 6,551 | 11,583 | 11,269 |
| Reptiles | Reptiles | 50 | 380 | 0 |
| Amphibians | Rana | 600 | 623 | 308 |
|  | Xenopus | 574 | 441 | 261 |
|  | Other amphibians | 1,894 | 3,923 | 2,694 |
| Fish | Zebra fish | 20,519 | 24,607 | 29,158 |
|  | Other fish | 14,355 | 18,024 | 33,940 |
| Cephalopods | Cephalopods | 0 | 0 | 0 |
|  | **Total uses** | **254,789** | **345,433** | **325,838** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Severity** | **2015** | | **2016** | | **2017** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Non-recovery | 11,034 | *4* | 6,427 | *2* | *9,324* | *3* |
| Mild (up to and including) | 92,991 | *37* | 112,034 | *32* | *109,950* | *34* |
| Moderate | 132,628 | *52* | 197,395 | *57* | *165,089* | *51* |
| Severe | 18,136 | *7* | 29,577 | *9* | *41,475* | *13* |
| **Totally** | **258,345** | ***100*** | **345,433** | ***100*** | ***325,838*** | ***100*** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Genetic Status** | **2015** | | **2016** | | **2017** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Not genetically altered | 109,855 | *43* | 146,110 | *42* | *150,383* | *46* |
| Genetically altered without a harmful phenotype | 126,664 | *50* | 177,030 | *51* | *138,526* | *43* |
| Genetically altered with a harmful phenotype | 18,270 | *7* | 22,293 | *6* | *36,929* | *11* |
| **Totally** | **254,789** | ***100*** | **345,433** | ***100*** | ***325,838*** | ***100*** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Regulatory use and routine production** | **2015** | | **2016** | | **2017** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Quality control (incl batch safety and potency testing) | 0 | *0* | 1,048 | *40* | *773* | *32* |
| Other efficacy and tolerance testing | 144 | *7* | 120 | *5* | *235* | *10* |
| Toxicity and other safety testing including pharmacology | 2,044 | *93* | 1,426 | *55* | *1,416* | *58* |
| Routine production | 0 | *0* | 5 | *<1* | *0* | *0* |
| **Totally** | **2,188** | ***100*** | **2,599** | ***100*** | ***2,424*** | ***100*** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Re-use** | **2015** | | **2016** | | **2017** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| No | 235,961 | *93* | 339,299 | *98* | 319,236 | *98* |
| Yes | 18,828 | *7* | 6,134 | *2* | 6,602 | *2* |
| **Totally** | **254,789** | ***100*** | **345,433** | ***100*** | **325,838** | ***100*** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Basic research**  **(first use and re-use)** | **2015** | | **2016** | | **2017** | |
|  | ***Number of*** | ***%*** | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Oncology | 13,825 | *7* | 28,930 | *10* | *22,557* | *10* |
| Cardiovascular Blood and Lymphatic System | 28,833 | *14* | 39,229 | *14* | *44,731* | *19* |
| Nervous System | 44,616 | *22* | 51,837 | *18* | *53,838* | *23* |
| Respiratory System | 1,652 | *1* | 2,732 | *1* | *7,362* | *3* |
| Gastrointestinal System including Liver | 3,971 | *2* | 6,256 | *2* | *1,531* | *1* |
| Musculoskeletal System | 4,597 | *2* | 7,120 | *3* | *4,220* | *2* |
| Immune System | 29,358 | *15* | 42,537 | *15* | *23,611* | *10* |
| Urogenital/Reproductive System | 2,892 | *1* | 2,658 | *1* | *6,543* | *3* |
| Sensory Organs (skin, eyes and ears) | 3,495 | *2* | 4,523 | *2* | *3,150* | *1* |
| Endocrine System/Metabolism | 18,578 | *9* | 25,651 | *9* | *28,055* | *12* |
| Multisystemic | 18,073 | *9* | 31,111 | *11* | *10,201* | *4* |
| Ethology / Animal Behaviour /Animal Biology | 19,510 | *10* | 16,487 | *6* | *16,914* | *7* |
| Other basic research | 13,050 | *6* | 24,836 | *9* | *10,528* | *5* |
| **Totally** | ***202,450*** | ***100*** | ***283,907*** | ***100*** | ***233,241*** | ***100*** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Translational and applied research (first use and re-use)** | **2015** | | **2016** | | **2017** | |
| ***Number of*** | ***%*** | ***Number of*** | ***%*** | ***Number of*** | ***%*** |
| Human Cancer | 11,929 | *30* | 14,014 | *28* | 10,841 | *19* |
| Human Infectious Disorders | 883 | *2* | 973 | *2* | 1,328 | *2* |
| Human Cardiovascular Disorders | 7,234 | *18* | 5,606 | *11* | 6,483 | *12* |
| Human Nervous and Mental Disorders | 2,777 | *7* | 4,523 | *9* | 9,737 | *17* |
| Human Respiratory Disorders | 6,436 | *16* | 5,806 | *11* | 5,077 | *9* |
| Human Gastrointestinal Disorders including Liver | 386 | *1* | 279 | *1* | 0 | *0* |
| Human Musculoskeletal Disorders | 263 | *1* | 246 | *<1* | 862 | *2* |
| Human Immune Disorders | 2,053 | *5* | 1,441 | *3* | 9,271 | *17* |
| Human Urogenital/Reproductive Disorders | 117 | *<1* | 75 | *<1* | 255 | *<1* |
| Human Sensory Organ Disorders (skin, eyes and ears) | 109 | *<1* | 292 | *1* | 500 | *1* |
| Human Endocrine/Metabolism Disorders | 2,914 | *7* | 3,288 | *7* | 5,687 | *10* |
| Other Human Disorders | 1,636 | *4* | 3,802 | *8* | 2,323 | *4* |
| Animal Diseases and Disorders | 728 | *2* | 1,160 | *2* | 704 | *1* |
| Animal Welfare | 18 | *<1* | 6,578 | *13* | 105 | *<1* |
| Diagnosis of diseases | 239 | *1* | 530 | *1* | 542 | *1* |
| Plant diseases | 0 | *0* | 0 | *0* | 0 | *0* |
| Non-regulatory toxicology and ecotoxicology | 2,163 | *5* | 1,955 | *4* | 1,998 | *4* |
| **Totally** | ***39,885*** | ***100*** | ***50,568*** | ***100*** | ***55,713*** | ***100*** |

## Sweden: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 220281 | 67.83% |
| Rats | 19321 | 5.95% |
| Guinea-Pigs | 409 | 0.13% |
| Hamsters (Syrian) | 34 | 0.01% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil |  |  |
| Other Rodents | 5 | 0% |
| Rabbits | 1574 | 0.48% |
| Cats | 104 | 0.03% |
| Dogs | 386 | 0.12% |
| Ferrets |  |  |
| Other carnivores | 140 | 0.04% |
| Horses, donkeys and cross-breeds | 41 | 0.01% |
| Pigs | 1557 | 0.48% |
| Goats | 30 | 0.01% |
| Sheep | 35 | 0.01% |
| Cattle | 1420 | 0.44% |
| Prosimians |  |  |
| Marmoset and tamarins |  |  |
| Cynomolgus monkey | 2 | 0% |
| Rhesus monkey | 23 | 0.01% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 327 | 0.1% |
| Domestic fowl | 1452 | 0.45% |
| Other birds | 11269 | 3.47% |
| Reptiles |  |  |
| Rana | 308 | 0.09% |
| Xenopus | 261 | 0.08% |
| Other Amphibians | 2694 | 0.83% |
| Zebra fish | 29158 | 8.98% |
| Other Fish | 33940 | 10.45% |
| Cephalopods |  |  |
| Total | 324771 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 249147 | 78.31% |
| Animals born in the EU but not at a registered breeder | 64675 | 20.33% |
| Animals born in rest of Europe | 1608 | 0.51% |
| Animals born in rest of world | 2714 | 0.85% |
| Total | 318144 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU |  |  |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 6 | 24% |
| Animals born in America | 19 | 76% |
| Animals born in Africa |  |  |
| Animals born elsewhere |  |  |
| Total | 25 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 25 | 100% |
| Self-sustaining colony |  |  |
| Total | 25 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 232174 | 71.49% |
| Translational and applied research | 55713 | 17.15% |
| Regulatory use and Routine production | 2424 | 0.75% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 27916 | 8.6% |
| Preservation of species | 617 | 0.19% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 4248 | 1.31% |
| Forensic enquiries |  |  |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 1679 | 0.52% |
| Total | 324771 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 22549 | 9.71% |
| Cardiovascular Blood and Lymphatic System | 44502 | 19.17% |
| Nervous System | 53425 | 23.01% |
| Respiratory System | 7362 | 3.17% |
| Gastrointestinal System including Liver | 1531 | 0.66% |
| Musculoskeletal System | 4220 | 1.82% |
| Immune System | 23194 | 9.99% |
| Urogenital/Reproductive System | 6543 | 2.82% |
| Sensory Organs (skin, eyes and ears) | 3150 | 1.36% |
| Endocrine System/Metabolism | 28055 | 12.08% |
| Multisystemic | 10201 | 4.39% |
| Ethology / Animal Behaviour /Animal Biology | 16914 | 7.29% |
| Other basic research | 10528 | 4.53% |
| Total | 232174 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 10841 | 19.46% |
| Human Infectious Disorders | 1328 | 2.38% |
| Human Cardiovascular Disorders | 6483 | 11.64% |
| Human Nervous and Mental Disorders | 9737 | 17.48% |
| Human Respiratory Disorders | 5077 | 9.11% |
| Human Gastrointestinal Disorders including Liver |  |  |
| Human Musculoskeletal Disorders | 862 | 1.55% |
| Human Immune Disorders | 9271 | 16.64% |
| Human Urogenital/Reproductive Disorders | 255 | 0.46% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 500 | 0.9% |
| Human Endocrine/Metabolism Disorders | 5687 | 10.21% |
| Other Human Disorders | 2323 | 4.17% |
| Animal Diseases and Disorders | 704 | 1.26% |
| Animal Welfare | 105 | 0.19% |
| Diagnosis of diseases | 542 | 0.97% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 1998 | 3.59% |
| Total | 55713 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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% |
| Routine production |  |  |
| Total | 2424 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing |  |  |
| Other quality controls |  |  |
| Pyrogenicity testing |  |  |
| Batch potency testing | 773 | 100% |
| Total | 773 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute |  |  |
| Carcinogenicity |  |  |
| Developmental toxicity |  |  |
| Ecotoxicity |  |  |
| Eye irritation/corrosion |  |  |
| Genotoxicity |  |  |
| Neurotoxicity |  |  |
| Other toxicity/safety testing |  |  |
| Pharmaco-dynamics (incl safety pharmacology) |  |  |
| Phototoxicity |  |  |
| Reproductive toxicity |  |  |
| Safety testing in food and feed area |  |  |
| Skin irritation/corrosion |  |  |
| Skin sensitisation |  |  |
| Target animal safety |  |  |
| Repeated dose toxicity | 113 | 7.98% |
| Kinetics | 1303 | 92.02% |
| Total | 1416 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 |  |  |
| Other lethal methods |  |  |
| Non lethal methods |  |  |
| Total |  |  |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 113 | 100% |
| 29 - 90 days |  |  |
| > 90 days |  |  |
| Total | 113 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity |  |  |
| Chronic toxicity |  |  |
| Reproductive ecotoxicity |  |  |
| Endocrine activity |  |  |
| Bioaccumulation |  |  |
| Other ecotoxicity |  |  |
| Total |  |  |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products |  |  |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types |  |  |
| Total |  |  |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by 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% |
| Medical devices legislation |  |  |
| Industrial chemicals legislation |  |  |
| Plant protection product legislation |  |  |
| Biocides legislation |  |  |
| Food legislation including food contact material |  |  |
| Feed legislation including legislation for the safety of target animals, workers and environment |  |  |
| Cosmetics legislation |  |  |
| Other legislation |  |  |
| Total | 2424 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 2424 | 100% |
| Legislation satisfying national requirements only [within EU] |  |  |
| Legislation satisfying Non-EU requirements only |  |  |
| Total | 2424 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 318169 | 97.97% |
| Yes | 6602 | 2.03% |
| Total | 324771 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 9324 | 2.87% |
| Mild [up to and including] | 109850 | 33.82% |
| Moderate | 164539 | 50.66% |
| Severe | 41058 | 12.64% |
| Total | 324771 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 291525 | 89.76% |
| Yes | 33246 | 10.24% |
| Total | 324771 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 149970 | 46.18% |
| Genetically altered without a harmful phenotype | 137872 | 42.45% |
| Genetically altered with a harmful phenotype | 36929 | 11.37% |
| Total | 324771 | 100.00% |

# United Kingdom

## United Kingdom: Narrative 2015

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2015 data for Great Britain on the 20 July 2016 and the statistical release can be accessed online here:

<https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2015>.  
  
The Northern Ireland Department for Health data is available here:

<https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland>.  
  
The information submitted to the EU differs from the information published by the Home Office and what will be published by the Department for Health. The key difference is that the UK releases include procedures assessed as having sub-threshold severity for the purpose of procedure ‘[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures’ whereas this information is not provided to the EU. The UK releases additionally include, for all other purposes of procedure, procedures assessed as having sub-threshold or mild severity but such procedures are submitted to the EU in the “Mild [up to and including]” category. Additional breakdowns are also collected for the source of animals (distinguishing between animals born in the UK and animals born in the rest of the EU), as are further species breakdowns for some animals (birds, dogs). These breakdowns are aggregated to form the EU categories prior to submission to the EU.

Comparison between the 2015 and 2014 data should be exercised with caution due to some under-reporting and misclassification in 2014. See introductory section, data quality section (page 7) of ‘Annual Statistics of Scientific Procedures on Living Animals Great Britain 2015’ for further information. The report can be accessed online at:

<https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/537708/scientific-procedures-living-animals-2015.pdf>.

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

In 2015, a total of 3.17 million procedures were completed. This represents an increase of 3% (92 thousand) compared with the 3.08 million procedures completed in 2014.

Of the 3.17 million procedures, 2.10 million (66%) were experimental procedures and 1.07 million (34%) related to the creation/breeding of genetically altered animals that were not used in further procedures. Since 2014, experimental procedures have increased by 8% (155 thousand) and creation/breeding procedures have decreased by 6% (63 thousand).

There were 3.10 million animals used for the first time in completed procedures in 2015, representing an increase of 3% (89 thousand) compared with 2014.

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

Of the 2.10 million experimental procedures completed in 2015, the majority involved the use of mice (61%), fish (14%), and rats (12%). Comparing with 2014, there were notable changes[[2]](#footnote-2) to the number of procedures involving:

* mice, which increased by 107 thousand (9%) to 1.28 million procedures in 2015;
* fish[[3]](#footnote-3), which increased by 29 thousand (11%) to 294 thousand procedures in 2015;
* rats, which increased by 24 thousand (10%) to 258 thousand procedures in 2015;
* pigs, which increased by 1,900 (45%) to 6,100 procedures in 2015;
* hamsters[[4]](#footnote-4), which decreased by 1,300 (-46%) to 1,500 procedures in 2015;
* goats, which decreased by 240 (-69%) to 110 procedures in 2015.

Of the 1.07 million procedures in 2015 related to the creation/breeding of genetically altered animals not used in further procedures, the majority involved mice (87%), fish (12%), and amphibians (0.7%). Comparing with 2014, there were notable changes[[5]](#footnote-5) to the number of procedures involving:

* fish[[6]](#footnote-6), which increased by 47 thousand (61%) to 124 thousand procedures in 2015;
* amphibians[[7]](#footnote-7), which increased by 6,000 thousand (414%) to 7,400 procedures in 2015;
* mice, which decreased by 105 thousand (-10%) to 932 thousand procedures in 2015;
* rats, which decreased by 11 thousand (-60%) to 6,900 procedures in 2015;
* sheep, which decreased by 80 (-71%) to 30 procedures in 2015.

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

Of the 2.10 million experimental procedures completed in 2015:

* 6% (123 thousand) were assessed as non-recovery (compared with 7% in 2014);
* 64% (1.34 million) were assessed as (up to and including) mild (compared with 60% in 2014);
* 24% (509 thousand) were assessed as moderate (compared with 25% in 2014);
* 6% (124 thousand) were assessed as severe (compared with 8% in 2014).

Of the 1.07 million procedures in 2015 related to the creation/breeding of genetically altered animals not used in further procedures:

* 0.2% (2,100) were assessed as non-recovery (compared with 0.2% in 2014);
* 88% (940 thousand) were assessed as (up to and including) mild (compared with 90% in 2014);
* 6% (67 thousand) were assessed as moderate (compared with 7% in 2014);
* 6% (62 thousand) were assessed as severe (compared with 3% in 2014).

The changes in severity from 2014 to 2015 are compared as proportions only due to the suspected under-reporting of procedures that occurred in 2014. Changes in the proportions of severity assessments reported may be an effect of increased familiarity with the reporting procedure, rather than a true change in the severity of procedures. Given that severity information has only been collected since 2014, clear trends in this data will take several years to emerge.

In relation to the creation/breeding of genetically altered animals not used in further procedures, the main reason for severe assessments is that animals in breeding colonies were found dead with no clear explanation for the cause of death. Further guidance is required in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other member states, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals and work is ongoing to improve guidance for users on this matter.

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

The UK has subscribed to the three principles of replacement, reduction and refinement (the 3Rs) for a number of years but recent years has seen the principles of the 3Rs placed more firmly at the core of animal scientific research through the project licence evaluation process, advice given by the Inspectorate of the Animals in Science Regulation Unit and through the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This commitment is not focused on baseline numbers, which would be evident through the statistics, and which are influenced by a range of extraneous factors. Instead, it encompasses replacement, reduction and refinement more broadly, putting them at the heart of a science-led approach.

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

Basic research “other category” included:

* Embryology and molecular biology;
* Parasitology;
* Some probable erroneous entries caused by confusion, e.g. research on renal system which could have been returned under urogenital/reproduction. The Home Office intends to clarify the instructions to data suppliers in the UK to improve data quality in the future;
* Studies of infectious agents where it was the agent, rather than the disease, under investigation.

Applied research “other” category included:

* Pharmacokinetic and/or Pharmacodynamic (PK/PD) studies;
* Mitochondrial disease;
* Haematology.

Regulatory use, routine production “other”:

* Antigens, infectious agents including parasites, oocytes, etc;
* Antibodies (but not by ascites method);
* Urine.

Regulatory use, quality control “other”:

* Method development, agent standardisation;
* Vaccine stability and testing of seed materials.

Regulatory use, legislative purpose “other”:

* Most commonly to meet industry required standards, rather than legislative requirements.

Regulatory use, ecotoxicity “other”:

* Effects on non-target (i.e. ASPA non-Schedule 2) species

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

Not applicable.

## United Kingdom: Statistical Data 2015

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 2208377 | 69.7% |
| Rats | 264697 | 8.35% |
| Guinea-Pigs | 21831 | 0.69% |
| Hamsters (Syrian) | 1500 | 0.05% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 278 | 0.01% |
| Other Rodents | 1763 | 0.06% |
| Rabbits | 14224 | 0.45% |
| Cats | 322 | 0.01% |
| Dogs | 4753 | 0.15% |
| Ferrets | 626 | 0.02% |
| Other carnivores | 496 | 0.02% |
| Horses, donkeys and cross-breeds | 8356 | 0.26% |
| Pigs | 6350 | 0.2% |
| Goats | 105 | 0% |
| Sheep | 47237 | 1.49% |
| Cattle | 4629 | 0.15% |
| Prosimians |  |  |
| Marmoset and tamarins | 131 | 0% |
| Cynomolgus monkey | 3333 | 0.11% |
| Rhesus monkey | 148 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 720 | 0.02% |
| Domestic fowl | 128718 | 4.06% |
| Other birds | 14061 | 0.44% |
| Reptiles |  |  |
| Rana | 378 | 0.01% |
| Xenopus | 15577 | 0.49% |
| Other Amphibians | 1840 | 0.06% |
| Zebra fish | 271773 | 8.58% |
| Other Fish | 146257 | 4.62% |
| Cephalopods |  |  |
| Total | 3168480 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 2830494 | 91.43% |
| Animals born in the EU but not at a registered breeder | 239430 | 7.73% |
| Animals born in rest of Europe | 8705 | 0.28% |
| Animals born in rest of world | 17316 | 0.56% |
| Total | 3095945 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 221 | 9.89% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 596 | 26.68% |
| Animals born in America |  |  |
| Animals born in Africa | 1417 | 63.43% |
| Animals born elsewhere |  |  |
| Total | 2234 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 598 | 26.77% |
| Self-sustaining colony | 1636 | 73.23% |
| Total | 2234 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 1408901 | 44.47% |
| Translational and applied research | 417992 | 13.19% |
| Regulatory use and Routine production | 556113 | 17.55% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 18200 | 0.57% |
| Preservation of species | 757 | 0.02% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1845 | 0.06% |
| Forensic enquiries | 121 | 0% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 764551 | 24.13% |
| Total | 3168480 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 161953 | 11.49% |
| Cardiovascular Blood and Lymphatic System | 95627 | 6.79% |
| Nervous System | 256944 | 18.24% |
| Respiratory System | 30767 | 2.18% |
| Gastrointestinal System including Liver | 27312 | 1.94% |
| Musculoskeletal System | 31016 | 2.2% |
| Immune System | 247072 | 17.54% |
| Urogenital/Reproductive System | 50092 | 3.56% |
| Sensory Organs (skin, eyes and ears) | 29681 | 2.11% |
| Endocrine System/Metabolism | 34373 | 2.44% |
| Multisystemic | 274443 | 19.48% |
| Ethology / Animal Behaviour /Animal Biology | 90950 | 6.46% |
| Other basic research | 78671 | 5.58% |
| Total | 1408901 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 84909 | 20.31% |
| Human Infectious Disorders | 62048 | 14.84% |
| Human Cardiovascular Disorders | 8285 | 1.98% |
| Human Nervous and Mental Disorders | 55650 | 13.31% |
| Human Respiratory Disorders | 9648 | 2.31% |
| Human Gastrointestinal Disorders including Liver | 6115 | 1.46% |
| Human Musculoskeletal Disorders | 2637 | 0.63% |
| Human Immune Disorders | 19467 | 4.66% |
| Human Urogenital/Reproductive Disorders | 3666 | 0.88% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 11059 | 2.65% |
| Human Endocrine/Metabolism Disorders | 5416 | 1.3% |
| Other Human Disorders | 84111 | 20.12% |
| Animal Diseases and Disorders | 28285 | 6.77% |
| Animal Welfare | 5283 | 1.26% |
| Diagnosis of diseases | 3182 | 0.76% |
| Plant diseases | 9 | 0% |
| Non-regulatory toxicology and ecotoxicology | 28222 | 6.75% |
| Total | 417992 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 185742 | 33.4% |
| Other efficacy and tolerance testing | 18374 | 3.3% |
| Toxicity and other safety testing including pharmacology | 211600 | 38.05% |
| Routine production | 140397 | 25.25% |
| Total | 556113 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 16803 | 9.05% |
| Pyrogenicity testing | 2609 | 1.4% |
| Batch potency testing | 154450 | 83.15% |
| Other quality controls | 11880 | 6.4% |
| Total | 185742 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 16115 | 7.62% |
| Skin irritation/corrosion | 340 | 0.16% |
| Skin sensitisation | 5304 | 2.51% |
| Eye irritation/corrosion | 173 | 0.08% |
| Repeated dose toxicity | 44153 | 20.87% |
| Carcinogenicity | 15365 | 7.26% |
| Genotoxicity | 5335 | 2.52% |
| Reproductive toxicity | 26842 | 12.69% |
| Developmental toxicity | 64814 | 30.63% |
| Neurotoxicity | 395 | 0.19% |
| Kinetics | 4792 | 2.26% |
| Pharmaco-dynamics (incl safety pharmacology) | 4240 | 2% |
| Phototoxicity |  |  |
| Ecotoxicity | 12433 | 5.88% |
| Safety testing in food and feed area | 681 | 0.32% |
| Target animal safety | 7004 | 3.31% |
| Other toxicity/safety testing | 3614 | 1.71% |
| Total | 211600 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 8898 | 55.22% |
| Other lethal methods | 285 | 1.77% |
| Non lethal methods | 6932 | 43.02% |
| Total | 16115 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 24189 | 54.78% |
| 29 - 90 days | 12736 | 28.85% |
| > 90 days | 7228 | 16.37% |
| Total | 44153 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 4152 | 33.39% |
| Chronic toxicity | 6816 | 54.82% |
| Reproductive ecotoxicity |  |  |
| Endocrine activity | 932 | 7.5% |
| Bioaccumulation | 265 | 2.13% |
| Other ecotoxicity | 268 | 2.16% |
| Total | 12433 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 48690 | 34.68% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 91707 | 65.32% |
| Total | 140397 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 269750 | 48.51% |
| Legislation on medicinal products for veterinary use and their residues | 128586 | 23.12% |
| Medical devices legislation | 8308 | 1.49% |
| Industrial chemicals legislation | 75640 | 13.6% |
| Plant protection product legislation | 22056 | 3.97% |
| Biocides legislation | 1550 | 0.28% |
| Food legislation including food contact material | 1934 | 0.35% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 5971 | 1.07% |
| Cosmetics legislation |  |  |
| Other legislation | 42318 | 7.61% |
| Total | 556113 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 536912 | 96.55% |
| Legislation satisfying national requirements only [within EU] | 161 | 0.03% |
| Legislation satisfying Non-EU requirements only | 19040 | 3.42% |
| Total | 556113 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 3098179 | 97.78% |
| Yes | 70301 | 2.22% |
| Total | 3168480 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 125003 | 3.95% |
| Mild [up to and including] | 2281252 | 72% |
| Moderate | 576163 | 18.18% |
| Severe | 186062 | 5.87% |
| Total | 3168480 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 2861245 | 90.3% |
| Yes | 307235 | 9.7% |
| Total | 3168480 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1485634 | 46.89% |
| Genetically altered without a harmful phenotype | 1220639 | 38.52% |
| Genetically altered with a harmful phenotype | 462207 | 14.59% |
| Total | 3168480 | 100.00% |

## United Kingdom: Narrative 2016

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2016 data for Great Britain on the 13 July 2017 and the statistical release can be accessed online here:

<https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2016>.  
  
The Northern Ireland Department for Health data is available here:

<https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland>.  
  
The information submitted to the EU differs from the information published by the Home Office and what will be published by the NIDH. The key difference is that the UK releases include procedures assessed as having sub-threshold severity for the purpose of procedure ‘[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures’, whereas this information is neither required by nor provided to the EU. In addition, the UK data releases separate procedures assessed as being of sub-threshold or mild severity, whereas all such procedures are combined into the “Mild [up to and including]” category when the data is submitted to the EU. Likewise, additional details are also collected in the UK data for the source of animals (i.e. distinguishing between animals born in the UK and animals born in the rest of the EU), as are further species breakdowns for some animals (e.g. birds, dogs). These sub-categories of data are aggregated to form the EU categories prior to submission to the EU.

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

In 2016, a total of 2.79 million procedures were completed. This represents a decrease of 12% (378,000) compared with the 3.17 million procedures completed in 2015.

Of the 2.79 million procedures, 2.04 million (73%) were experimental procedures and 751,000 (27%) related to the creation/breeding of genetically altered animals that were not used in further procedures. Since 2015, experimental procedures have decreased by 3% (57,000) and creation/breeding procedures have decreased by 30% (321,000). The reduction in the number of procedures recorded as being for creation and/or breeding appears to occur because licensees are more accurately recording actual severity, rather than returning procedures according to the prospective severity category. As such, in 2016, a substantially greater proportion of breeding procedures prospectively accorded mild severity were returned as sub-threshold and therefore not included in this dataset.

There were 2.72 million animals used for the first time in completed procedures in 2016, representing a decrease of 12% (378,000) compared with 2015. This difference from the previous year may be explained, at least in part, by an improvement in the accuracy of recording the procedural severity. Licensees are increasingly correctly returning the actual severity suffered by the animal rather than the prospective severity of the procedure as described in their licence, as explained above. Other reasons why the number of animals has dropped sharply may also include an actual reduction in the number in experimental animals required and the reported improved efficiencies in the creation of new strains, in particular by the use of CRISPR/Cas9 technology.

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

Of the 2.04 million experimental procedures completed in 2016, the majority involved the use of mice (60%), fish (14%), and rats (12%). Comparing with 2015, there were notable changes[[8]](#footnote-8) to the number of procedures involving:

* mice, which decreased by 47,000 (-4%) to 1.23 million procedures in 2016;
* rats, which decreased by 19,000 (-7%) to 239,000 procedures in 2016;
* birds[[9]](#footnote-9), which increased by 8,100 (6%) to 150,000 procedures in 2016;
* guinea pigs, which increased by 4,400 (20%) to 26,000 procedures in 2016;
* ferrets, which decreased by 150 (-24%) to 480 procedures in 2016;
* goats, which increased by 110 (104%) to 210 procedures in 2016.

Of the 751,000 procedures in 2016 related to the creation/breeding of genetically altered animals not used in further procedures, the majority involved mice (83%), fish (16%), and rats (1%). Comparing with 2015, there were notable changes[[10]](#footnote-10) to the number of procedures involving:

* mice, which decreased by 309,000 (-33%) to 623,000 procedures in 2016;
* amphibians[[11]](#footnote-11), which decreased by 6,200 (-83%) to 1,300 procedures in 2016;
* fish[[12]](#footnote-12), which decreased by 5,300 (-4%) to 119,000 procedures in 2016;
* birds[[13]](#footnote-13), which increased by 500 (83%) to 1,100 procedures in 2016;
* sheep, which increased by 160 (516%) to 190 procedures in 2016.

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

Of the 2.04 million experimental procedures completed in 2016:

* 8% (155,000) were assessed as non-recovery, compared with 6% (123,000) in 2015;
* 58% (1.18 million) were assessed as (up to and including) mild, compared with 64% (1.34 million) in 2015;
* 29% (589,000) were assessed as moderate, compared with 24% (509,000) in 2015;
* 6% (115,000) were assessed as severe, compared with 6% (124,000) in 2015.

Of the 751,000 procedures in 2016 related to the creation/breeding of genetically altered animals not used in further procedures:

* 0.2% (1,500) were assessed as non-recovery, compared with 0.2% (2,100) in 2015;
* 88% (659,000) were assessed as (up to and including) mild, compared with 88% (940,000) in 2015;
* 7% (51,000) were assessed as moderate, compared with 6% (67,000) in 2015;
* 5% (40,000) were assessed as severe, compared with 6% (62,000) in 2015).

Changes in the proportions of severity assessments reported may be an effect of increased familiarity with the reporting procedure, rather than a true change in the severity of procedures. Given that severity information has only been collected since 2014, clear trends in this data will take several years to emerge.

In relation to the creation/breeding of genetically altered animals not used in further procedures, the main reason for severe assessments is that animals in breeding colonies were found dead with no clear explanation for the cause of death; the default position being that where the death cannot be excluded from being procedural, it is recorded as ‘severe’. Home Office continues to look to improve the guidance provided in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other Member States, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals. Nevertheless, the reduction in the overall numbers of procedures by severity for creation and breeding of animals for use in 2016 suggests that the ongoing education and improved guidance for users on this matter is having an impact.

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

The UK has subscribed to the three principles of replacement, reduction and refinement (the 3Rs) for a number of years but recent years has seen the principles of the 3Rs placed more firmly at the core of animal scientific research. This is principally achieved through the project licence evaluation process, provision of advice by the Inspectorate of the Animals in Science Regulation Unit and through the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This commitment is not focused on baseline numbers, which would be evident through the statistics, and which are influenced by a range of extraneous factors. Instead, it encompasses replacement, reduction and refinement more broadly, putting them at the heart of a science-led approach.

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

Basic research “other category” included:

* Embryology and molecular biology;
* Parasitology;
* Studies of infectious agents where it was the agent, rather than the disease, under investigation.
* Some probable erroneous entries caused by confusion. The Home Office intends to clarify the instructions to data suppliers in the UK to improve data quality in the future;

Applied research “other” category included:

* Pharmacokinetic and/or Pharmacodynamic (PK/PD) studies;
* Mitochondrial diseases;
* Haematology.

Regulatory use, routine production “other”:

* Antigens, infectious agents including parasites, oocytes, etc;
* Antibodies (but not by ascites method);
* Urine.

Regulatory use, quality control “other”:

* Method development, agent standardisation;
* Vaccine stability and testing of seed materials.

Regulatory use, legislative purpose “other”:

* Most commonly to meet industry required standards, rather than legislative requirements.

Regulatory use, ecotoxicity “other”:

* Effects on non-target (i.e. ASPA non-Schedule 2) species

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

Not applicable.

## United Kingdom: Statistical Data 2016

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1852305 | 66.38% |
| Rats | 244904 | 8.78% |
| Guinea-Pigs | 26192 | 0.94% |
| Hamsters (Syrian) | 1239 | 0.04% |
| Hamsters (Chinese) | 230 | 0.01% |
| Mongolian gerbil | 236 | 0.01% |
| Other Rodents | 1521 | 0.05% |
| Rabbits | 15568 | 0.56% |
| Cats | 345 | 0.01% |
| Dogs | 5005 | 0.18% |
| Ferrets | 476 | 0.02% |
| Other carnivores | 236 | 0.01% |
| Horses, donkeys and cross-breeds | 8948 | 0.32% |
| Pigs | 6361 | 0.23% |
| Goats | 214 | 0.01% |
| Sheep | 48596 | 1.74% |
| Cattle | 4996 | 0.18% |
| Prosimians |  |  |
| Marmoset and tamarins | 197 | 0.01% |
| Cynomolgus monkey | 3240 | 0.12% |
| Rhesus monkey | 132 | 0% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 860 | 0.03% |
| Domestic fowl | 139789 | 5.01% |
| Other birds | 11543 | 0.41% |
| Reptiles |  |  |
| Rana | 225 | 0.01% |
| Xenopus | 10123 | 0.36% |
| Other Amphibians | 893 | 0.03% |
| Zebra fish | 308108 | 11.04% |
| Other Fish | 97910 | 3.51% |
| Cephalopods |  |  |
| Total | 2790392 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 2593408 | 95.42% |
| Animals born in the EU but not at a registered breeder | 108530 | 3.99% |
| Animals born in rest of Europe | 4803 | 0.18% |
| Animals born in rest of world | 11057 | 0.41% |
| Total | 2717798 | 100.00% |

### Source of non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| NHP Source (origin) | Number of animals | Percentage |
| Animals born at a registered breeder within EU | 263 | 10.78% |
| Animals born in rest of Europe |  |  |
| Animals born in Asia | 652 | 26.72% |
| Animals born in America |  |  |
| Animals born in Africa | 1525 | 62.5% |
| Animals born elsewhere |  |  |
| Total | 2440 | 100.00% |

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 |  |  |
| F2 or greater | 701 | 28.73% |
| Self-sustaining colony | 1739 | 71.27% |
| Total | 2440 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 1350177 | 48.39% |
| Translational and applied research | 354145 | 12.69% |
| Regulatory use and Routine production | 539454 | 19.33% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 18800 | 0.67% |
| Preservation of species | 1789 | 0.06% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1675 | 0.06% |
| Forensic enquiries | 92 | 0% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 524260 | 18.79% |
| Total | 2790392 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 173650 | 12.86% |
| Cardiovascular Blood and Lymphatic System | 89072 | 6.6% |
| Nervous System | 271513 | 20.11% |
| Respiratory System | 16937 | 1.25% |
| Gastrointestinal System including Liver | 28417 | 2.1% |
| Musculoskeletal System | 23767 | 1.76% |
| Immune System | 243534 | 18.04% |
| Urogenital/Reproductive System | 41652 | 3.08% |
| Sensory Organs (skin, eyes and ears) | 31810 | 2.36% |
| Endocrine System/Metabolism | 32237 | 2.39% |
| Multisystemic | 181829 | 13.47% |
| Ethology / Animal Behaviour /Animal Biology | 55479 | 4.11% |
| Other basic research | 160280 | 11.87% |
| Total | 1350177 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 86416 | 24.4% |
| Human Infectious Disorders | 86702 | 24.48% |
| Human Cardiovascular Disorders | 6491 | 1.83% |
| Human Nervous and Mental Disorders | 37303 | 10.53% |
| Human Respiratory Disorders | 15171 | 4.28% |
| Human Gastrointestinal Disorders including Liver | 6347 | 1.79% |
| Human Musculoskeletal Disorders | 5447 | 1.54% |
| Human Immune Disorders | 10463 | 2.95% |
| Human Urogenital/Reproductive Disorders | 2464 | 0.7% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 9052 | 2.56% |
| Human Endocrine/Metabolism Disorders | 6651 | 1.88% |
| Other Human Disorders | 8292 | 2.34% |
| Animal Diseases and Disorders | 29218 | 8.25% |
| Animal Welfare | 2908 | 0.82% |
| Diagnosis of diseases | 1434 | 0.4% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 39786 | 11.23% |
| Total | 354145 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use and Routine production | Number of uses | Percentage |
| Quality control (incl batch safety and potency testing) | 181199 | 33.59% |
| Other efficacy and tolerance testing | 26707 | 4.95% |
| Toxicity and other safety testing including pharmacology | 189460 | 35.12% |
| Routine production | 142088 | 26.34% |
| Total | 539454 | 100.00% |

### Regulatory use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl batch safety and potency testing) | Number of uses | Percentage |
| Batch safety testing | 7239 | 4% |
| Pyrogenicity testing | 2472 | 1.36% |
| Batch potency testing | 145190 | 80.13% |
| Other quality controls | 26298 | 14.51% |
| Total | 181199 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology | Number of uses | Percentage |
| Acute and sub-acute | 18993 | 10.02% |
| Skin irritation/corrosion | 266 | 0.14% |
| Skin sensitisation | 4586 | 2.42% |
| Eye irritation/corrosion | 128 | 0.07% |
| Repeated dose toxicity | 43054 | 22.72% |
| Carcinogenicity | 3742 | 1.98% |
| Genotoxicity | 3746 | 1.98% |
| Reproductive toxicity | 39078 | 20.63% |
| Developmental toxicity | 44812 | 23.65% |
| Neurotoxicity | 280 | 0.15% |
| Kinetics | 4197 | 2.22% |
| Pharmaco-dynamics (incl safety pharmacology) | 4472 | 2.36% |
| Phototoxicity |  |  |
| Ecotoxicity | 15038 | 7.94% |
| Safety testing in food and feed area | 346 | 0.18% |
| Target animal safety | 2265 | 1.2% |
| Other toxicity/safety testing | 4457 | 2.35% |
| Total | 189460 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 11204 | 58.99% |
| Other lethal methods | 326 | 1.72% |
| Non lethal methods | 7463 | 39.29% |
| Total | 18993 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 20143 | 46.79% |
| 29 - 90 days | 14889 | 34.58% |
| > 90 days | 8022 | 18.63% |
| Total | 43054 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity | Number of uses | Percentage |
| Acute toxicity | 3786 | 25.18% |
| Chronic toxicity | 8066 | 53.64% |
| Reproductive ecotoxicity | 2370 | 15.76% |
| Endocrine activity | 389 | 2.59% |
| Bioaccumulation | 427 | 2.84% |
| Other ecotoxicity |  |  |
| Total | 15038 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 52732 | 37.11% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 89356 | 62.89% |
| Total | 142088 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 250469 | 46.43% |
| Legislation on medicinal products for veterinary use and their residues | 127249 | 23.59% |
| Medical devices legislation | 9641 | 1.79% |
| Industrial chemicals legislation | 71086 | 13.18% |
| Plant protection product legislation | 17480 | 3.24% |
| Biocides legislation | 3149 | 0.58% |
| Food legislation including food contact material | 1904 | 0.35% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 12988 | 2.41% |
| Cosmetics legislation |  |  |
| Other legislation | 45488 | 8.43% |
| Total | 539454 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 517132 | 95.86% |
| Legislation satisfying national requirements only [within EU] | 96 | 0.02% |
| Legislation satisfying Non-EU requirements only | 22226 | 4.12% |
| Total | 539454 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 2720238 | 97.49% |
| Yes | 70154 | 2.51% |
| Total | 2790392 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 156086 | 5.59% |
| Mild [up to and including] | 1839922 | 65.94% |
| Moderate | 640064 | 22.94% |
| Severe | 154320 | 5.53% |
| Total | 2790392 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 2564079 | 91.89% |
| Yes | 226313 | 8.11% |
| Total | 2790392 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1380447 | 49.47% |
| Genetically altered without a harmful phenotype | 1041325 | 37.32% |
| Genetically altered with a harmful phenotype | 368620 | 13.21% |
| Total | 2790392 | 100.00% |

## United Kingdom: Narrative 2017

Please note that the submitted data combines data from the separate Great Britain and Northern Ireland collections. The Home Office published 2017 data for Great Britain on the 19 July 2018 and the statistical release can be accessed online here:

<https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2017>.  
  
The Northern Ireland Department for Health (NIDH) published their 2017 data here:

<https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland>.  
  
The information submitted to the EU differs from the information published by the Home Office and what will be published by the NIDH. The key difference is that the UK releases include procedures assessed as having sub-threshold severity for the purpose of procedure ‘[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures’, whereas this information is neither required by nor provided to the EU. In addition, the UK data releases separate procedures assessed as being of sub-threshold from those of mild severity, whereas all such procedures (i.e. all procedures other than PG43) are combined into the “Mild [up to and including]” category when the data is submitted to the EU. Likewise, additional details are also collected in the UK data for the source of animals (i.e. distinguishing between animals born in the UK and animals born in the rest of the EU), as are further species breakdowns for some animals (e.g. birds, dogs). These sub-categories of data are aggregated to form the EU categories prior to submission to the EU.

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

In 2017, a total of 2.57 million procedures were completed. This represents a decrease of 8% (216,000) compared with the 2.79 million procedures completed in 2016.

Of the 2.57 million procedures, 1.91 million (74%) were experimental procedures and 669,000 (26%) related to the creation/breeding of genetically altered animals that were not used in further procedures. Since 2016, experimental procedures have decreased by 7% (134,000) and creation/breeding procedures have decreased by 11% (82,000). The reduction in the number of procedures recorded as being for creation and/or breeding appears to be due largely for two reasons: i) a decrease in the number of zebra fish bred but not used compared to 2016 and ii) more accurate recording of actual severity (a greater proportion of animals reported to be subthreshold instead of mild and hence omitted from the UK return).

There were 2.51 million animals used for the first time in completed procedures in 2017, representing a decrease of 8% (214,000) compared with 2016. The reason for this is not clear but appears to reflect a reduction in research activity across several sectors and is not confined to any particular purpose.

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

Of the 1.91 million experimental procedures completed in 2017, the majority involved the use of mice (58%), fish (16%) and rats (12%). Comparing with 2016, there were notable changes[[14]](#footnote-14) to the number of procedures involving:

* mice, which decreased by 124,000 (-10%) to 1.10 million procedures in 2017;
* birds[[15]](#footnote-15), which decreased by 19,000 (-13%) to 131,000 procedures in 2017;
* Rana, which decreased by 120 (-52%) to 110 procedures in 2017.
* other rodents, which increased by 810 (+53%) to 2,300 procedures in 2017;
* cattle, which increased by 4,100 (+82%) to 9,100 procedures in 2017;
* fish[[16]](#footnote-16), which increased by 22,000(+8%) to 309,000 procedures in 2017;

Of the 669,000 procedures in 2017 related to the creation/breeding of genetically altered animals not used in further procedures, the majority involved mice (84%), fish (15%), and rats (0.5%). Comparing with 2016, there were notable changes[[17]](#footnote-17) to the number of procedures involving:

* mice, which decreased by 63,000 (-10%) to 560,000 procedures in 2017;
* fish[[18]](#footnote-18), which decreased by 16,000 (-13%) to 104,000 procedures in 2017;
* rats, which decreased by 2,400 (-45%) to 3,100 procedures in 2017;
* sheep, which decreased by 170 (-91%) to 20 procedures in 2017;
* pigs, which decreased by 120 (-49%) to 120 procedures in 2017;
* amphibians[[19]](#footnote-19), which decreased by 620 (-49%) to 640 procedures in 2017;

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

Of the 1.91 million experimental procedures completed in 2017:

* 7% (135,000) were assessed as non-recovery, compared with 8% (155,000) in 2016;
* 61% (1.17 million) were assessed as (up to and including) mild, compared with 58% (1.18 million) in 2016;
* 26% (504,000) were assessed as moderate, compared with 29% (589,000) in 2016;
* 5% (95,000) were assessed as severe, compared with 6% (115,000) in 2016.

Of the 669,000 procedures in 2017 related to the creation/breeding of genetically altered animals not used in further procedures:

* 0.07% (470) were assessed as non-recovery, compared with 0.2% (1,500) in 2016;
* 85% (570,000) were assessed as (up to and including) mild, compared with 88% (658,000) in 2016;
* 8% (55,000) were assessed as moderate, compared with 7% (51,000) in 2016;
* 6% (43,000) were assessed as severe, compared with 5% (40,000) in 2016.

Changes in the proportions of severity assessments reported may be an effect of increased familiarity with the reporting procedure, rather than a true change in the severity of procedures. Given that severity information has only been collected since 2014, clear trends in this data will take several years to emerge.

In relation to the creation/breeding of genetically altered animals not used in further procedures, the main reason for severe assessments is that animals in breeding colonies were found dead with no clear explanation for the cause of death; the default position being that where the death cannot be excluded from being procedural, it is recorded as ‘severe’. Home Office continues to look to improve the guidance provided in this area, particularly with respect to fish.

Because the UK has in the past regulated the breeding of genetically altered (GA) animals (regardless of phenotype), in contrast to most other Member States, there remain a large number of animals bred on mild severity protocols which were assessed as having mild actual severity. Some of these reflect invasive genotyping methods, and this is particularly common for fish. The Home Office believes however that there remains some over reporting of the actual severity of GA animals. Nevertheless, the reduction in the overall numbers of procedures by severity for creation and breeding of animals for use in 2017 suggests that the ongoing education and improved guidance for users on this matter is having an impact.

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

The UK has subscribed to the three principles of replacement, reduction and refinement (the 3Rs) for a number of years but recent years has seen the principles of the 3Rs placed more firmly at the core of animal scientific research. This is principally achieved through the project licence evaluation process, provision of advice by the Inspectorate of the Animals in Science Regulation Unit and through the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This commitment is not focused on baseline numbers, which would be evident through the statistics, and which are influenced by a range of extraneous factors. Instead, it encompasses replacement, reduction and refinement more broadly, putting them at the heart of a science-led approach.

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

Basic research “other category” included:

* Embryology, cell and molecular biology;
* Genetics;
* Parasitology;
* Studies of infectious agents where it was the agent, rather than the disease, under investigation;
* Some probable erroneous entries eg. renal disease, caused by confusion as to which category to use. The Home Office intends to clarify the instructions to data suppliers in the UK to improve data quality in the future.

Applied research “other” category included:

* Pharmacokinetic and/or Pharmacodynamic (PK/PD) studies;
* Mitochondrial diseases;
* Haematology;
* Wound healing;
* Pain disorders;
* Sleep.

Regulatory use, routine production “other”:

* Antigens, infectious agents including parasites, oocytes, etc;
* Antibodies (but not by ascites method);
* Urine.

Regulatory use, quality control “other”:

* Method development, agent standardisation;
* Vaccine stability and testing of seed materials.
* Rodenticide evaluation (not field trials).

Regulatory use, legislative purpose “other”:

* Most commonly to meet industry required standards, rather than legislative requirements.

Regulatory use, toxicity “other”:

* Effects on non-target (i.e. ASPA non-Schedule 2) species;
* Metabolism.

Regulatory Use: Other legislative requirements

* Mainly production to meet industry specifications.

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

Not applicable.

## United Kingdom: Statistical Data 2017

### All uses of animals by species

|  |  |  |
| --- | --- | --- |
| Animal Species | Number of animals | Percentage |
| Mice | 1665386 | 64.68% |
| Rats | 237831 | 9.24% |
| Guinea-Pigs | 22560 | 0.88% |
| Hamsters (Syrian) | 1126 | 0.04% |
| Hamsters (Chinese) |  |  |
| Mongolian gerbil | 311 | 0.01% |
| Other Rodents | 2327 | 0.09% |
| Rabbits | 10444 | 0.41% |
| Cats | 288 | 0.01% |
| Dogs | 3949 | 0.15% |
| Ferrets | 405 | 0.02% |
| Other carnivores | 244 | 0.01% |
| Horses, donkeys and cross-breeds | 10600 | 0.41% |
| Pigs | 4742 | 0.18% |
| Goats | 304 | 0.01% |
| Sheep | 47946 | 1.86% |
| Cattle | 9085 | 0.35% |
| Prosimians |  |  |
| Marmoset and tamarins | 166 | 0.01% |
| Cynomolgus monkey | 2662 | 0.1% |
| Rhesus monkey | 132 | 0.01% |
| Vervets (Chlorocebus spp.) |  |  |
| Baboons |  |  |
| Squirrel monkey |  |  |
| Other species of non-human primates |  |  |
| Other species of Old World Monkeys (Cercopithecoidea) |  |  |
| Other species of New World Monkeys (Ceboidea) |  |  |
| Apes |  |  |
| Other Mammals | 804 | 0.03% |
| Domestic fowl | 125670 | 4.88% |
| Other birds | 6729 | 0.26% |
| Reptiles | 92 | 0% |
| Rana | 108 | 0% |
| Xenopus | 8095 | 0.31% |
| Other Amphibians | 533 | 0.02% |
| Zebra fish | 320146 | 12.43% |
| Other Fish | 92190 | 3.58% |
| Cephalopods |  |  |
| Total | 2574875 | 100.00% |

### Place of birth of animals other than non-human primates as registered at first use

|  |  |  |
| --- | --- | --- |
| Place of birth | Number of animals | Percentage |
| Animals born in the EU at a registered breeder | 2377256 | 94.92% |
| Animals born in the EU but not at a registered breeder | 112655 | 4.5% |
| Animals born in rest of Europe | 3240 | 0.13% |
| Animals born in rest of world | 11315 | 0.45% |
| Total | 2504466 | 100.00% |

### Source of non-human primates as registered at first use

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

### Generation of non-human primates

|  |  |  |
| --- | --- | --- |
| NHP Generation | Number of animals | Percentage |
| F0 |  |  |
| F1 | 1 | 0.05% |
| F2 or greater | 587 | 26.5% |
| Self-sustaining colony | 1627 | 73.45% |
| Total | 2215 | 100.00% |

### Purposes for which animals are used

|  |  |  |
| --- | --- | --- |
| Purpose Category | Number of uses | Percentage |
| Basic Research | 1314541 | 51.05% |
| Translational and applied research | 335968 | 13.05% |
| Regulatory use and Routine production | 505504 | 19.63% |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 11901 | 0.46% |
| Preservation of species | 1925 | 0.07% |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills | 1235 | 0.05% |
| Forensic enquiries | 88 | 0% |
| Maintenance of colonies of established genetically altered animals, not used in other procedures | 403713 | 15.68% |
| Total | 2574875 | 100.00% |

### Basic Research

|  |  |  |
| --- | --- | --- |
| Basic Research | Number of uses | Percentage |
| Oncology | 176024 | 13.39% |
| Cardiovascular Blood and Lymphatic System | 78397 | 5.96% |
| Nervous System | 273172 | 20.78% |
| Respiratory System | 11654 | 0.89% |
| Gastrointestinal System including Liver | 26197 | 1.99% |
| Musculoskeletal System | 28423 | 2.16% |
| Immune System | 246232 | 18.73% |
| Urogenital/Reproductive System | 34838 | 2.65% |
| Sensory Organs (skin, eyes and ears) | 23477 | 1.79% |
| Endocrine System/Metabolism | 29411 | 2.24% |
| Multisystemic | 173366 | 13.19% |
| Ethology / Animal Behaviour /Animal Biology | 67223 | 5.11% |
| Other basic research | 146127 | 11.12% |
| Total | 1314541 | 100.00% |

### Translational and applied research

|  |  |  |
| --- | --- | --- |
| Translational and applied research | Number of uses | Percentage |
| Human Cancer | 90879 | 27.05% |
| Human Infectious Disorders | 70203 | 20.9% |
| Human Cardiovascular Disorders | 4374 | 1.3% |
| Human Nervous and Mental Disorders | 42354 | 12.61% |
| Human Respiratory Disorders | 12633 | 3.76% |
| Human Gastrointestinal Disorders including Liver | 3943 | 1.17% |
| Human Musculoskeletal Disorders | 6113 | 1.82% |
| Human Immune Disorders | 7354 | 2.19% |
| Human Urogenital/Reproductive Disorders | 3541 | 1.05% |
| Human Sensory Organ Disorders (skin, eyes and ears) | 10854 | 3.23% |
| Human Endocrine/Metabolism Disorders | 7815 | 2.33% |
| Other Human Disorders | 10850 | 3.23% |
| Animal Diseases and Disorders | 23507 | 7% |
| Animal Welfare | 2843 | 0.85% |
| Diagnosis of diseases | 3476 | 1.03% |
| Plant diseases |  |  |
| Non-regulatory toxicology and ecotoxicology | 35229 | 10.49% |
| Total | 335968 | 100.00% |

### Regulatory use and Routine production

|  |  |  |
| --- | --- | --- |
| Regulatory use 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 use - Quality control (including batch safety and potency testing)

|  |  |  |
| --- | --- | --- |
| Regulatory use - Quality control (incl 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 use - Toxicity and other safety testing including pharmacology

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Phototoxicity |  |  |
| 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 use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Acute and sub-acute toxicity testing methods | Number of uses | Percentage |
| LD50, LC50 | 10622 | 64.07% |
| Other lethal methods | 98 | 0.59% |
| Non lethal methods | 5860 | 35.34% |
| Total | 16580 | 100.00% |

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

|  |  |  |
| --- | --- | --- |
| Regulatory use - Toxicity and other safety testing including pharmacology - Repeated dose toxicity | Number of uses | Percentage |
| up to 28 days | 21572 | 53.36% |
| 29 - 90 days | 11727 | 29.01% |
| > 90 days | 7130 | 17.64% |
| Total | 40429 | 100.00% |

### Regulatory use - Toxicity and other safety testing including pharmacology - Ecotoxicity

|  |  |  |
| --- | --- | --- |
| Regulatory use - 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% |
| Other ecotoxicity |  |  |
| Total | 11444 | 100.00% |

### Routine production

|  |  |  |
| --- | --- | --- |
| Routine production | Number of uses | Percentage |
| Blood based products | 55197 | 39.5% |
| Monoclonal antibody by mouse ascites method |  |  |
| Other product types | 84527 | 60.5% |
| Total | 139724 | 100.00% |

### Uses of animals to meet legislative requirements

|  |  |  |
| --- | --- | --- |
| Testing by Legislation | Number of uses | Percentage |
| Legislation on medicinal products for human use | 208938 | 41.33% |
| Legislation on medicinal products for veterinary use and their residues | 118458 | 23.43% |
| Medical devices legislation | 7285 | 1.44% |
| Industrial chemicals legislation | 86337 | 17.08% |
| Plant protection product legislation | 18417 | 3.64% |
| Biocides legislation | 292 | 0.06% |
| Food legislation including food contact material | 1688 | 0.33% |
| Feed legislation including legislation for the safety of target animals, workers and environment | 14831 | 2.93% |
| Cosmetics legislation |  |  |
| Other legislation | 49258 | 9.74% |
| Total | 505504 | 100.00% |

### Legislative requirements

|  |  |  |
| --- | --- | --- |
| Legislative requirement | Number of uses | Percentage |
| Legislation satisfying EU requirements | 478397 | 94.64% |
| Legislation satisfying national requirements only [within EU] | 1670 | 0.33% |
| Legislation satisfying Non-EU requirements only | 25437 | 5.03% |
| Total | 505504 | 100.00% |

### First uses and re-uses

|  |  |  |
| --- | --- | --- |
| Re-use | Number of uses | Percentage |
| No | 2506681 | 97.35% |
| Yes | 68194 | 2.65% |
| Total | 2574875 | 100.00% |

### Actual severity of uses

|  |  |  |
| --- | --- | --- |
| Severity | Number of uses | Percentage |
| Non-recovery | 135780 | 5.27% |
| Mild [up to and including] | 1741624 | 67.64% |
| Moderate | 559401 | 21.73% |
| Severe | 138070 | 5.36% |
| Total | 2574875 | 100.00% |

### Use in creation of a new genetic line

|  |  |  |
| --- | --- | --- |
| Creation of new GL | Number of uses | Percentage |
| No | 2309701 | 89.7% |
| Yes | 265174 | 10.3% |
| Total | 2574875 | 100.00% |

### Uses by genetic status

|  |  |  |
| --- | --- | --- |
| Genetic Status | Number of uses | Percentage |
| Not genetically altered | 1263597 | 49.07% |
| Genetically altered without a harmful phenotype | 1102809 | 42.83% |
| Genetically altered with a harmful phenotype | 208469 | 8.1% |
| Total | 2574875 | 100.00% |

1. http://www.oecd.org/chemicalsafety/oecd-encourages-development-of-non-animal-test-methods-for-detection-of-thyroid-disruptors.htm [↑](#footnote-ref-1)
2. Covers the three largest numeric and the three largest percentage changes between 2014 and 2015. [↑](#footnote-ref-2)
3. Specifically, Zebrafish and other fish species. [↑](#footnote-ref-3)
4. Specifically, Syrian Hamsters. [↑](#footnote-ref-4)
5. Covers the three largest numeric and the three largest percentage changes between 2014 and 2015. One of the species listed has one of the three largest percentage changes and, in addition, one of the three largest numeric changes, hence there being five species listed. [↑](#footnote-ref-5)
6. Specifically, Zebrafish and other fish species. [↑](#footnote-ref-6)
7. Specifically, Xenopus (Laevis and Tropicalis). [↑](#footnote-ref-7)
8. Covers the three largest numeric and the three largest percentage changes between 2015 and 2016. [↑](#footnote-ref-8)
9. Specifically, domestic fowl and other bird species. [↑](#footnote-ref-9)
10. Covers the three largest numeric and the three largest percentage changes between 2015 and 2016. One of the species listed has one of the three largest percentage changes and, in addition, one of the three largest numeric changes, hence there being five species listed. [↑](#footnote-ref-10)
11. Specifically, Xenopus (Laevis and Tropicalis). [↑](#footnote-ref-11)
12. Specifically, Zebrafish and other fish species. [↑](#footnote-ref-12)
13. Specifically domestic fowl. [↑](#footnote-ref-13)
14. Covers the three largest numeric and the three largest percentage changes between 2016 and 2017. [↑](#footnote-ref-14)
15. Specifically, domestic fowl and other bird species. [↑](#footnote-ref-15)
16. Specifically, Zebrafish and other fish species. [↑](#footnote-ref-16)
17. Covers the three largest numeric and the three largest percentage changes between 2016 and 2017. [↑](#footnote-ref-17)
18. Specifically, Zebrafish and other fish species. [↑](#footnote-ref-18)
19. Specifically, Xenopus (Laevis and Tropicalis). [↑](#footnote-ref-19)