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PART 1/2

COMMISSION STAFF WORKING DOCUMENT

**Summary Report on the statistics on the use of animals for scientific purposes in the
Member States of the European Union and Norway in 2019**

Report of statistical information on the use of animals in procedures

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Report of statistical information on the use of animals in procedures

I. Executive Summary

This report presents statistical data on the use of animals for scientific purposes in the Member States of the European Union (EU) and Norway during 2019 under Directive 2010/63/EU¹ (“the Directive”) on the protection of animals used for scientific purposes.

The presentation of data follows that of the previous reports distinguishing animals used directly in research, testing, routine production and for educational (including training) purposes (“research and testing” from here on), from those used for the creation and maintenance of genetically altered animals in support of the Union research needs.

As for 2018, this current report continues to incorporate data from Norway. However, 2019 data is the last set that will include data from the United Kingdom. It is important, therefore, that any comparisons to previous years are made using the same reporting countries.

1.1. Numbers and origins of animals

In 2019, the total number of animals used for the first time **in research and testing** covering the 29 countries (EU-28 and Norway) is 10.4 million. This is 1,5% lower than in 2018.

	2015	2016	2017	2018 (EU-28 incl. NO) ²	2019 (EU-28 incl. NO) ²
Total	9,590,379	9,817,946	9,388,162	10,572,305	10,401,673

Table 1: Total numbers of animals used for the first time for research, testing, routine production and education purposes in the Union between 2015 and 2019 with the inclusion of data from Norway in 2018 and 2019

¹ Directive 2010/63/EU OJ L276, 20.10.2010, p.33-79

² NO : including data from Norway

The number of animals used for the first time for **the creation and maintenance of genetically altered (GA) animal lines** to meet the research needs in the Union is around 1.2 million. This shows a significant reduction of over 20%. However, the accurate reporting of animals under the maintenance of existing GA lines is particularly challenging, which may partly explain the continued fluctuation of numbers.

	2015	2016	2017	2018 (EU-28 incl. NO)	2019 (EU-28 incl.NO)
GA creation	591,033	493,156	634,705	588,062	508,320
GA maintenance	996,993	700,536	641,882	932,729	699,985
Total GA creation and maintenance	1,588,025	1,193,692	1,276,587	1,520,791	1,208,305

Table 2: Total numbers of animals used for the creation and maintenance of genetically altered animal lines

The distribution of species that were used for the first time in research and testing remains relatively stable when compared with previous years.

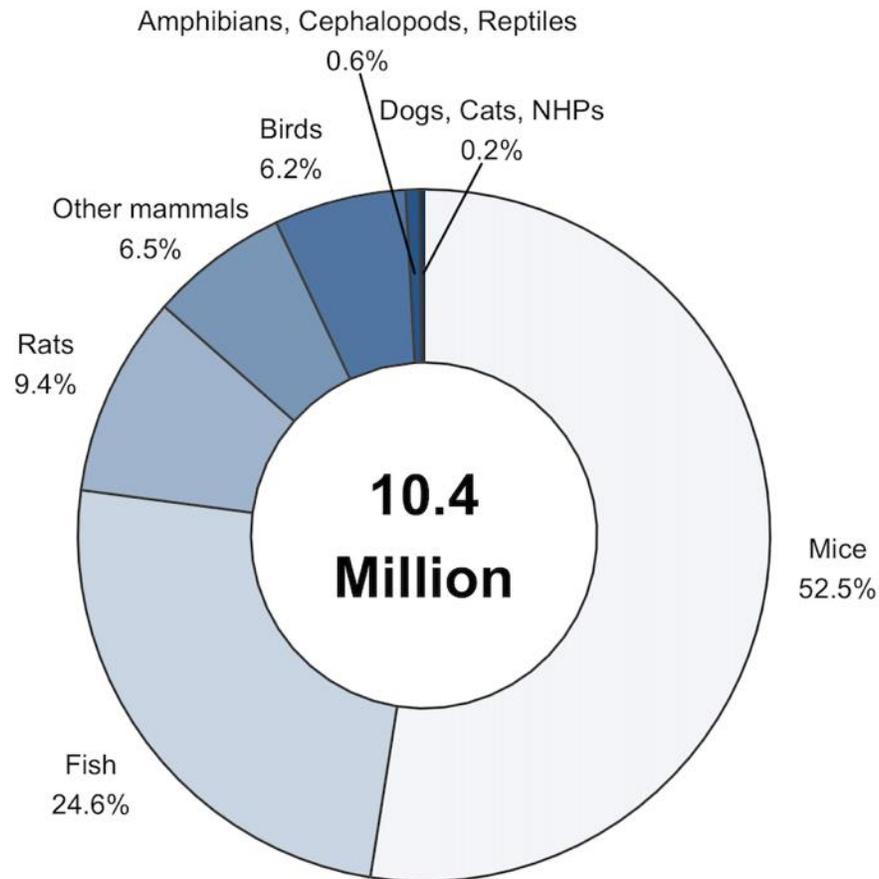


Figure 1: Numbers of animals used for the first time by main classes of species in 2019

In 2019, when looking at more significant changes, the numbers of “Other rodents” used for the first time increased (+70%), there was an increase also in the first time use of cats (+40%), birds (+10%), “Other carnivores” (+9%) and the group of amphibians and cephalopods (+96%). Even if small in over-all numbers, it is interesting to note that the increase in the uses of other amphibians (+274%) was for a large part for the preservation of the species and cephalopods almost exclusively (+398%) for the purposes of animal welfare.

Contrary to the previous year, the first time uses of dogs and non-human primates decreased significantly, -26% and -13% respectively. The use of guinea-pigs continued to decrease (-4%) and there was also a decrease in the use of fish (-7%) and farm animals (-3%).

The origin of animals is reported. Animals bred outside the Union do not benefit from the accommodation and care standards provided by the Directive. Moreover, an increase in transport times may negatively impact their welfare.

In 2019, the proportion of animals born outside of the EU continue to represent only 1% of all animals used for the first time (excluding non-human primates). The proportion of animals born in the EU but not at a registered breeder increased representing 12%. It is important to note that this category includes animals from, for example, farms, and studies carried out using wild animals, especially wild fish.

The Directive provides additional protection for non-human primates (NHP) due to their genetic proximity to human beings, their highly developed social skills and capacity to experience pain, suffering and distress. In order to end the capturing of animals from the wild including for the purposes of breeding, the Directive requires moving towards using NHPs that have been bred, ultimately, in self-sustaining colonies, from parents who themselves have been bred in captivity.

In 2019, the origin of non-human primates remains stable coming from Africa, Asia and Union-registered breeders, with a slight increase of those coming from EU registered breeders, now representing over 14% of all non-human primates used for the first time. The proportion of non-human primates coming from either self-sustaining colonies or being second or higher generation purpose-bred was 86%, a slight increase from 2018.

1.2. Uses of animals in research and testing

In 2019, 10.61 million uses (first and any subsequent reuse) of animals for scientific purposes were reported, including the data from Norway. The total number of uses decreased by just under 2%. As in previous years, the main purpose was research (72%) of which 45% of all uses were carried out for basic research and just under 27% for translational and applied research purposes. A further 17% of animal uses were for regulatory use to satisfy legislative requirements, followed by routine production (6%).

In absolute numbers, the most important changes, compared to 2018, were the number of uses having decreased for regulatory purposes (-8%) as well as translational and applied research (-7%) and basic research (-3%). However, preservation of species (+168%) and protection of the natural environment in the interest of the health or welfare of human beings or animals (+176%) increased significantly, concerning mostly “other fish”.

There was also a significant increase (+39%) in uses under category “Other basic research”. The Commission continues to monitor excessive use of this category. Where necessary, the Commission addresses it bilaterally with Member States where such use seems to be a result of a failure of the users to report under more appropriate pre-specified categories.

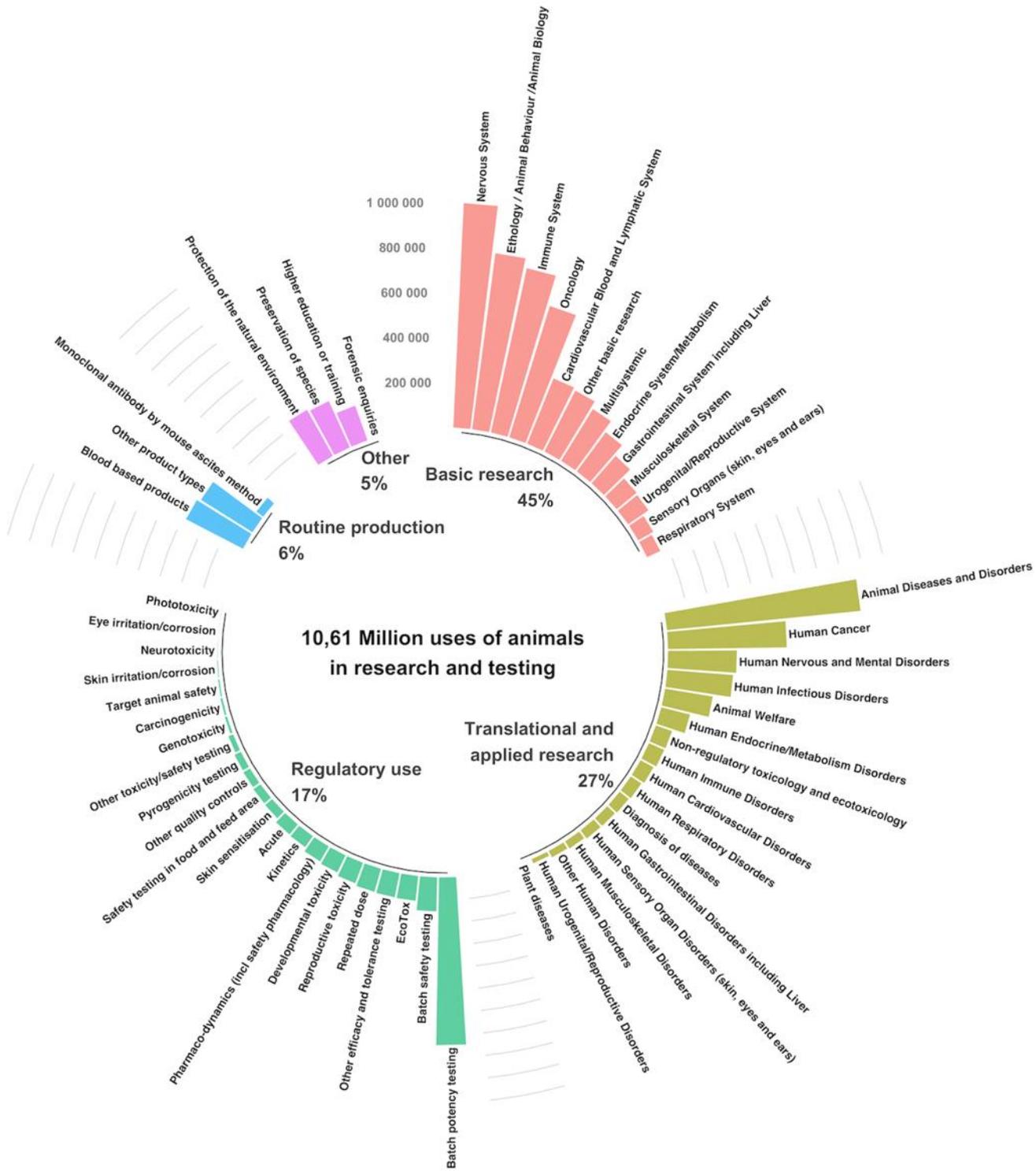


Figure 2: All uses of animals for research and testing in 2019

The actual severities reported for each use of an animal continue to remain rather stable in 2019 with a slight decrease in categories ‘moderate’ and ‘severe’, both down by 1% to 33% and 9% respectively. 6% of uses were reported as ‘non-recovery’.

	2017	2018 (EU-28 incl. NO)	2019 (EU-28 incl. NO)
Non-recovery	6% (621,054)	6% (612,094)	6% (586,373)
Mild [up to and including]	51% (4,865,721)	50% (5,469,214)	52% (5,512,134)
Moderate	32% (3,071,828)	34% (3,658,621)	33% (3,510,993)
Severe	11% (1,023,138)	10% (1,064,925)	9% (999,264)
Total	100% (9,581,741)	100% (10,804,854)	100% (10,608,764)

Table 3: Severity of uses

The graphical presentation below shows the purpose areas with most severe uses. The patterns seem very similar to 2018. In 2019, most of these were conducted for regulatory purposes while routine production was mostly mild. Uses in translational and applied research tended to be more severe than those reported in basic research. When analysing all the sub-categories of purposes, batch potency testing continue to result in the highest number of severe uses (over 215,000 uses). Looking at the proportion of severe uses within a sub-category: the production of monoclonal antibodies was again the highest (91% of all uses for this purpose), followed by acute toxicity studies in the area of ecotoxicity (39%) and LD50, LC50 in the area of acute and sub-acute toxicity testing (29%).

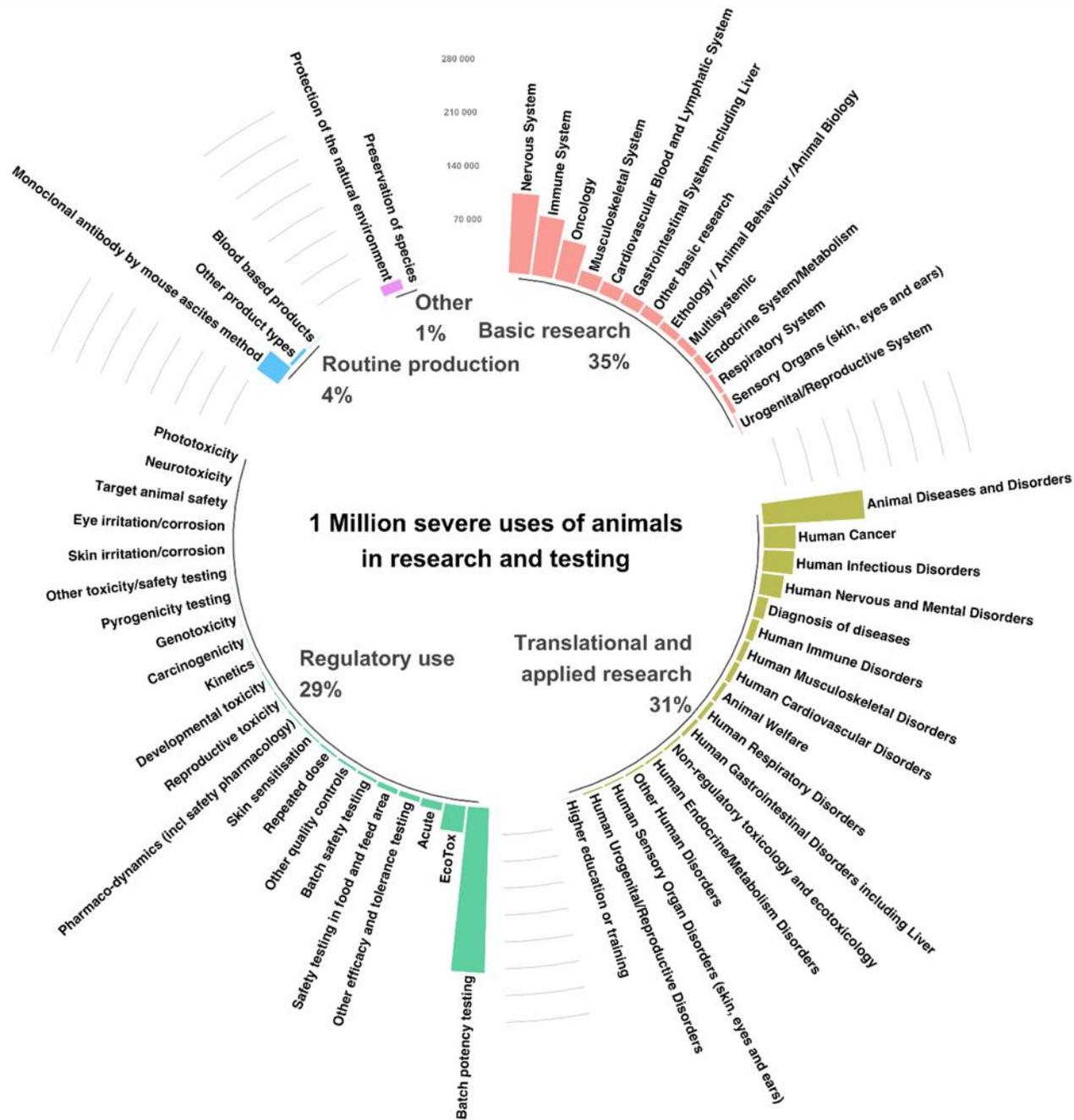


Figure 3: Severe uses of animals for research and testing in 2019

In 2019, the majority of uses to satisfy regulatory requirements of specific sector legislation occurred in relation to placing on the market of medicinal products for humans (61%), veterinary medicinal products (18%) and industrial chemicals (9%) (Figure 4).

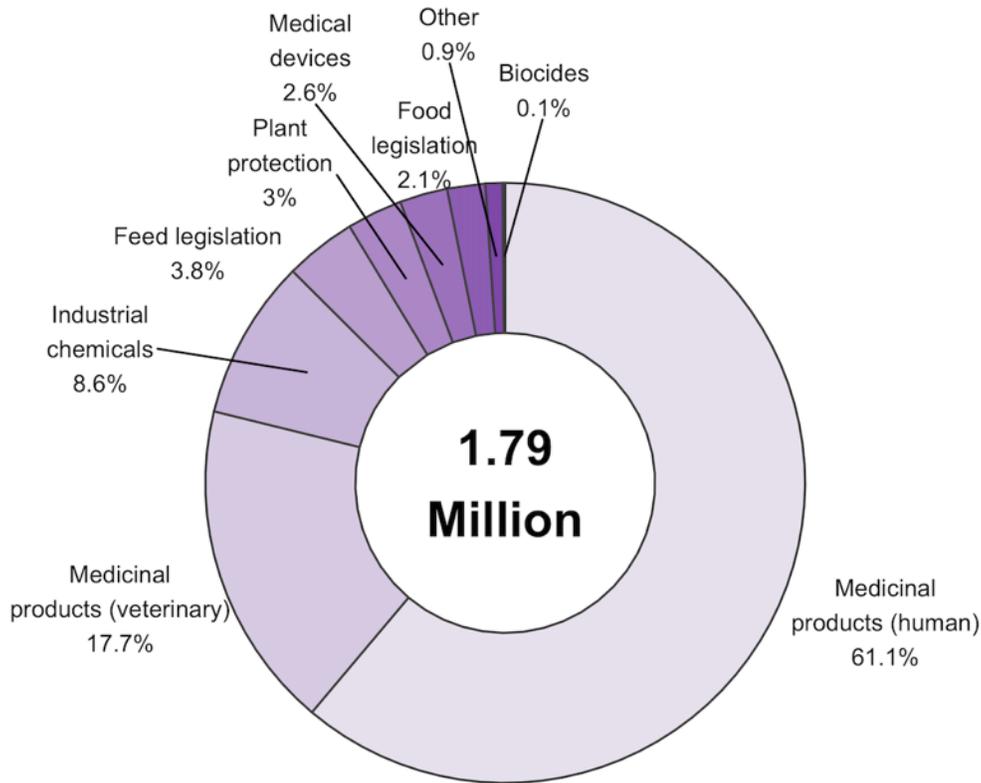


Figure 4: Regulatory uses by type of legislation in 2019

As in previous years, concerning the testing carried out to satisfy regulatory toxicity, safety and efficacy information requirements, the main legislative instruments were for medicinal products for human use (61%), veterinary medicinal products (18%) and industrial chemicals (9%). The majority of regulatory uses continues to be performed to comply with regulatory requirements originating from the European Union (94%).

In terms of severities in the area of animals used to satisfy regulatory requirements, 16% of these uses were reported as severe, 25% as moderate, 58% mild (and up to mild) and 1% as non-recovery.

In line with the principle of the Three Rs, the total number of animals used in procedures can be reduced by performing more than one procedure on an animal, however, under strict conditions taking into account the lifetime experience of the individual animal. The reuses remained stable at 2% of all uses. Proportionally, large mammals are reused more often, such as horses, donkeys and cross-breeds, sheep, and some species of non-human primate. However, also the reuse of reptiles is high (76%). Routine production and animals used for the purposes of education training have the highest proportions of reuses (11% and 10% respectively).

There was a slight increase in the proportion of genetically altered animals used in research and testing in 2019 from 24% to 25%. Of the 2.66 million uses that were carried out on animals that were genetically altered, 17% had a harmful phenotypic alteration. Zebra fish and mice continue to be the most commonly genetically altered species with 61% (+1%) and 41% (+2%) of these genetically altered respectively.

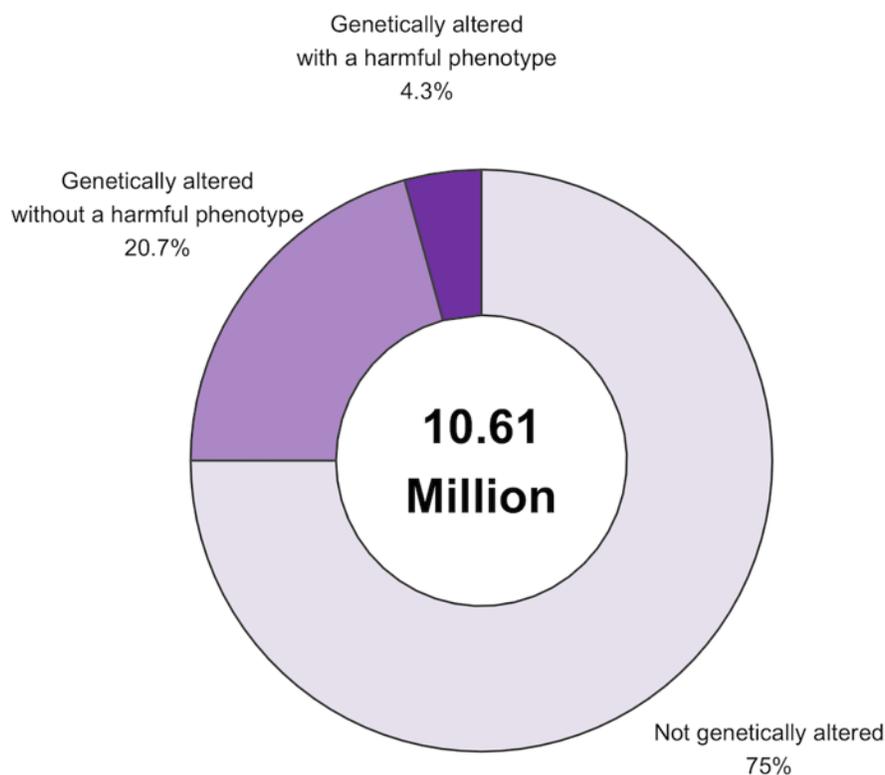


Figure 5: Genetic status of animals used in research and testing in 2019

Genetically altered animals are used almost exclusively for research purposes with basic research accounting for 77% of uses of genetically altered animals, a slight increase from 2018 (+3%).

1.3. Creation and maintenance of genetically altered animal lines for research purposes

In 2019, the number of animal uses for the creation of new genetically altered animal lines continued to decrease. After a decrease of 10% from 2017 to 2018, there was another decrease of close to 14%, from 592,000 to 511,348 uses. The main species used for this purpose were, as before, mice and zebra fish, 73% and 25% respectively. Other species include rats, other species of fish, xenopus, and domestic fowl. In 2017 and 2018, ten marmosets had been used for the creation of new genetically altered animal lines. In 2019, this had increased to 43 marmosets with the field of research interest identified as urogenital/reproductive systems and multisystemic studies.

In 2019, category basic research covered 95% of all uses for the creation of new genetically altered animal lines. The purposes for which these were created remained the same: multisystemic research (19%), nervous system (17%), oncology (14%) and immune system (13%). As with the previous year,

the most important sub-category under translational and applied research for which new genetically altered animal lines were created was human cancer (2%).

In comparison to 2018, animals used for the first time for the ‘maintenance of colonies of genetically altered animals of established lines’ decreased by 24%. However, the likely reason for the continued fluctuation of the numbers in this category is the complexity of the reporting requirements. As announced in our previous report, a guidance document on genetically altered animals under the Directive³ has been developed. It was endorsed by Member State National Contact Points responsible for the implementation of the Directive at their meeting in November 2021. This will be made available in all Union languages during 2022, and is also expected to improve harmonisation and accuracy of reporting of genetically altered animals.

I.4. Conclusions

The data from Norway has been included in the EU statistical reports now for two years. It is important to be aware, however, that there will be two further complications in the coming years that will make analysis of trends challenging. Firstly, as a result of the UK leaving the EU, the data from the UK will no longer be included from 2020 onwards. Secondly, with the revised reporting requirements to improve accuracy and precision, some of the reporting categories will change from 2021 onwards. The new reporting requirements can be found in Commission Implementing Decision 2020/569/EU⁴ and these aim to address, for example, excessive use of “other” categories by providing new categories for those most commonly reported under “other” species or “other” purposes.

The total numbers of animals used for the first time in research and testing continued to decrease slightly, from 10,6 million to 10,4 million between 2018 and 2019. A clear decrease was noted in the use of species of particular concern to the public, namely dogs and non-human primates, even if the use of cats increased. Also, some positive trends were seen with the reduction of testing in order to satisfy regulatory requirements. The main increases were seen in the use of animals for the preservation of species and protection of the natural environment in the interest of the health or welfare of human beings or animals, and these were mainly linked to the use of fish and amphibians. When taking into account all animals used for research and testing for the first time, and those used for the first time for the creation and maintenance of genetically altered animals, there was an overall reduction of 4% between 2018 and 2019.

Concerning the use of animals in areas where alternative methods are available, it is concerning that the decrease seen in previous years in the use of the rabbit pyrogenicity test did not continue in 2019. Further efforts should be made to speed up the transition to non-animal alternatives. The use of the mouse ascites method for the production of antibodies also continues to be of concern, even if it decreased by over a third. Its use is almost entirely reported by one Member State and efforts are currently under way by the authorities to review on-going projects where mouse ascites use may be involved. Such use can only be authorised if the project applicant provides robust scientific evidence why the use of alternatives is not possible. The revised data categories for 2021 data and onwards will allow for a better monitoring of animal use for the production of antibodies.

2021 was an important year for transparency in animal use in research and testing in the Union. During the summer, the European Commission launched two open access databases, available for all interested

³ https://ec.europa.eu/environment/chemicals/lab_animals/pdf/Genetically_Altered_Animals_EN_556755452.pdf

⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2020.129.01.0016.01.ENG&toc=OJ:L:2020:129:TOC

stakeholders, to facilitate identification of areas where replacement and refinement efforts are most urgently needed. The first database, ALURES Statistics⁵, allows statistical data mining at Union level. The second database, ALURES NTS⁶, contains Member State publications of non-technical project summaries that provide further understanding of why and how animals are still used in research and testing. These can also be of interest to those planning animal use, to identify ways in which the Three Rs have been applied in already authorised projects.

The European Commission invites all stakeholders, including public and private research organisations and funding bodies, to actively use these tools to support initiatives to strategically progress towards the ultimate goal of full replacement as set out by the Directive.

⁵ https://ec.europa.eu/environment/chemicals/lab_animals/alures_en.htm

⁶ https://ec.europa.eu/environment/chemicals/lab_animals/alures_nts_en.htm

BACKGROUND

The objective of the Commission Staff Working Document is to present statistical information on the use of animals in procedures in the European Union and Norway under Directive 2010/63/EU⁷ of 22 September 2010 on the protection of animals used for scientific purposes. The obligation to collect statistical data is covered by Article 54(2) of the Directive. The data format for the 2019 data was laid out in now repealed Commission Implementing Decision 2012/707/EU⁸.

Regulation (EU) 2019/1010⁹ (“the Regulation”) amended Article 54(2) of the Directive taking effect in June 2019. This report is based on data provided by Member States in accordance with the previous wording of Article 54(2) requiring the collection on an annual basis of statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures. The amended Article 54(2) requires Member States to submit the statistical data by electronic transfer in a non-summarised format to the Commission.

As a result of the amendment to the Directive, also Commission Implementing Decision 2012/707/EU was required to be changed to accommodate the new obligations. A new Commission Implementing Decision 2020/569/EU¹⁰ was adopted on 16 April 2020. However, the first data sets under the revised statistical reporting format will cover the year 2021 to be submitted to the Commission by 11 November 2022 for publication by the Commission in 2023.

The Regulation also removed the obligation of the Commission to submit a formal statistical report to the European Parliament and the Council. However, since improved transparency is one of the key objectives of the Directive, the Commission considers it appropriate, as well as necessary in support of the other objectives of the Directive, that the data submitted by the Member States are made available on a yearly basis until 2023.

This current statistical report contains the results of the data collected by all 28 Member States and Norway in 2019. References to “EU” and “EU data” from here on in this report, are therefore to be understood to cover 28 EU Member States and Norway, unless otherwise specified.

II. DATA SUBMITTED AND GENERAL ASSESSMENT

III.1. Data Submitted

The data were collected according to the Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and the Council on the protection of animals used for scientific purposes.

⁷ Directive 2010/63/EU OJ L276, 20.10.2010, p.33-79

⁸ OJ L 320, 17.11.2012, p. 33–50

⁹ OJ L 170, 25.6.2019, p. 115–127

¹⁰ OJ L 129, 24.4.2020, p. 16–50

III.2. General Considerations

This report aims at providing a comprehensive overview on the use of animals in procedures in the European Union and Norway in 2019. The purposes of the use of animals have been analysed, and some of these purposes have been broken down into more precise sub-categories.

In this report, data are presented either in the form of figures or summary tables providing information on a specific aspect of the Directive. Overall numbers are given for the year 2019. On some occasions where the trend analysis provides information on the evolution of the Directive's figures. Numbers from previous years (2015-2018) are provided as well to support the comparison between years. Key findings are presented in the form of tables and graphics. However, in some cases, further information in the text may have been drawn both from annexed tables and Member State narratives (see Section C of this Staff Working Document). Member State narratives have been helpful in providing information such as for the content of 'other' categories (for example, "Other rodents", "Other basic research").

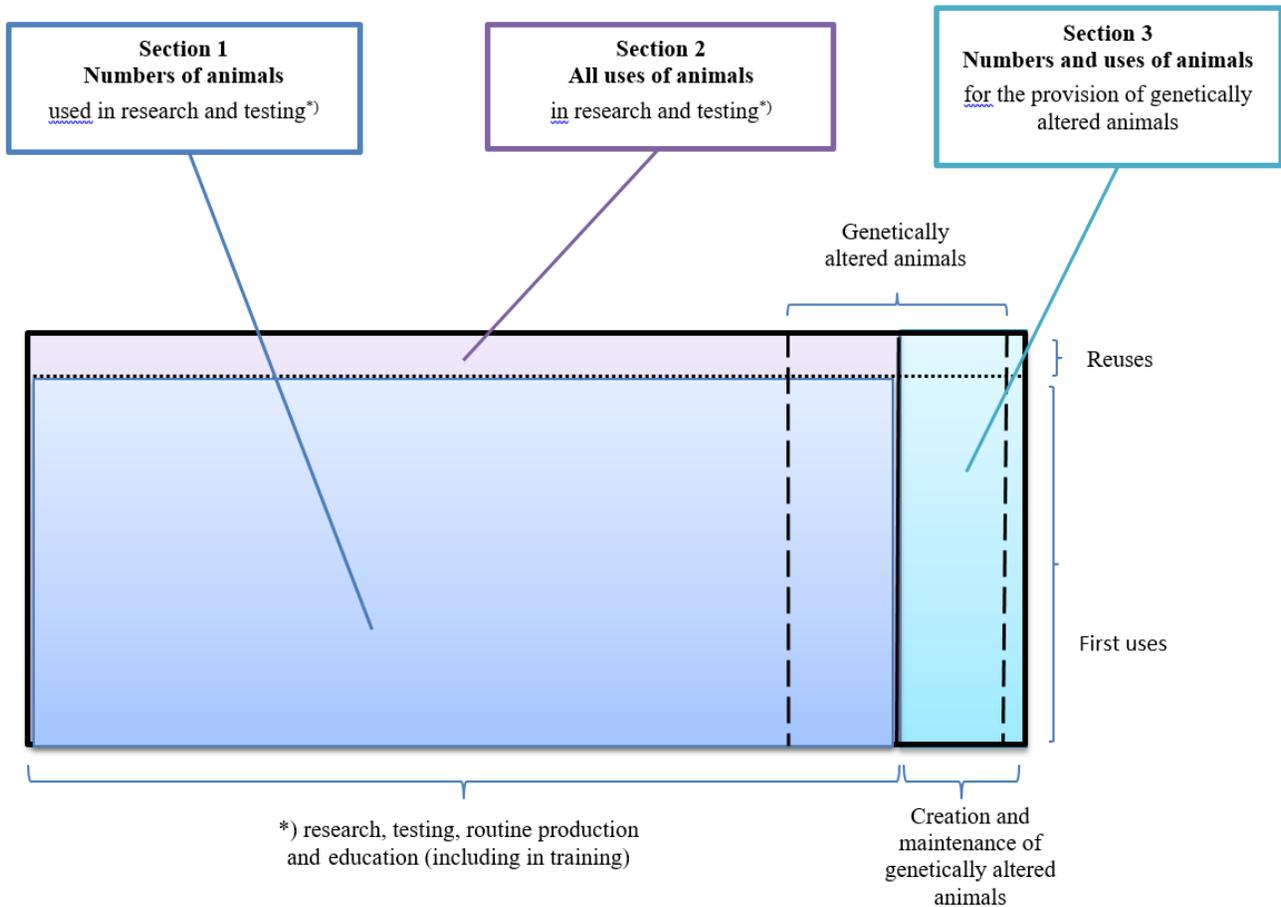
For the second year, statistical data from Norway are included in the report. In line with the EEA agreement, Norway transposed the Directive into their national legislation in July 2015. The introduction of data from Norway in the EU report has had a clear impact on both the overall numbers, the proportional distribution of species, and in some cases also of the purposes for which animals are used. The largest impact comes from studies involving fish, where individual studies can use a high number of animals. Consequently, this may also result in a high year-on-year fluctuation of fish and total numbers. Also, it is important to be mindful of the number of reporting countries if data comparisons between different reporting years are attempted.

The Commission and Member States continue to work together to address issues and questions arising from reporting obligations to ensure uniform understanding of the revised reporting requirements, such as the reporting of actual severity, animals used for the maintenance of genetically altered animal lines and accurate reporting under different purpose categories. In November 2021, Member State National Contact Points responsible for the implementation of the Directive endorsed an important guidance document on genetically altered animals³⁾ developed by experts from Member States and key stakeholders. The guidance document contains a dedicated section on statistical reporting requirements. The Commission will make it available in all Union languages to ensure the guidance is accessible to all those bound by the reporting obligations.

III.3. Report structure

The objective of this report is to present all these data structured in a manner that allows for an improved understanding of when and how animals are still used in science today. It is hoped that, in line with the Directive aims, this way of reporting will better facilitate the identification of animal use areas on which efforts for the development and validation of alternative approaches can be focused.

Therefore, Part A of the report is composed of three sections as illustrated in the picture below:



Numbers of animals used for research, testing, routine production and educational purposes¹¹ in the EU – Section 1 (IV.1)

The first section focuses on the *numbers of animals* used, for the first time, for the purposes of research, testing, routine production and education (the term ‘education’ in the context of this report also includes animals used for the purposes of training). These animals can be both conventional animals or those that have been genetically altered. This section reports on their numbers and origins. It excludes animals that have been used for the creation of a new genetically altered animal line, or maintenance of an existing genetically altered animal line. These are covered in section three below.

Details of all uses of animals for research, testing, routine production and educational purposes in the EU – Section 2 (IV.2)

The second section focuses on the way in which animals are used in these scientific procedures, *covering all uses, both the first and any subsequent reuse*. This serves to draw an overall picture of all uses of animals for the purposes of research, testing, routine production and education in the Union. This section

¹¹ In this context ‘Research’ means basic, applied and translational research, animals used for the purposes of protection of the natural environment in the interests of the health or welfare of human beings or animals, preservation of the species and forensic enquiries; ‘testing’ refers to regulatory use of animals and ‘education’ includes animals used for training purposes. Glossary in IV.4. provides further information on some of the categories of scientific use purposes.

takes into account the nature of the procedures, their legislative context, reuse of animals, the genetic status of the animals, and the severities experienced by the animals.

Numbers and uses of animals for the creation and maintenance of genetically altered animals in the EU – Section 3 (IV.3)

The third section focuses on the provision of *genetically altered animals* needed to support scientific research in the Union. It reports, on one hand, animals used in procedures for *the creation* of new genetically altered animal lines and, on the other, *the maintenance* of colonies of existing genetically altered animals. Like in section one of this report, it provides the actual numbers of animals, used for the first time, as well as more detailed information taking into account all uses (first, and any subsequent reuse) for the purposes of creation and maintenance of genetically altered animal lines. It also provides further information on the type of research for which new genetically altered animal lines are being created. These animals have not been used in other scientific procedures, in other words the data are separate from those covered in parts one and two of this report.

Part B of this report contains Union level data that have been used as the basis for conclusions in Part A of the report. Part C of this report provides data from the Member States together with their respective narratives.

Information outside of the scope of the statistical report

What remains outside of the scope of annual statistical reporting – even if covered by the scope and provisions of the Directive, are:

- Foetal forms of mammals;
- Animals killed solely for organs and tissues, and sentinels, unless the killing is performed under a project authorisation using a method not included in Annex IV of Directive 2010/63/EU;
- Animals bred and killed without being used, apart from genetically altered animals with intended and exhibited harmful phenotypes, and those having been genotyped with an invasive method before being killed.

Additional information on animals bred and killed without being used will be reported in the five-year report on the implementation of the Directive in line with Article 54(1) of the Directive.

PART A: COMPILATION AND OVERVIEW OF THE EU DATA BETWEEN 2015 AND 2019

IV.1 Numbers of animals used for research, testing, routine production and educational purposes in the EU

This part focuses on the numbers of animals used *for the first time* in procedures for the purposes of research, testing, routine production and education. Therefore, it excludes all reuses of animals that are considered in the second part. It also excludes animals that are used either for the creation of new genetic altered lines or the maintenance of colonies of established genetically altered animal lines. However, animals used for research, testing, routine production and educational purposes can be conventional or genetically altered.

In addition to the numbers of animals, this part also provides information on the species in relation to their origin, and for non-human primates, information on progress to purpose-bred animals, by recording generation.

IV.1.1. Numbers of animals used for the first time

In 2019, the number of animals used for the first time in the Union is 10.40 million, including the data from Norway and the United Kingdom.

	2015	2016	2017	2018 (EU-28 incl. NO) ¹²	2019 (EU-28 incl. NO) ¹²
Total	9,590,379	9,817,946	9,388,162	10,572,305	10,401,673

Table 4: Total numbers of animals used for the first time for research, testing, routine production and education purposes in the Union between 2015 and 2019

Figure 6 below illustrates the impact of the data from Norway to past numbers. With 29 countries reporting since 2018, the total number of animals used for the first time is above 10 million. However, when taking into account only the 28 countries that reported between 2015 and 2017, the total number of animals is around 9 million (9.14 million), an increase of 2% compared to 2018.

¹² NO : including data from Norway

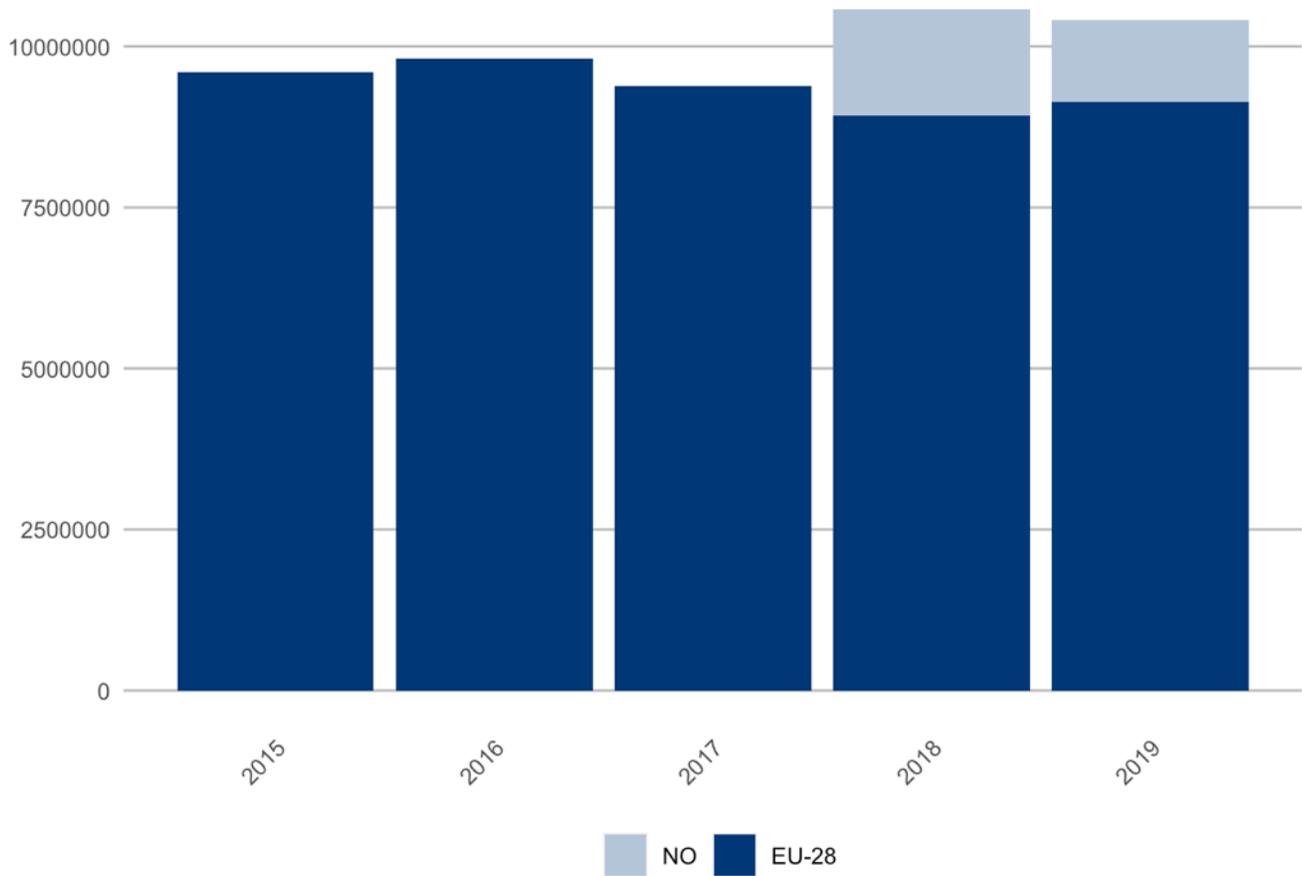


Figure 6: Evolution of total numbers of animals used for the first time for research, testing, routine production and education purposes between 2015 and 2019 within EU-28 and Norway

In 2019, the main species used for the first time for research, testing, routine production and educational purposes were mice, fish, rats and birds that together represented 93% of the total number of animals. Species of particular public concern (dogs, cats and non-human primates (NHP)) represented 0.2% of the total number of animals. No great apes are used for scientific purposes in the European Union (Figure 7).

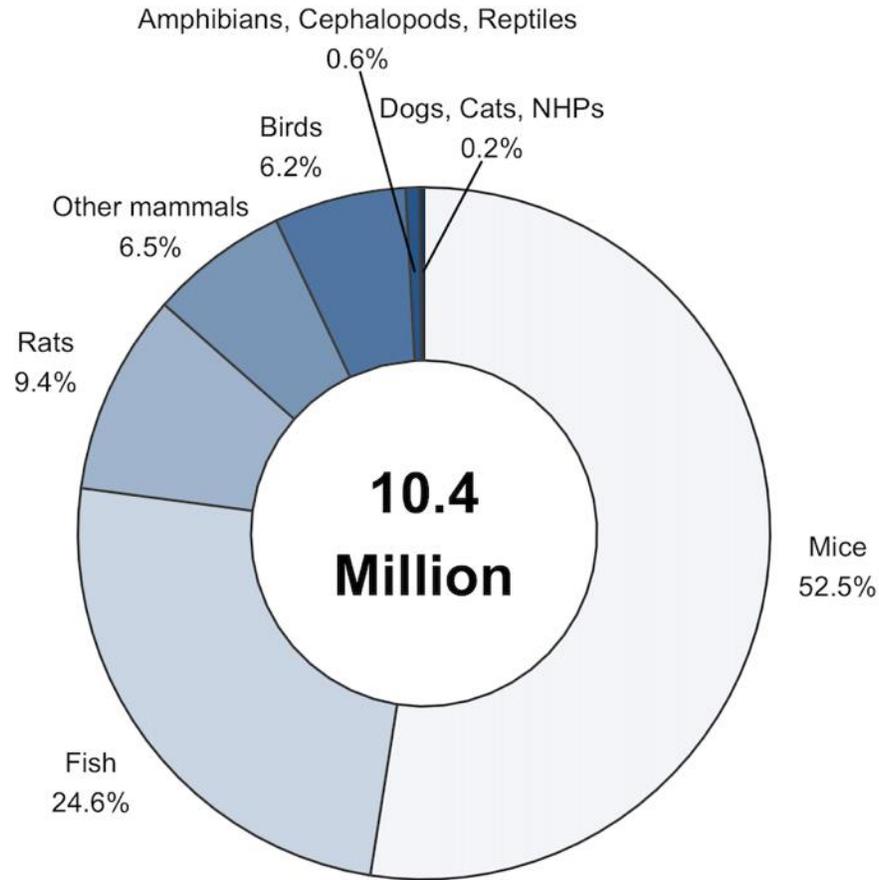


Figure 7: Numbers of animals used for the first time by main classes of species in 2019

The proportional distribution of species used for the first time is similar compared to 2018 for mice (-1%), rats (-2%), “Other mammals” (+2%) uses with a decrease of fish uses (-7%) and a significant increase of amphibians, cephalopods and reptiles (+96%) (table 5).

	2019
Mice	5,459,433
Rats	978,305
Other mammals	696,360
Fish	2,559,532
Birds	642,287
Amphibians, Cephalopods, Reptiles	65,756
Total	10,401,673

Table 5: Numbers of animals used for the first time by main classes of species

For fish, the Directive distinguishes zebra fish (20% of fish in 2019) from other fish species. The main "other" fish species (2,042,339 in 2019 - Table 7) was salmon with about 1,000,000.

For birds, the Directive distinguishes domestic fowl (80% of birds in 2019) from other birds. The main species reported as “Other birds” (122,991 in 2019 – Table 7) were turkey and the Great Tit (*Parus major*).

In this context, it is important to note that from 2021 data onward, further species of fish and turkey have been added as separate categories to reduce the use of “other” categories.¹³

For amphibians, the Directive distinguishes rana (13% of amphibians in 2019) and xenopus (35% of amphibians in 2019) from other amphibians. The main species reported as “Other amphibians” (20,661 – Table 7) were bufo (toads), *ambystoma mexicanum* (axolotl) and rana dalmatina (agile frog).

First uses of mammals in 2019 are reported in more detail in table 6 below. First uses of mammals decreased slightly (-1%) compared to 2018.

	2019
Mice	5,459,433
Rats	978,305
Guinea-Pigs	124,487
Other rodents	50,914
Rabbits	353,831
Cats	2,180
Dogs	13,076
Other carnivores	6,609
Farm animals	132,443
Non-human primates	7,475
Other mammals	5,345
Total	7,134,098

Table 6: Numbers of animals used for the first time in the Mammal category

Farm animals include horses, donkeys and cross-breeds, pigs, goats, sheep and cattle. "Other carnivores" (6,609 in 2019) reported were mainly mink while "Other rodents" (50,914) included bank and common voles and house mice; and "Other mammals" (5,345) mainly bats.

In 2019, the numbers of rabbits used for the first time increased (+3%), cats (+40%) and “Other carnivores” (+9%). Uses of other species decreased: dogs (-26%), guinea-pigs (-4%), farm animals (-3%) and “Other rodents” (-17%).

The number of non-human primates reported during the period decreased (-13%). Species used were prosimians, marmosets and tamarins, cynomolgus monkey, rhesus monkey, vervets (*chlorocebus spp*), baboons, and other species of old world monkeys (*cercopithecoidea*). In line with the general ban on the use of great apes, introduced by the Directive, no such use was reported during the period 2015-2019.

¹³ Commission Implementing Decision 2020/569/EU, Annex III

	2019
Mice	5,459,433
Rats	978,305
Guinea-Pigs	124,487
Hamsters (Syrian)	12,131
Hamsters (Chinese)	17
Mongolian gerbil	4,103
Other rodents	34,663
Rabbits	353,831
Cats	2,180
Dogs	13,076
Ferrets	1,883
Other carnivores	4,726
Horses, donkeys and cross-breeds	1,431
Pigs	82,819
Goats	1,202
Sheep	21,742
Cattle	25,249
Prosimians	194
Marmoset and tamarins	222
Cynomolgus monkey	6,748
Rhesus monkey	251
Vervets (Chlorocebus spp.)	25
Baboons	33
Other species of Old World Monkeys (Cercopithecoidea)	2
Other mammals	5,345
Domestic fowl	519,296
Other birds	122,991
Reptiles	2,012
Rana	6,317
Xenopus	19,798
Other amphibians	20,661
Zebra fish	517,193
Other fish	2,042,339
Cephalopods	16,968
Total	10,401,673

Table 7: Numbers of animals used for the first time by species

IV.1.2. Origin of animals used for the first time

The origin (place of birth) of animals is divided into two categories depending on whether the species belongs to the category of non-human primates or not. For non-human primates, more detailed

information is collected on their origin (continent of origin) and in addition their generation is reported (see Part IV.1.2.2.2).

IV.1.2.1. Place of birth of animals (other than non-human primates)

In 2019, almost 86% of the animals used for scientific purposes for the first time were born in the EU at registered breeders¹⁴ and 1% were born outside of the EU (either in the rest of Europe or outside of Europe). Categories of animals born in the EU but not at a registered breeder' includes animals from, for example, farms, and studies carried out using wild animals, especially wild fish (Figure 8).

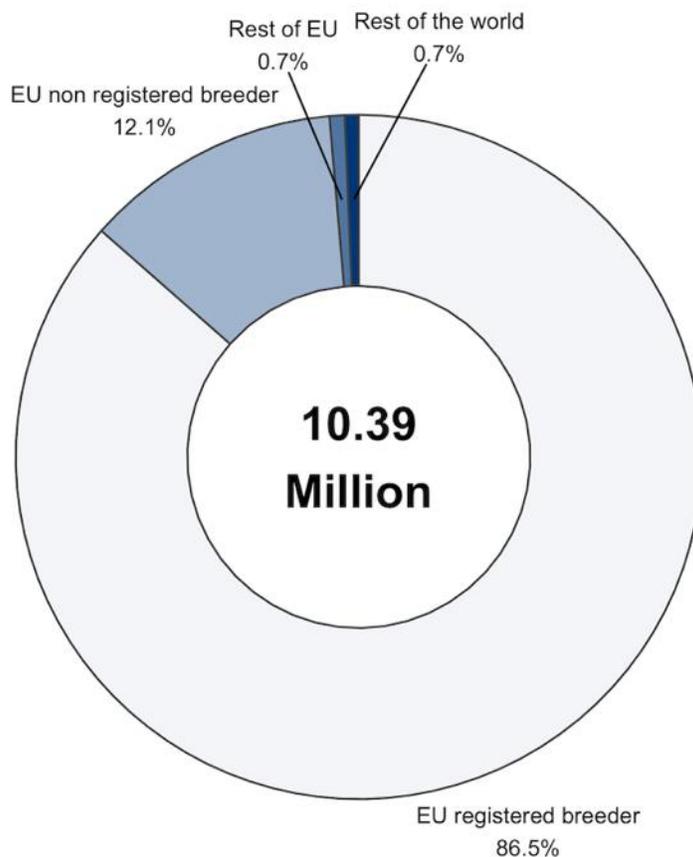


Figure 8: Place of birth of animals other than non-human primates in 2019

In 2019, the proportion of animals born in the EU at a registered breeder decreased (-3%) or in the rest of Europe (-1%) while animals born in the EU but not at a registered breeder (+3%) increased. Animals born in the rest of the world remained stable.

¹⁴ This includes animals born at registered breeders in Norway authorised under the conditions of Directive 2010/63/EU.

	2019
Animals born in the EU at a registered breeder	86% (8,990,739)
Animals born in the EU but not at a registered breeder	12% (1,261,796)
Animals born in rest of Europe	1% (67,608)
Animals born in rest of world	1% (74,055)
Total	100% (10,394,198)

Table 8: Place of birth of animals other than non-human primates

Annex I of the Directive contains a list of animals that may only be used where those animals have been bred for use in procedures (see Article 10). Figure 9 shows all the animal species listed in Annex I, except non-human primates.

In 2019, amongst the species listed in Annex I, rodents, rabbits and zebra fish were, for the vast majority, born at EU registered breeders (Figure 9). Cats (50%), frogs (37%) and to a lesser extent dogs (27%) had a higher proportion of animals born in the EU but at a non-registered breeder (Section B – Table 2). The most common reason for using dogs and cats that came from non-registered breeders in the EU were procedures in pet dogs and cats, which had blood samples taken for studies of genetic disorders, or pet animals, which were involved in patient studies for better treatment methods.

34% of dogs, 16% of hamsters (Syrian), 11% of cats, and 7% of frogs were imported from the rest of the world (Section B – Table 2).

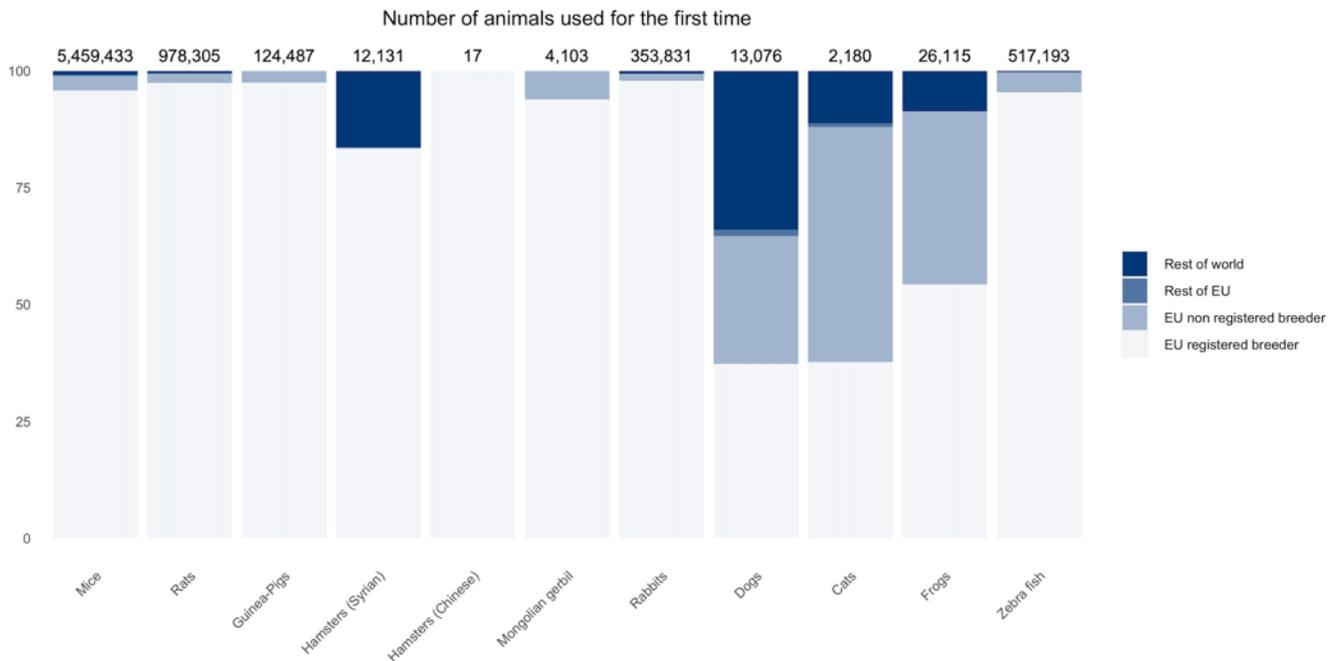


Figure 9: Place of birth of animals other than non-human primates listed in Annex I in 2019

IV.1.2.2. Origin of non-human primates

The Directive provides additional protection for non-human primates due to their genetic proximity to human beings, their highly developed social skills and capacity to experience pain, suffering and distress. Furthermore, the Directive recognises that the capture of non-human primates from the wild is highly stressful for the animals concerned and carries an elevated risk of injury and suffering during capture and transport. In order to end the capture of animals from the wild including for the purposes of breeding, the Directive introduced provisions with the objective of moving towards using non-human primates that have been bred, ultimately, in self-sustaining colonies, from parents who themselves have been bred in captivity (see Article 10 of the Directive).

In order to monitor progress, more detailed information is collected on both the origin and generation of non-human primates used in scientific procedures in the Union.

IV.1.2.2.1. Non-human primates - Source

In 2019, the three main sources of non-human primates were Africa, Asia and EU registered breeders represented 96% of non-human primates used for scientific purposes (Figure 10).

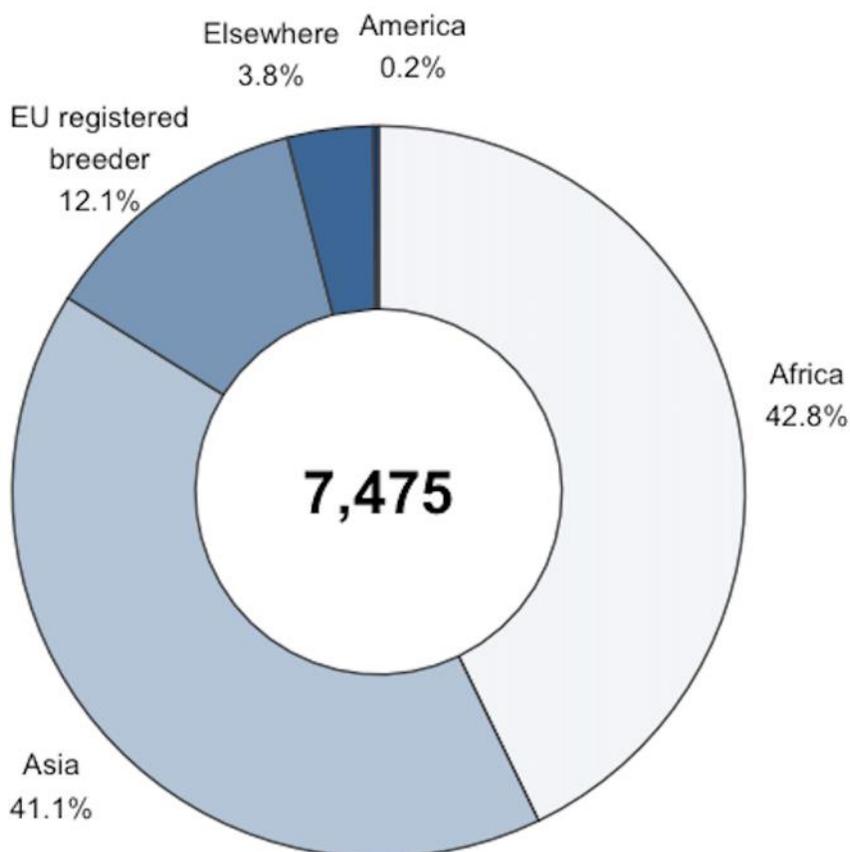


Figure 10: Source of non-human primates in 2019

In 2019, cynomolgus monkeys represented 87% of non-human primates used for the first time. These were sourced almost entirely from outside of the EU (Table 9). In contrast, other species of non-human primates were mainly sourced from EU registered breeders with the exception of Vervet (*Chlorocebus spp*), and “Other species of old world monkeys” (*Cercopithecoidea*).

	Animals born at a registered breeder within EU	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere	Total
Prosimians	100% (194)	<1% (0)	<1% (0)	<1% (0)	<1% (0)	100% (194)
Marmoset and tamarins	100% (222)	<1% (0)	<1% (0)	<1% (0)	<1% (0)	100% (222)
Cynomolgus monkey	3% (226)	47% (3,175)	<1% (0)	46% (3,071)	4% (276)	100% (6,748)
Rhesus monkey	88% (222)	9% (23)	<1% (0)	<1% (0)	2% (6)	100% (251)
Vervets (Chlorocebus spp.)	28% (7)	<1% (0)	72% (18)	<1% (0)	<1% (0)	100% (25)
Baboons	100% (33)	<1% (0)	<1% (0)	<1% (0)	<1% (0)	100% (33)
Other species of Old World Monkeys (Cercopithecoidea)	<1% (0)	100% (2)	<1% (0)	<1% (0)	<1% (0)	100% (2)
Total	12% (904)	43% (3,200)	<1% (18)	41% (3,071)	4% (282)	100% (7,475)

Table 9: Source of non-human primates by species in 2019

IV.1.2.2.2. Non-human primates - Generation

With regard to the generation of non-human primates being bred in captivity in 2018, the majority of non-human primates were sourced either from self-sustaining colonies (29%) or as second or higher generation purpose-bred (56%). No non-human primates were sourced from the wild (Table 10) in 2018.

	2015	2016	2017	2018	2019
Self-sustaining colony	39% (2,748)	31% (2,271)	30% (2,504)	29% (2,471)	39% (2,883)
F2 or greater	37% (2,614)	47% (3,435)	53% (4,368)	56% (4,822)	47% (3,515)
F1	25% (1,773)	21% (1,528)	17% (1,363)	15% (1,290)	14% (1,077)
F0	<1% (1)	<1% (5)	<1% (0)	<1% (0)	<1% (0)
Total	100% (7,136)	100% (7,239)	100% (8,235)	100% (8,583)	100% (7,475)

Table 10: Generation of non-human primates 2015-2019

In line with the Directive’s objectives, the proportion of non-human primates coming from self-sustaining colonies increased (+10%) compared to 2018. The proportion of those being second or higher

generation purpose-bred decreased (-9%) as well as those being of first-generation purpose-bred decreased (-1%). This is confirmed over the past four years of reporting (Figure 11).

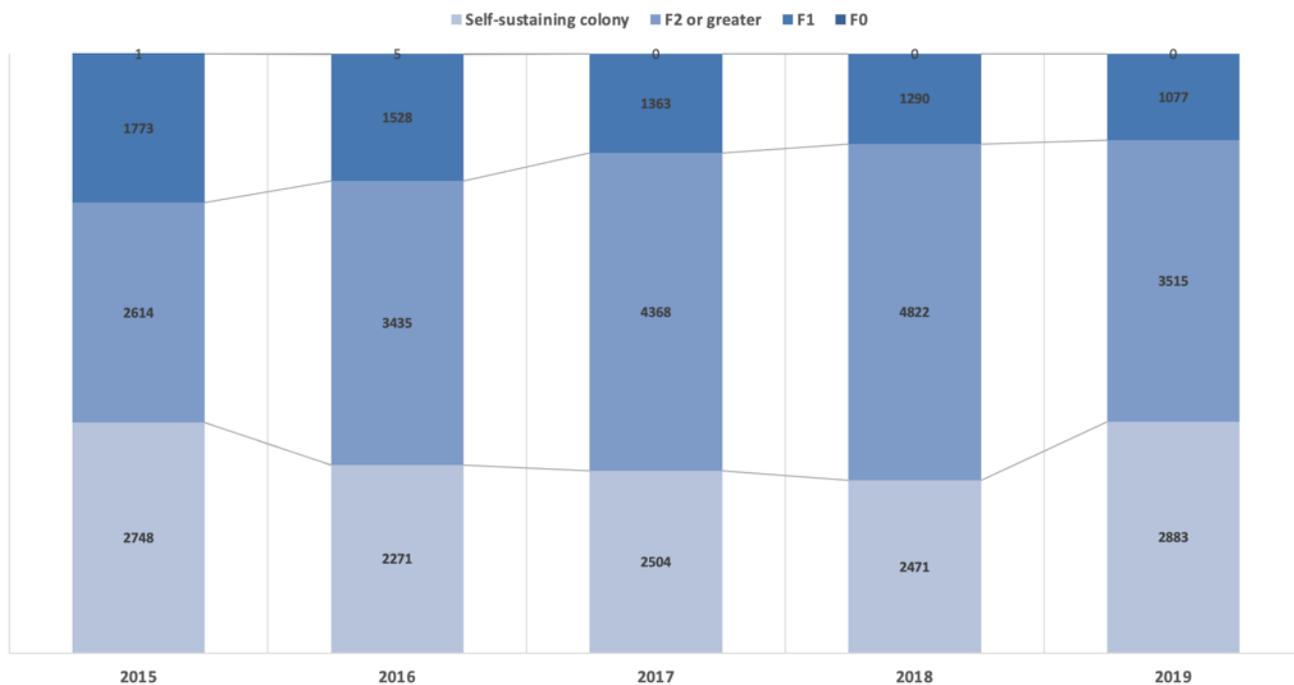


Figure 11: Evolution of the repartition of generation of non-human primates between 2015 and 2019

Looking at different non-human primate species and their generation:

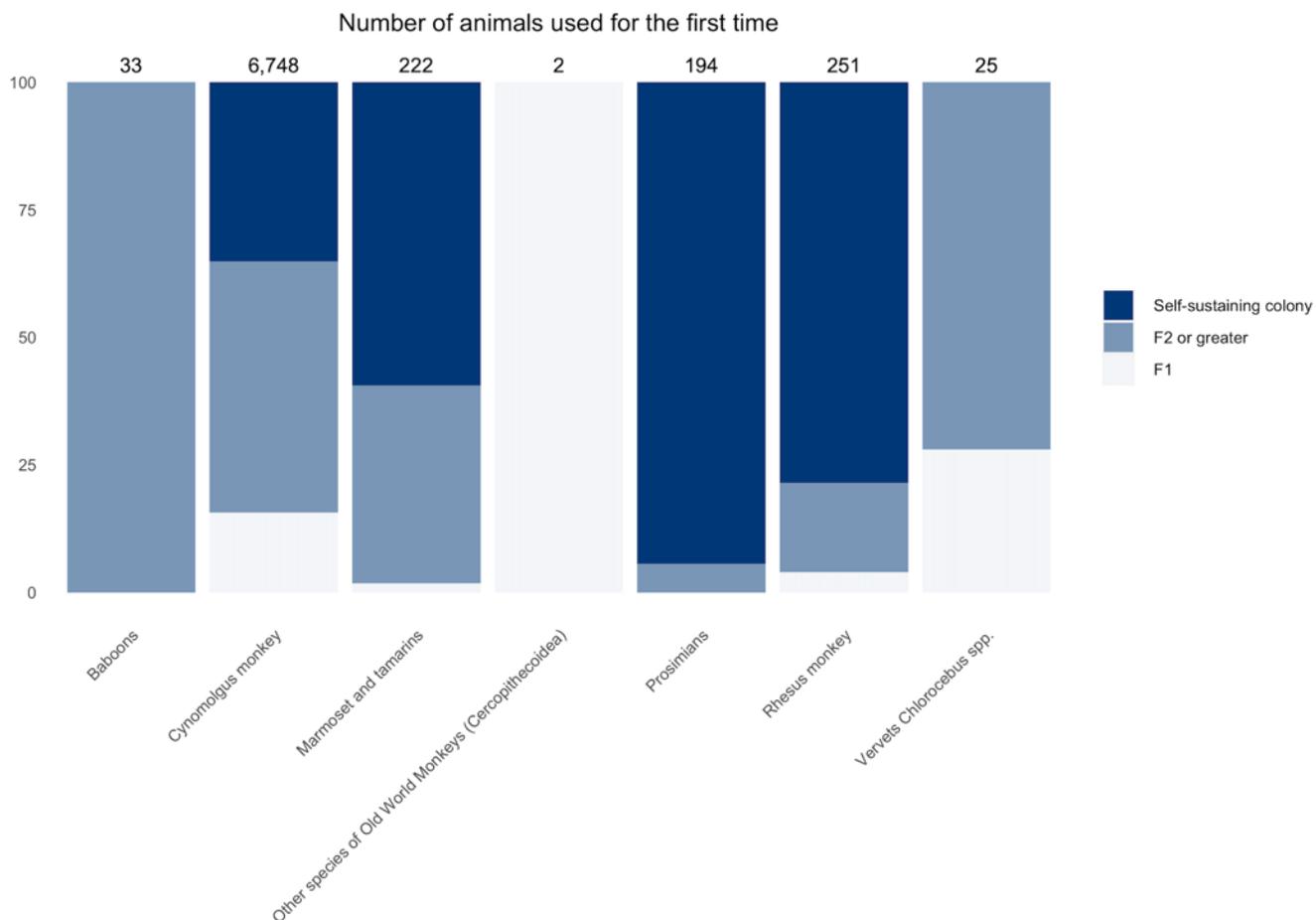


Figure 12: Generation of non-human primates by species in 2019

For non-human primates born at a registered breeder in the EU or in Asia, only 2% of non-human primates used for the first time were from the first generation. In Africa, first generation animals represented 26% and first generation non-human primates from elsewhere represented 69% (Table 11) in 2019.

	Animals born at a registered breeder within EU	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere
F2 or greater	30% (270)	51% (1,628)	100% (18)	49% (1,511)	31% (88)
Self-sustaining colony	69% (620)	47% (1,513)	<1% (0)	24% (750)	<1% (0)
F1	2% (14)	2% (59)	<1% (0)	26% (810)	69% (194)
Total	100% (904)	100% (3,200)	100% (18)	100% (3,071)	100% (282)

Table 11: Generation of non-human primates by source in 2019

IV.2. Details of all uses of animals for research, testing, routine production and educational purposes in the EU

This part focuses on all uses of animals for the purposes of research, testing, routine production and education, including the first and any subsequent reuse. It provides detailed information on the reason for use (for example the specific research area, or type of testing) as well as additional information related to the actual severity experienced by the animals, their genetic status and reuse. In addition, information on the use of animals to satisfy legislative requirements is collected.

IV.2.1. Overview of the main scientific purposes and the related severities

In 2019, the total number of all uses (first use and any subsequent reuse) for the purposes of research, testing, routine production and education is 10,6 million. This is a decrease of just under 2%. Since 2018, the numbers contain data from EU-28 and Norway.

	2015	2016	2017	2018 (EU-28 incl. NO)	2019 (EU-28 incl. NO)
Total	9,782,570	10,028,498	9,581,741	10,804,854	10,608,764

Table 12: Total number of uses of animals between 2015 and 2019

Without taking into account the data from Norway, the total number of animal uses in EU-28 increased slightly, being 9,339,032 uses (+2%) in 2019.

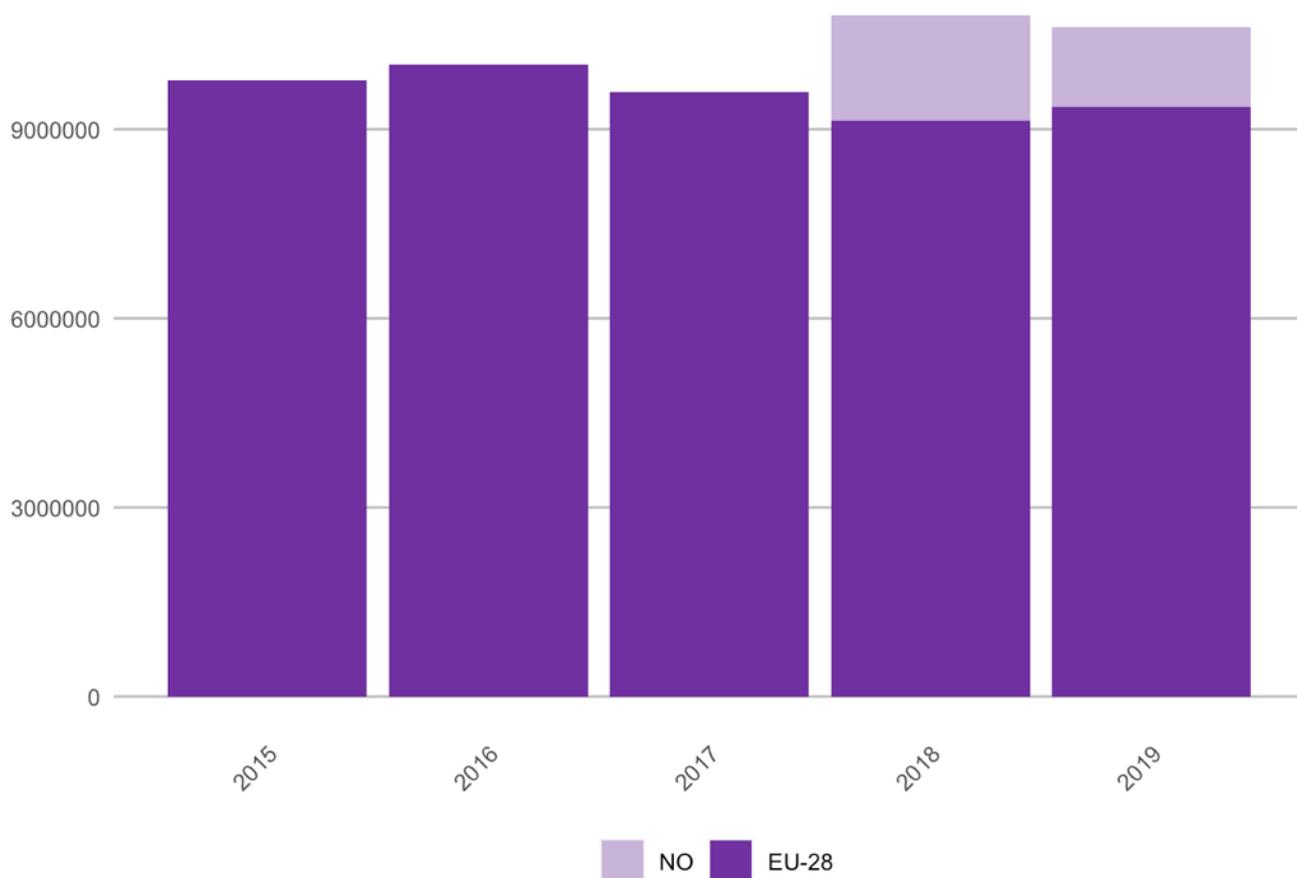


Figure 13: Evolution of total numbers of uses of animals between 2015 and 2019 within EU-28 and Norway

IV.2.1.1. Main categories of scientific purposes

In 2019, 10.6 million uses of animals were reported for scientific purposes in the EU-28 including Norway.

Most uses were conducted for research purposes (72%) with 45% of the uses being carried out for basic research and 27% for translational and applied research purposes. A further 17% of animal uses in procedures were carried out for regulatory use to satisfy regulatory requirements, followed by routine production (6%). Compared to 2018, the proportion of animals used for routine production increased (+1%) while the proportion of uses for regulatory requirements decreased (-1%).

Other categories (5%) include the protection of the natural environment in the interest of the health or welfare of human beings or animals, the preservation of species, the higher education or training for the acquisition, maintenance or improvement or vocational skills and forensic enquiries (Figure 14).

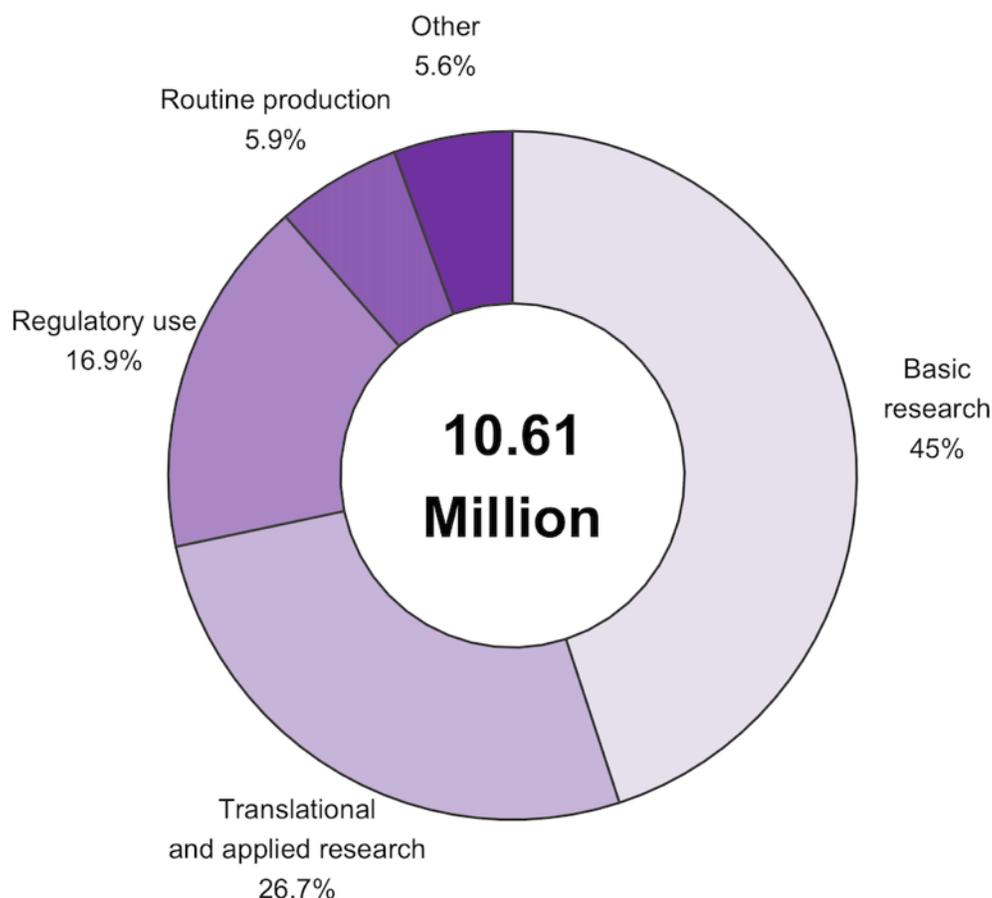


Figure 14: Uses of animals used for scientific purposes in 2019

Compared to 2018, the number of uses for regulatory purposes decreased (-8%) as well as translational and applied research (-7%) and basic research (-3%). Preservation of species (+168%) and protection of the natural environment in the interest of the health or welfare of human beings or animals (+176%), Routine production (+4%) showed an increase. (Table 13).

	2019 (EU-28 incl. NO)
Basic research	4,771,386
Translational and applied research	2,833,086
Regulatory use	1,788,779
Routine production	591,885
Higher education or training for the acquisition, maintenance or improvement of vocational skills	163,047
Protection of the natural environment in the interests of the health or welfare of human beings or animals	234,707
Preservation of species	225,484
Forensic enquiries	390

Total	10,608,764
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Table 13: Uses of animals by main scientific purposes

IV.2.1.2. Severity of uses

Directive 2010/63/EU requires the reporting of the actual severity experienced by each animal when used for scientific purposes. In 2019, 52%, of uses, were reported as ‘mild’ (up to and including), 33% as ‘moderate’, and 9% as ‘severe’. 6% of uses were reported as ‘non-recovery’.

The number of uses reported as severe and moderate decreased proportionally in 2019 (-1%) while mild uses increased (+2%) (Table 14).

Since the actual severities are linked to the type of uses, and the use patterns vary between Member States, it is not advisable to compare overall actual severities between Member States. As an example, a Member State with high proportion of animal use for the purposes of regulatory testing is likely to have higher proportion of severe uses compared to another Member State having mainly uses in the areas of routine production or education and training.

	2018	2019
Non-recovery	6% (612,094)	6% (586,373)
Mild [up to and including]	50% (5,469,214)	52% (5,512,134)
Moderate	34% (3,658,621)	33% (3,510,993)
Severe	10% (1,064,925)	9% (999,264)
Total	100% (10,804,854)	100% (10,608,764)

Table 14: Severity of uses

In 2019, when looking at high level purposes, most of the uses reported as severe were conducted for regulatory purposes (16% of regulatory uses), while routine production was mostly mild. Uses in translational and applied research tended to be more severe than those reported in basic research (Figure 15).

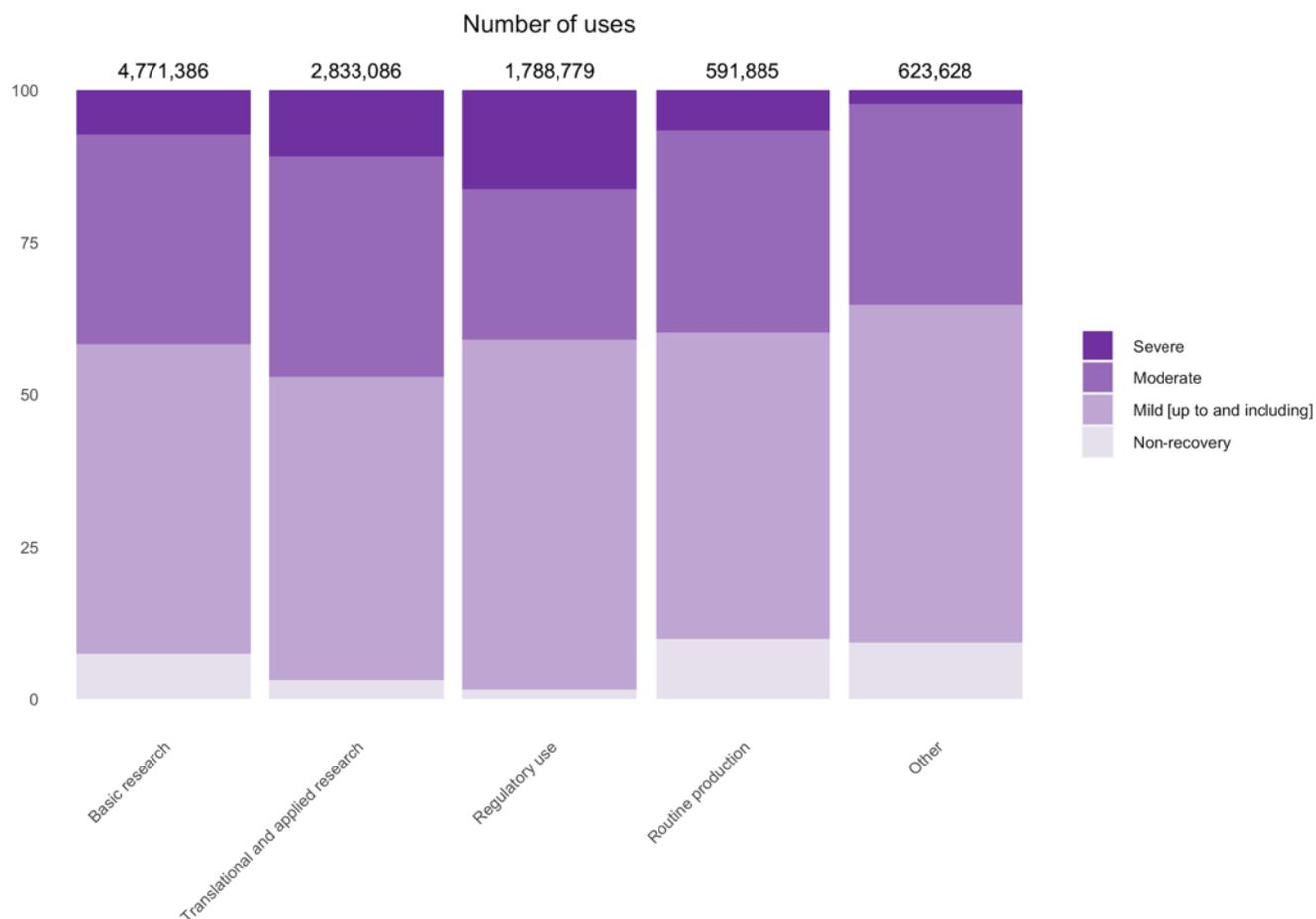


Figure 15: Uses of animals by severity and main categories of scientific purposes in 2019

When analysing all the sub-categories of purposes, batch potency testing resulted in the highest number of severe uses (over 215,000 uses - Figure 19), followed by animal diseases and disorders (133,000 - Figure 18) studies on nervous system (over 104,000 uses - Figure 17) and immune system (over 77,000 uses - Figure 17). Of the purposes listed above, it is important to note that whilst resulting in the highest number of severe uses, batch potency testing decreased by 15% since 2018.

When analysing the proportion of severe uses within a sub-category with more than 30,000 uses: the production of monoclonal antibodies was the highest. 91% of all uses for the production of monoclonal antibodies by ascites method were severe – Figure 27), followed by acute toxicity studies in the area of ecotoxicity (39% - Figure 24) and LD50, LC50 in the area of Acute and sub-acute toxicity testing methods (29% - Figure 22).

Taking into account sub-categories with more than 30,000 uses, the lowest severities (severe uses below 1% of all uses within the sub-category) can be found in preservation of species (0.1% of 227,000 uses – Figure 28), followed by production of blood based products (0.1% of 285,000 uses – Figure 27), education and training (0.2% of 163,000 uses – Figure 28) and pyrogenicity testing (0.9% of 31,000 uses – Figure 21)

IV.2.1.3. Main animal species used by high level purpose categories

In 2019, the main species used in basic research were mice (64%), other fish (14%), zebra fish (8%), rats (6%) and domestic fowl (3%). Similar species feature for applied and translational research with proportionally high uses of mice (50%), other fish (30%) and rat (7%).

For regulatory use, the distribution changes again slightly with mice covering now only less than half (45%), followed by rat (26%), domestic fowl (7%), other fish (6%) and guinea-pigs (6%).

Routine production has a relatively different pattern compared with the other purpose groups, with rabbits accounting for less than half (44%), followed by domestic fowl (20%), mice (19%) and sheep (8%).

When looking at different groups of species and the likely purposes they will be used for, other mammals (bats), other carnivores (minks), fish, mice, amphibians, cephalopods, reptiles and rodents are most likely to be used in basic research. Rabbits, farmed species and birds are mostly used in routine production and finally guinea-pigs, non-human primates and rats for regulatory purposes (Figure 16).

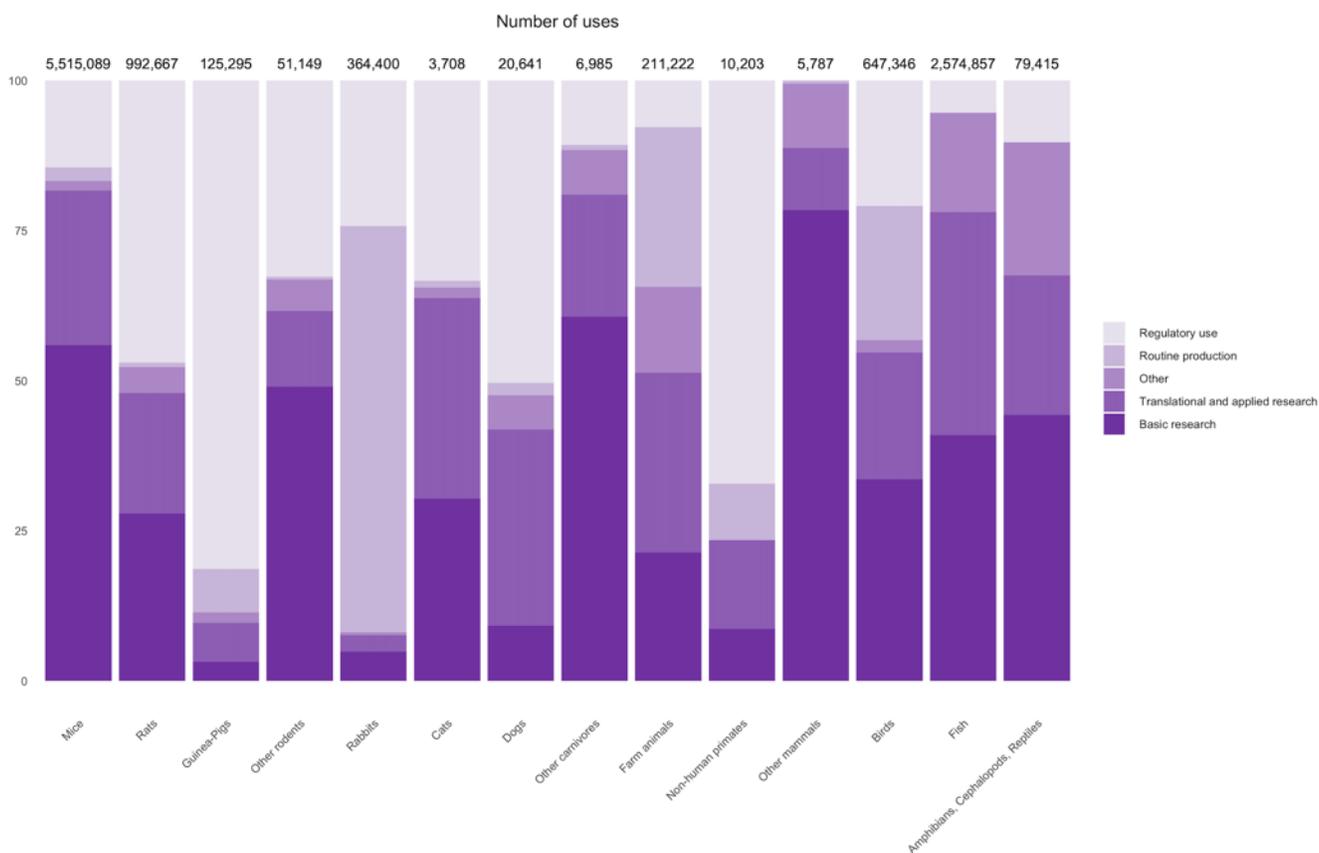


Figure 16: Uses of animals grouped by main classes of species and the main scientific purpose categories in 2019

Looking at the details of the uses of non-human primates, 67% are to satisfy regulatory requirements for medicinal products for human use (of these 68% are on studies for repeated dose toxicity and 13% for kinetics). In the areas of basic and applied research, non-human primates are mainly used for studying human infectious disorders (16% of all non-human primate uses) and nervous system (3%). Routine production, of mostly blood based products represents 8% of non-human primate uses.

The actual reported severities of uses of non-human primates are lower than the Union averages for all species. In 2019, 61% were of mild severity. Only 1.5% of uses were assessed as severe.

IV.2.2. Detailed information on use purposes

IV.2.2.1. Research related uses

Research-related uses are split between basic research on one side and translational and applied research on the other. Results on these purpose categories are presented with information on related reported actual severities.

IV.2.2.1.1 Basic research

Basic research was the main area for which animals were used with more than 4.81 million uses in 2019.

The four main domains of basic research using most animals are nervous system, ethology / animal behaviour / animal biology and immune system that all together account for more than half of the uses in basic research (Figure 17).

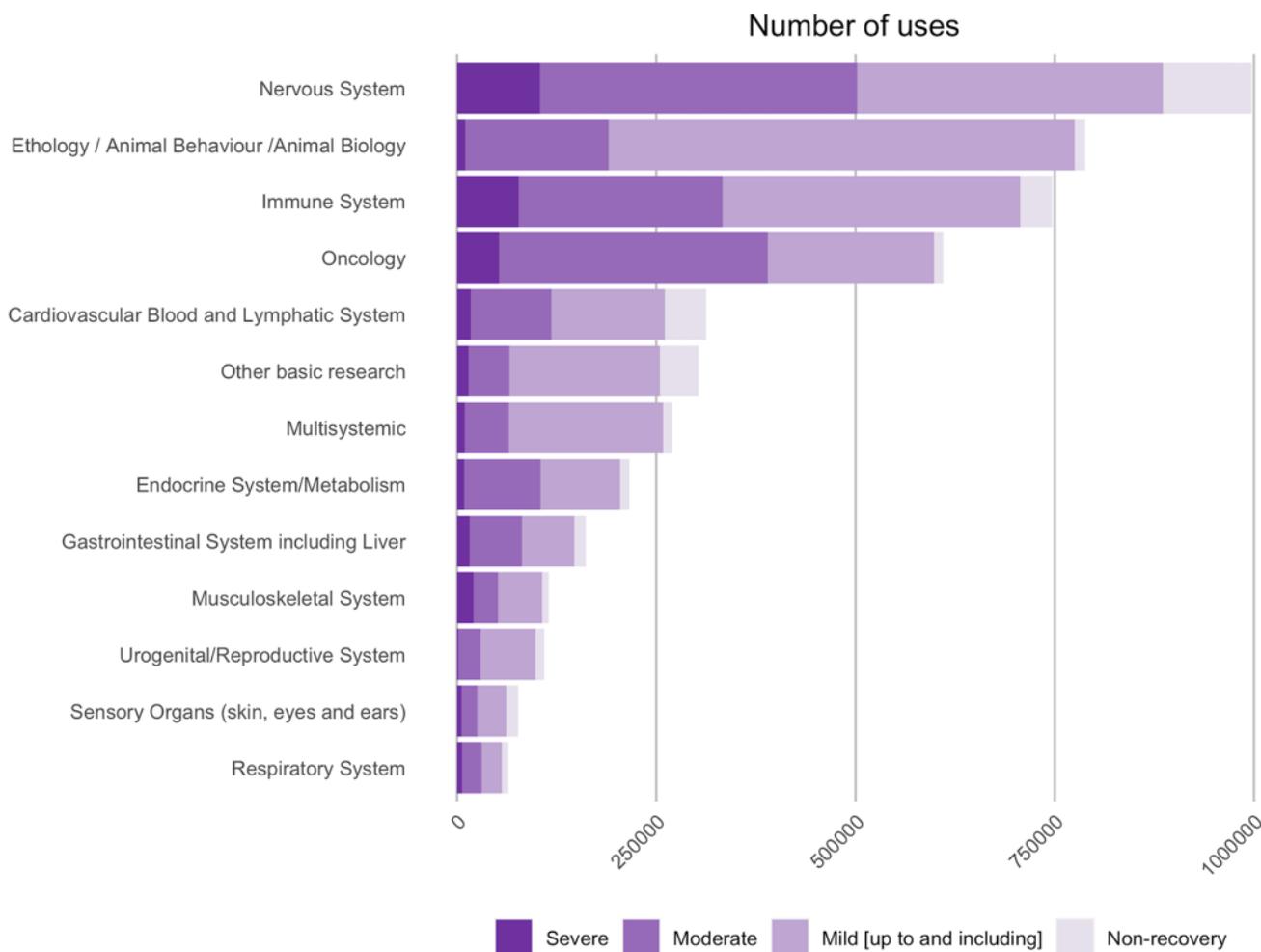


Figure 17: Basic research related uses by type of research and severity in 2019

In 2019, other basic research (+39%), nervous system (+10%), oncology (+10%), musculoskeletal system (+7%) showed an increase.

During the same period, the sub-categories multisystemic (-30%), ethology / animal behaviour / animal biology (-26%) and gastrointestinal system including liver (-5%) saw some decreases in terms of uses of animals (Table 2.4).

In 2019, in the area of basic research, proportionally highest severities were reported in following sub-categories: musculoskeletal system (18%), nervous system (10%), immune system (10%), gastrointestinal system including liver (10%), respiratory system (10%) and oncology (10%).

Proportionally lowest severities were reported for urogenital/reproductive system, ethology/animal behaviour/animal biology, multisystemic and Endocrine system/metabolism (Figure 17).

	2019
Nervous System	997,386
Ethology / Animal Behaviour / Animal Biology	788,232
Immune System	746,606
Oncology	610,349
Cardiovascular Blood and Lymphatic System	312,655
Other basic research	302,796
Multisystemic	269,405
Endocrine System/Metabolism	216,119
Gastrointestinal System including Liver	161,767
Musculoskeletal System	114,799
Urogenital/Reproductive System	109,760
Sensory Organs (skin, eyes and ears)	76,876
Respiratory System	64,636
Total	4,771,386

Table 15: Basic research related uses by type of research

“Other basic research” includes for example collection of blood, plasma and serum, and studies on nutrition and developmental biology. It is important to note in this context that from 2021 data onward, the uses under developmental biology will be reported separately.¹⁵

IV.2.2.1.2. Translational and applied research

Translational and applied research accounted for about 2.84 million uses of animals in 2019.

¹⁵ Commission Implementing Decision 2020/569/EU, Annex III

The four main areas of translational and applied research were animal diseases and disorders, human cancer, human nervous and mental disorders and human infectious disorders.

Animal welfare (+50%), human urogenital/reproductive disorders (+34%) and human endocrine/metabolism disorders (+11%) and human infectious disorders (+10%) showed an increase compared to 2018, while diagnosis of diseases (-66%), human immune disorders (-18%), human musculoskeletal disorders (-16%) and non-regulatory toxicology and ecotoxicology (-13%) had a decrease of uses.

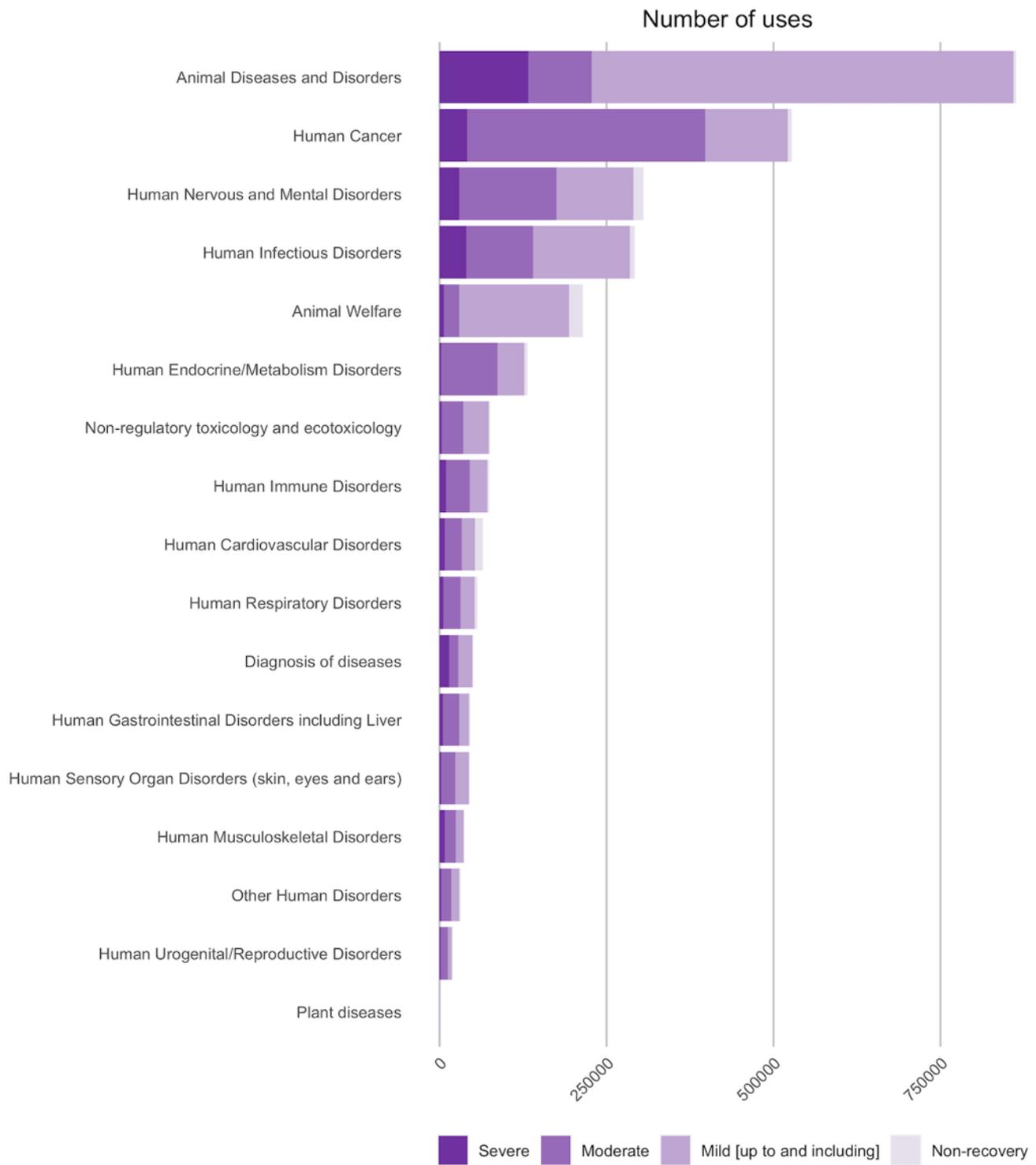


Figure 18: Translational and applied research related uses by type of research and severity in 2019

In 2019, in the area of translational and applied research, proportionally highest severities were reported in the following sub-categories: diagnosis of diseases (27%), animal diseases disorders (15%), human musculoskeletal disorders (21%), human infectious disorders (14%), and human immune disorders (13%).

Proportionally lowest severities were reported for plant diseases, animal welfare, human endocrine/metabolism disorders and animal welfare (Figure 18).

	2019
Animal Diseases and Disorders	863,012
Human Cancer	527,026
Human Nervous and Mental Disorders	305,177
Human Infectious Disorders	292,225
Animal Welfare	214,108
Human Endocrine/Metabolism Disorders	131,319
Non-regulatory toxicology and ecotoxicology	75,740
Human Immune Disorders	74,003
Human Cardiovascular Disorders	65,028
Human Respiratory Disorders	56,105
Diagnosis of diseases	50,724
Human Gastrointestinal Disorders including Liver	45,933
Human Sensory Organ Disorders (skin, eyes and ears)	44,858
Human Musculoskeletal Disorders	36,678
Other Human Disorders	31,579
Human Urogenital/Reproductive Disorders	19,463
Plant diseases	108
Total	2,833,086

Table 16: Translational and applied research related uses by type of research

“Other Human Disorders” (-10%) includes areas such as genetics, pharmacokinetics and haemophilia.

IV.2.2.2. Uses of animals for regulatory purposes

Regulatory uses cover the use of animals in procedures with a view to satisfying regulatory requirements, that is to say for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed. It also includes tests carried out on products/substances for which a regulatory submission was foreseen but ultimately not made, for instance because these were deemed unsuitable for the market by the developer and thus failed to reach the end of the development process. Compared to 2018, the total number of uses for regulatory purposes decreased (-8%).

In 2019, regulatory uses accounted for 1.79 million uses. 54% of these uses were related to quality control (including batch safety and potency testing), 40% related to toxicity and other safety testing including pharmacology and the remainder (6%) were for other efficacy and tolerance testing (Table 17).

	2019
Quality control (incl batch safety and potency testing)	960,212
Toxicity and other safety testing including pharmacology	719,855
Other efficacy and tolerance testing	108,712
Total	1,788,779

Table 17: Regulatory uses by main types of uses

IV.2.2.2.1. Details of the regulatory use purposes

IV.2.2.2.1.1. Quality control related uses

Quality control includes uses of animals in the testing of purity, stability, efficacy, potency and other quality control parameters product (and its constituents) such as vaccines, and any controls carried out during the manufacturing process for registration purposes, to satisfy any other national or international regulatory requirements or to satisfy the in-house policy of the manufacturer.

Quality control related uses represented 960,000 uses in 2019. A large majority of these uses were related to batch potency-testing purposes (78%).

With more than 215,000 severe uses (-15% uses compared to 2018), batch potency testing was the most severe type of procedure, representing more than 24% (1% less compared to 2018) of all severe uses in the Union (Figure 19). Pyrogenicity testing is the least severe with less than 1% of severe uses.

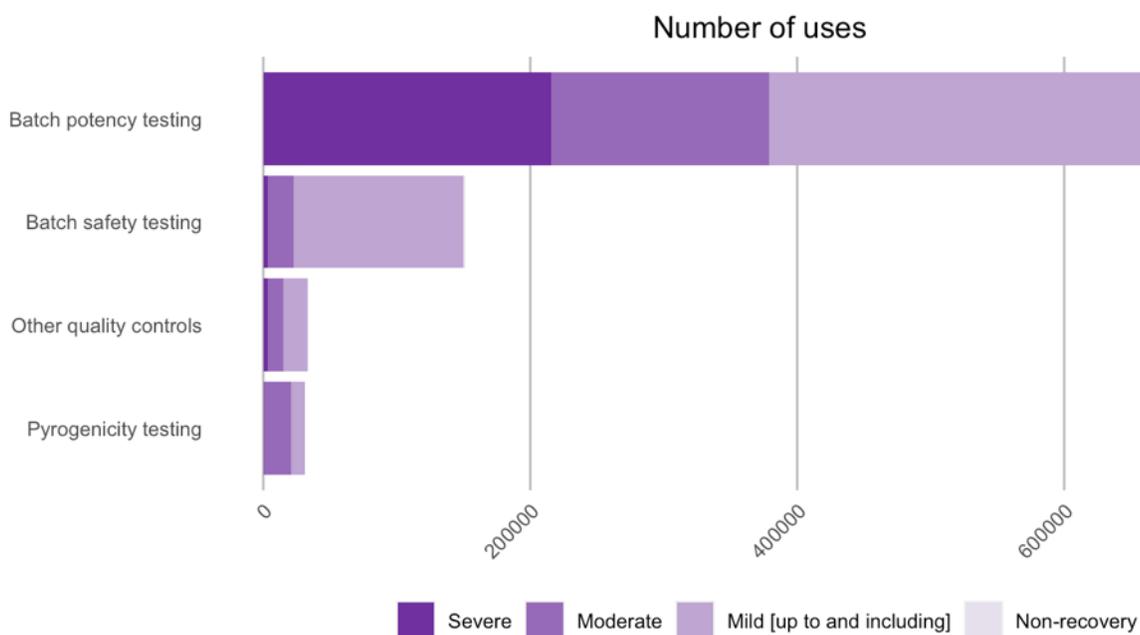


Figure 19: Quality control related uses by type of use and severity in 2019

In 2019, quality control related uses decreased (-11%) with a decrease for other quality control (-22%) and for batch potency testing (-13%) (Table 18). Batch safety testing (+4%) and pyrogenicity testing (+2%) slightly increased

“Other quality controls” are related for example to cell lines characterisation, pathogenicity tests or product purity.

	2019
Batch potency testing	744,710
Batch safety testing	150,977
Other quality controls	33,613
Pyrogenicity testing	30,912
Total	960,212

Table 18: Quality control related uses by type of use

Between 2015 and 2018, pyrogenicity testing decreased regularly (-35%) (Figure 20), however, in 2019, the downward trend stopped. These uses mainly come from three countries covering 89% of all pyrogenicity testing, namely France (39%), Spain (29%) and Germany (21%).

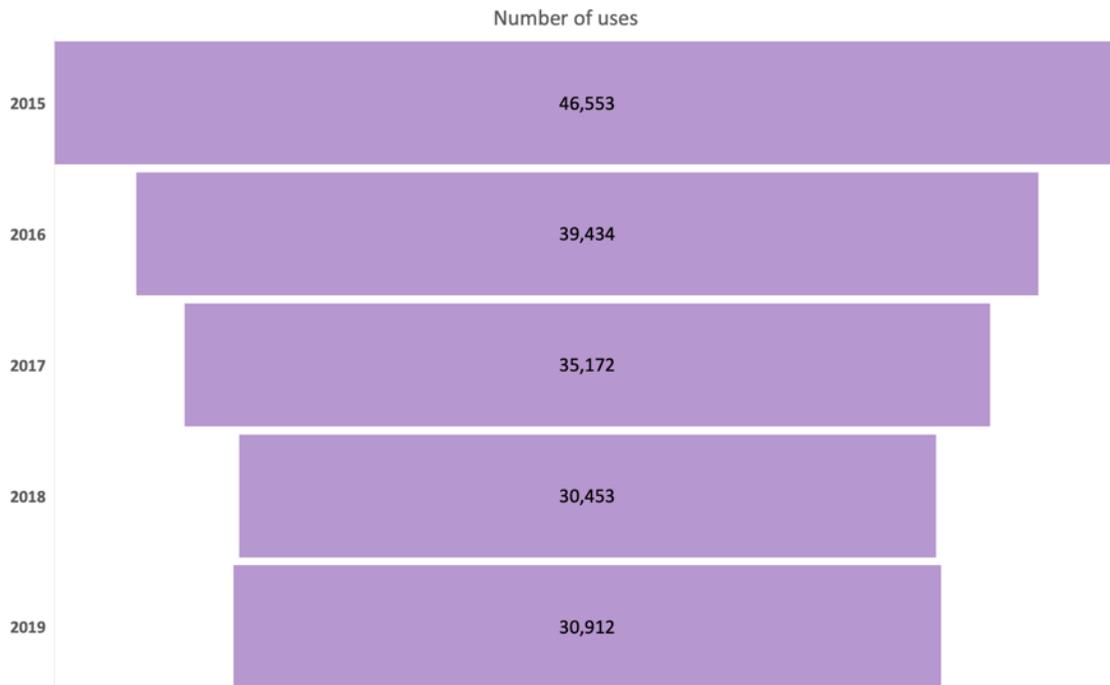


Figure 20: Evolution of total numbers of uses of animals for pyrogenicity testing between 2015 and 2019

IV.2.2.2.1.2. Toxicity and other safety testing including pharmacology

Toxicity and other safety testing (including safety evaluation of products and devices for human medicine and dentistry and veterinary medicine) covers studies carried out on any product or substance to determine its potential to cause any dangerous or undesirable effects in humans or animals as a result of its intended or abnormal use, manufacture or as a potential or actual contaminant in the environment.

Toxicity and other safety testing including pharmacology represented less than 720,000 uses of animals in 2019, which corresponds to 7% of all uses of animals.

Most of the uses in this area were related to ecotoxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity and pharmaco-dynamics.

In 2019, proportionally highest severities were reported in following sub-categories: ecotoxicity (31%), eye irritation/corrosion (20%), acute and sub-acute toxicity (18%) and safety testing in food and feed area (17%). Concerning eye irritation/corrosion, it is important to note that this concerns only very few uses, less than 500. Since alternative methods are available for this end-point, these tests are likely to have been carried out on substances which are not within the applicability domain of the alternative methods.

Proportionally lowest severities were reported for Phototoxicity, Neurotoxicity, Target animal safety and other toxicity/safety testing (Figure 21).

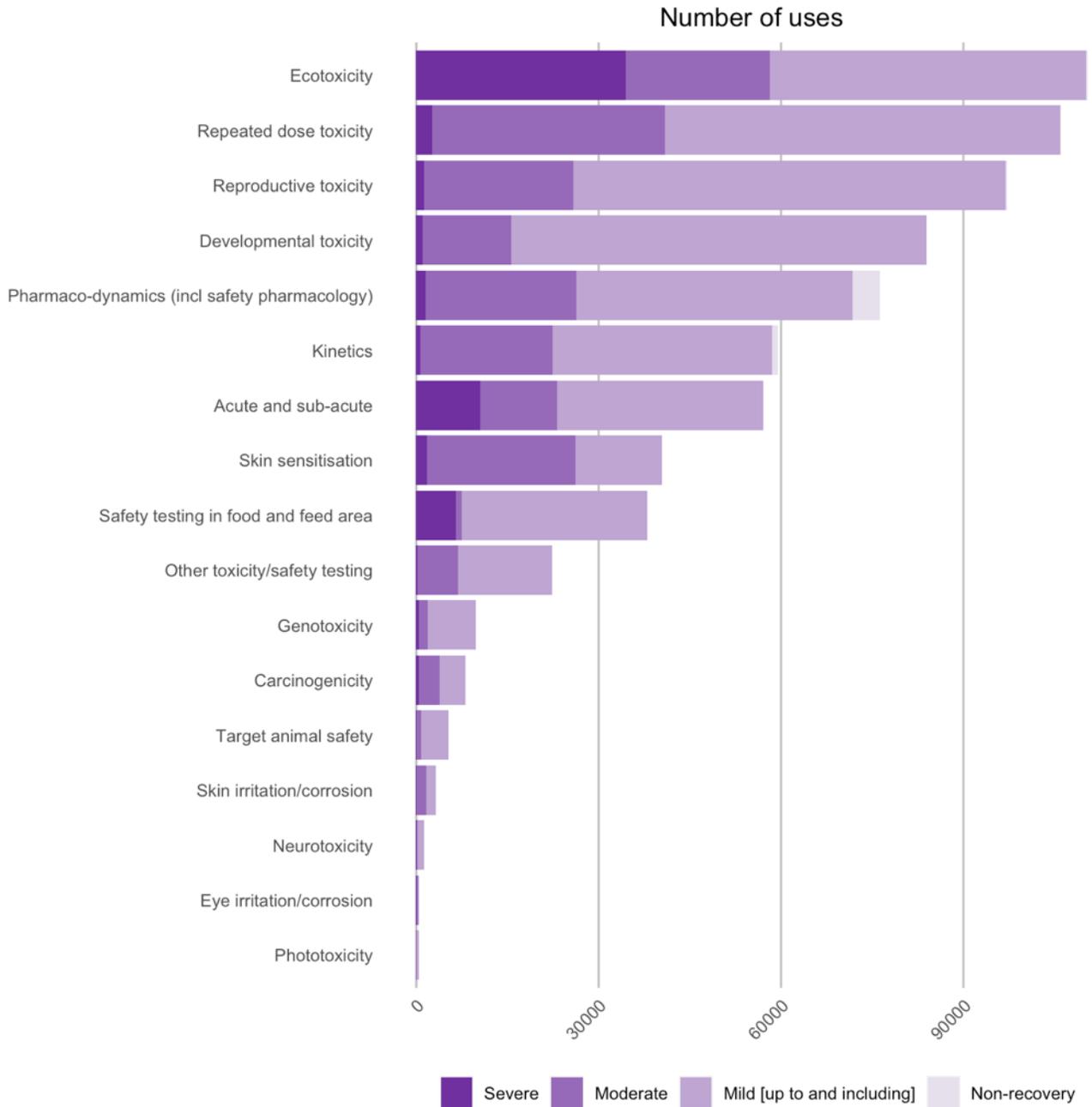


Figure 21: Toxicity and other safety testing including pharmacology by type of use and severity in 2019

In 2019 (Table 19), the total number of uses for toxicity and other safety testing including pharmacology decreased (-2%).

Genotoxicity (+13%), ecotoxicity (+10%) developmental toxicity (+7%) and reproductive toxicity (+7%) related uses saw an increase.

A significant decrease in the number of uses was observed in 2019 compared to 2018 for the following areas: neurotoxicity (-73%), eye irritation/corrosion (-46%), carcinogenicity (-40%), target animal safety (-22%), skin irritation/corrosion (-21%) and phototoxicity (-20%) (Table 19).

“Other toxicity/safety testing” saw a significant increase (+119%) are related for example to immunogenicity testing. About half of these come from one Member State (Germany), of which 9000 uses were reported in relation to the legislative requirements arising from plant protection product legislation.

	2019
Ecotoxicity	110,415
Repeated dose toxicity	106,056
Reproductive toxicity	97,133
Developmental toxicity	83,914
Pharmaco-dynamics (incl safety pharmacology)	76,259
Kinetics	59,480
Acute and sub-acute	57,124
Skin sensitisation	40,433
Safety testing in food and feed area	38,038
Other toxicity/safety testing	22,388
Genotoxicity	9,807
Carcinogenicity	8,093
Target animal safety	5,338
Skin irritation/corrosion	3,267
Neurotoxicity	1,222
Eye irritation/corrosion	474
Phototoxicity	414
Total	719,855

Table 19: Toxicity and other safety testing including pharmacology by type of use

Acute and sub-acute testing methods uses

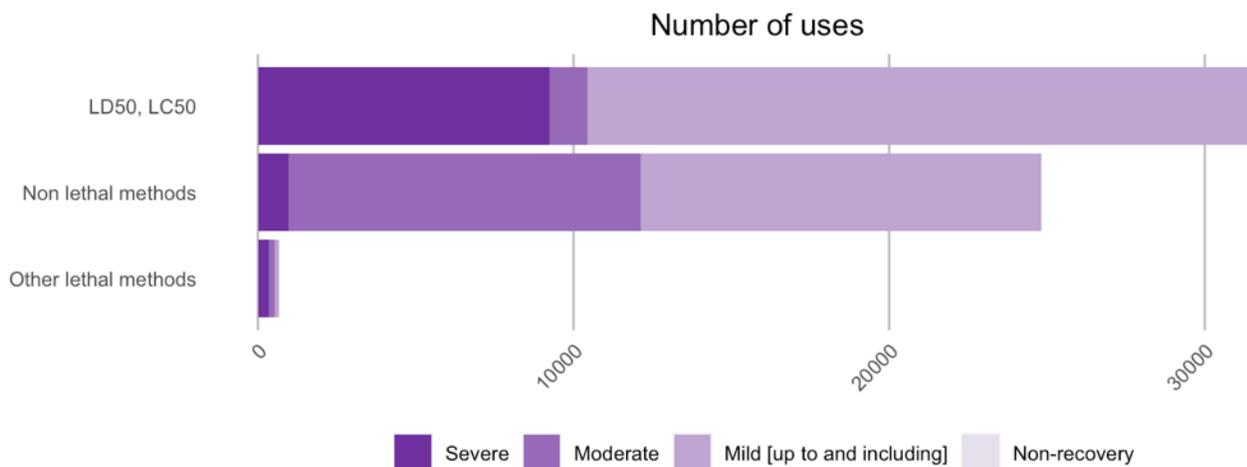


Figure 22: Acute and sub-acute uses testing methods by type of uses and severity in 2019

	2019
LD50, LC50	31,654
Non lethal methods	24,814
Other lethal methods	656
Total	57,124

Table 20: Acute and sub-acute uses testing methods by type of use

Repeated dose toxicity uses

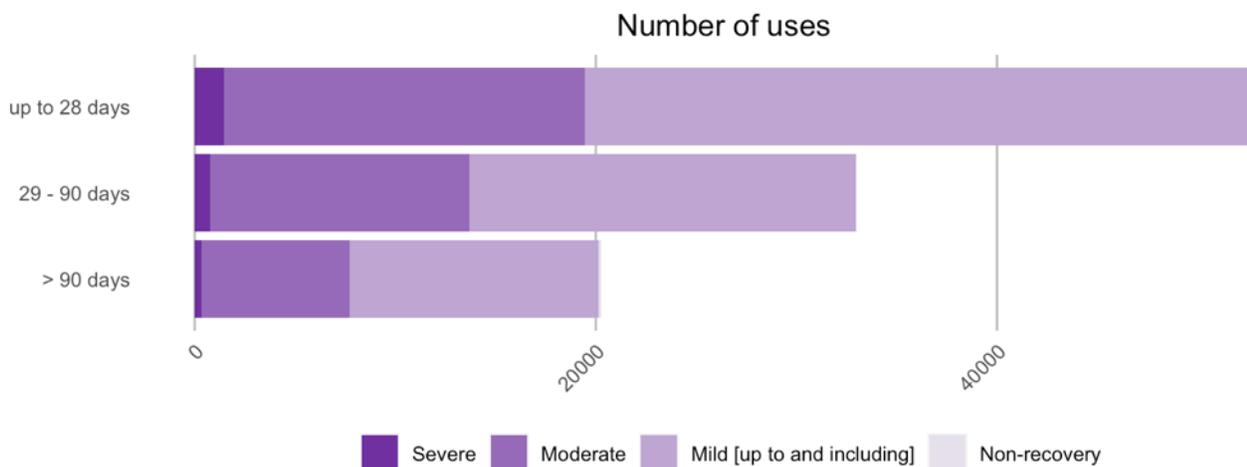


Figure 23: Repeated dose toxicity by type of uses and severity in 2019

2019	
up to 28 days	52,814
29 - 90 days	32,985
> 90 days	20,257
Total	106,056

Table 21: Repeated dose toxicity by type of use

Ecotoxicity

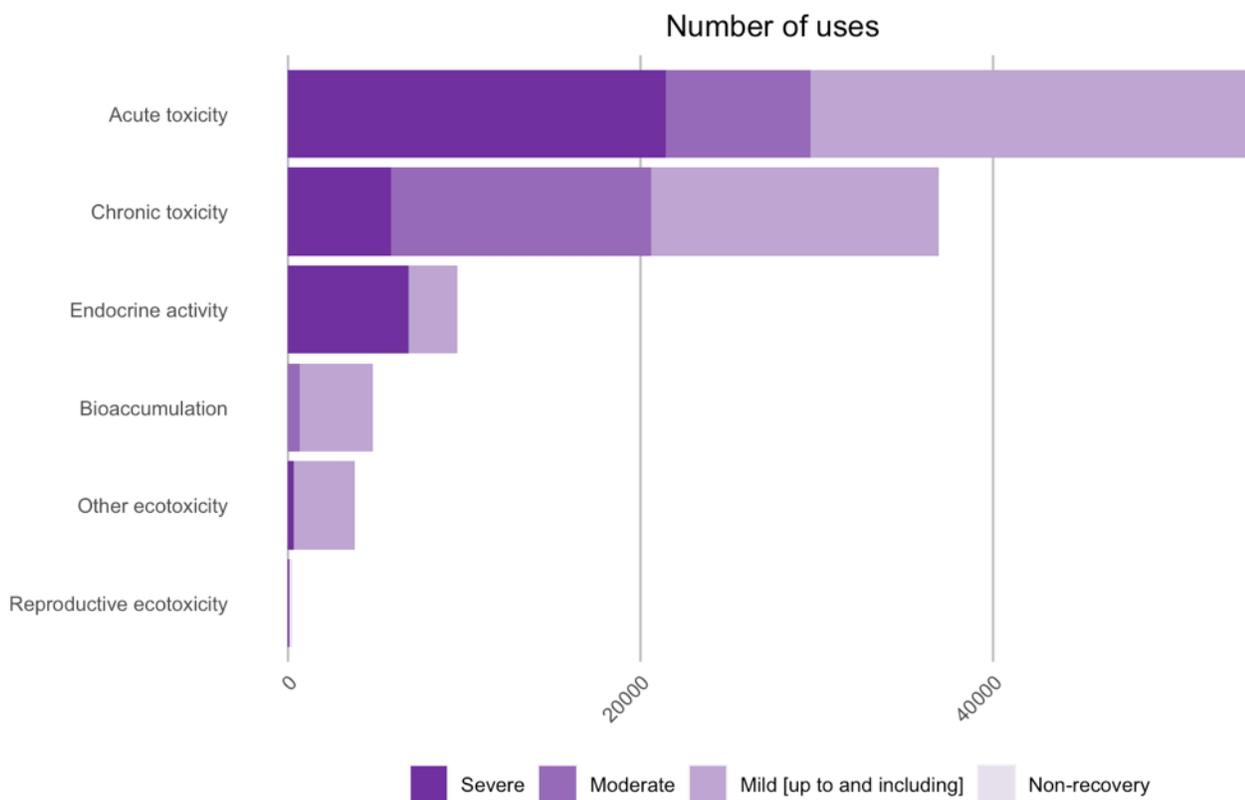


Figure 24: Ecotoxicity by type of uses and severity in 2019

2019	
Acute toxicity	55,052
Chronic toxicity	36,939
Endocrine activity	9,616
Bioaccumulation	4,818
Other ecotoxicity	3,766
Reproductive ecotoxicity	224
Total	110,415

Table 21: Ecotoxicity by type of use

IV.2.2.2.1.3. Other efficacy and tolerance testing

This category of regulatory use refers to uses that are neither linked to quality control nor to toxicity testing. These uses are related to, for example, efficacy (immunogenicity) of human and veterinary vaccines. They represented little more than 108,000 uses in 2019, a decrease (-13%) compared to 2018.

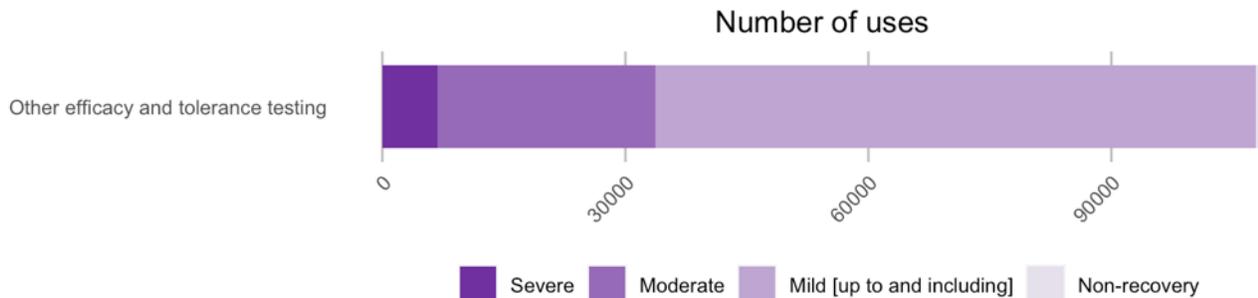


Figure 25: Other efficacy and tolerance testing by type of use and severity in 2019

	2019
Other efficacy and tolerance testing	108,712

Table 22: Other efficacy and tolerance testing

IV.2.2.2.2. Legislative aspects of regulatory uses

In 2019, the majority of uses to satisfy legislative requirements of specific sector legislation occurred in relation to placing on the market of medicinal products for humans (61%), veterinary medicinal products (18%) and industrial chemicals (9%) (Table 23).

	2015	2019
Legislation on medicinal products for human use	1,518,123	1,093,830
Legislation on medicinal products for veterinary use and their residues	368,571	316,365
Industrial chemicals legislation	195,950	154,397
Plant protection product legislation	72,084	68,863
Medical devices legislation	47,270	53,713
Food legislation including food contact material	61,864	45,974
Other legislation	47,342	36,718
Feed legislation including legislation for the safety of target animals, workers and environment	40,252	16,462
Biocides legislation	4,896	2,457
Total	2,356,352	1,788,779

Table 23: Regulatory uses by type of legislation

Between 2015 and 2019, regulatory uses knew a constant decrease (-24%) in all types of legislation (Figure 26) with the exception of medical devices legislation (+14%). The most important decreases in

uses were for biocides (-50%), medicinal products for human uses (-28%), food including food contact material (-22%), industrial chemicals (-21%) and medicinal products for veterinary uses and their residues (-14%).

In the same period, “Other legislation” uses decreased as well (-26%) (Table 23). Over 40% of this category seems to be related to waste legislation (Table 23).

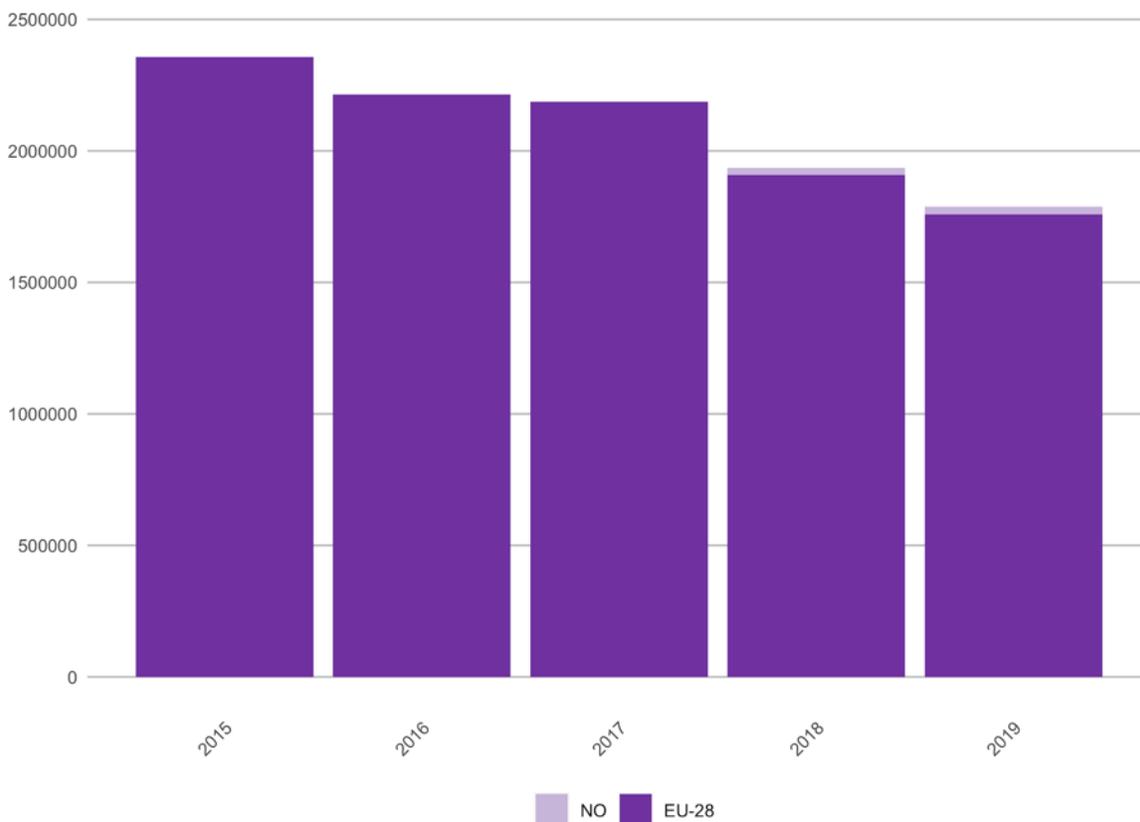


Figure 26: Evolution of total numbers of regulatory uses of animals between 2015 and 2019 within EU-28 and Norway

In 2019, the majority of regulatory uses were performed to satisfy regulatory requirements originating from the EU (94%). Non-EU requirements accounted for 4% and national requirements for 2% (Table 24).

The sub-category on legislation satisfying EU requirements also includes any requirements for which international harmonisation has been achieved, such as for testing to OECD, ICH¹⁶ and VICH¹⁷ standards. Harmonisation of testing requirements at a global level is of utmost importance when aiming to avoid unnecessary duplication of testing.

¹⁶ The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

¹⁷ The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

	2019
Legislation satisfying EU requirements	94% (1,678,078)
Legislation satisfying Non-EU requirements only	4% (70,797)
Legislation satisfying national requirements only [within EU]	2% (39,904)
Total	100% (1,788,779)

Table 24: Regulatory uses by origin of regulatory requirement

Legislation on medicinal products for human or veterinary uses is mainly related to quality controls. Industrial chemical legislation, Medical devices legislation, Food legislation including food contact material, Plant protection products legislation and other legislation focus more specifically on toxicity testing. Feed legislation is mainly related to other efficacy testing.

	Quality control (incl batch safety and potency testing)	Toxicity and other safety testing including pharmacology	Other efficacy and tolerance testing
Legislation on medicinal products for human use	715,652	313,983	64,195
Legislation on medicinal products for veterinary use and their residues	240,853	43,552	31,960
Medical devices legislation	2,646	49,735	1,332
Industrial chemicals legislation	0	153,940	457
Plant protection product legislation	180	68,036	647
Biocides legislation	0	1,905	552
Food legislation including food contact material	168	36,520	30
Feed legislation including legislation for the safety of target animals, workers and environment	19	7,092	9,351
Other legislation	694	45,092	188
Total	960,212	719,855	108,712

Table 25: Regulatory use by type of legislation in 2019

In terms of severity levels, in 2019, for the legislative context, 16% of total uses in the area of regulatory testing were reported as severe, 25% as moderate, 58% mild (and up to mild) and 1% as non-recovery (Figure 27).

Even if the total numbers of uses are not the most significant in the area of food legislation and biocides, the proportion of severe uses is relatively high. This category included still in 2018, for example, the use of mouse bioassay for the purposes of shellfish toxin testing. As provided by Regulation 2017/1980¹⁸, the mouse bioassay could still be used as reference method until the end of 2018, after which the

¹⁸ OJ L 285, 1.11.2017, p. 8–9

alternative, so-called Lawrence method, should have replaced its use. Subsequently, there was a decrease of 15% in the use of mouse in the area of “Food legislation including food contact material” for “Safety testing in food and feed area”. In the area of 'Other' legislation, about 30% of procedures were reported as severe.

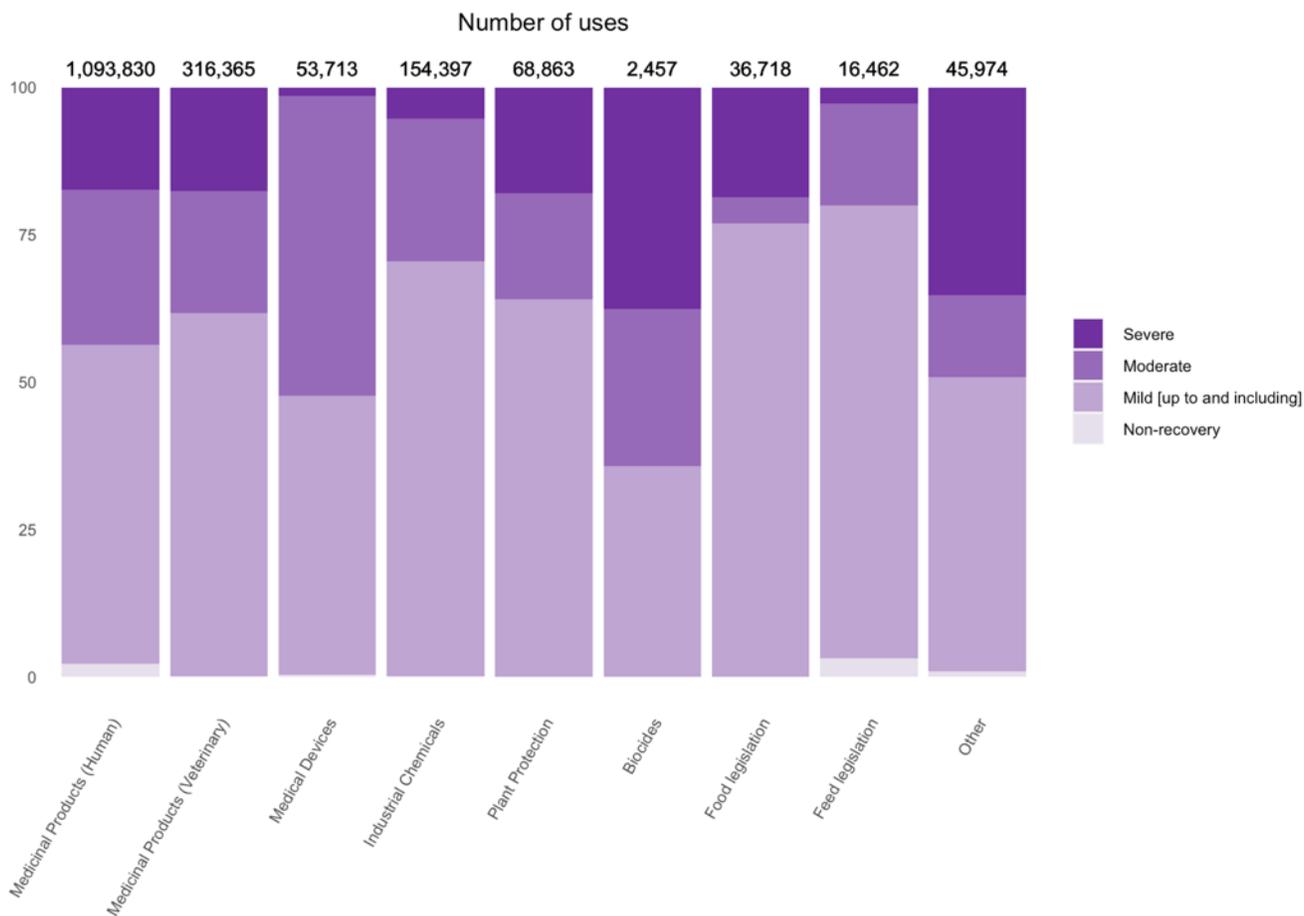


Figure 27: Regulatory use by type of legislation and severity in 2019

IV.2.2.3. Routine production uses

Routine production includes the production of antibodies and blood products, including polyclonal antisera by established methods.

In 2019, there were about 561,000 routine production uses, which represented 5% of all uses of animals in the Union. 51% of routine uses were related to the production of blood-based products and 7% for monoclonal antibodies production by mouse ascites method (Figure 28).

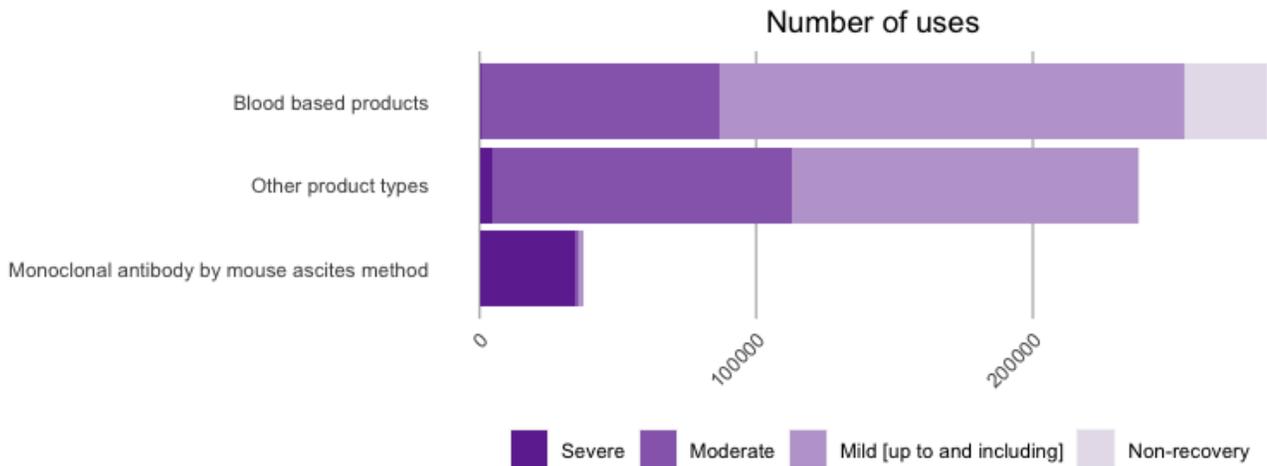


Figure 28: Routine production uses by product type and severity in 2019

While blood based products involved only mild and moderate levels of severity, monoclonal antibody production by mouse ascites method involved mostly severe uses (91%) (Figure 28).

	2019
Blood based products	284,577
Other product types	269,831
Monoclonal antibody by mouse ascites method	37,477
Total	591,885

Table 26: Routine production uses by product type

Other product types that represented 45% of the uses were mostly related to antigen and protein production.

Monoclonal antibody production by mouse ascites method showed a decrease of 35% between 2018 and 2019. Almost 36,000 uses of the 37,000 were carried out in one Member State (France). In total, only six Member States reported the use of mouse ascites method for the production of monoclonal antibodies. There is an additional concern related to severity since refined end-points exist to avoid reaching the highest severity level.

IV.2.2.4. Other types of uses

The last four categories of uses reported as part of the Directive covered about 625,000 uses: higher education and training for the acquisition, maintenance or improvement of vocational skills; protection of the natural environment in the interests of the health or welfare of human beings or animals; preservation of species; and forensic enquiries.

With more than 234,000 uses in 2019, Protection of the natural environment in the interests of the health or welfare of human beings or animals is the biggest category of the remaining purposes, followed by protection of species (227,000).

At the same time, it is important to note that the severities linked to higher education and training, and on studies on preservation of species, are some of the lowest. Higher education and training has the largest proportion of non-recovery uses. Forensic inquiry uses are limited to just a few hundreds. (Figure 29).

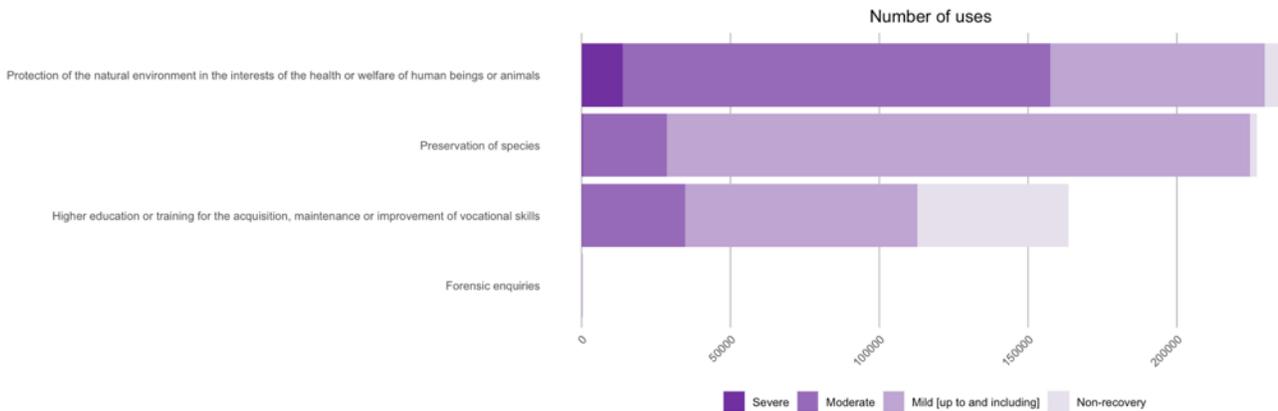


Figure 29: Other types of uses in 2019 including their severity

In 2019, there was a significant increase in the number of uses for the preservation of species (+168%) and protection of the natural environment (+176%) (Table 27). Over 90% of these concern the use of fish.

	2019
Protection of the natural environment in the interests of the health or welfare of human beings or animals	234,707
Preservation of species	225,484
Higher education or training for the acquisition, maintenance or improvement of vocational skills	163,047
Forensic enquiries	390
Total	623,628

Table 27: Other types of uses

IV.2.3. Information on reuses and genetic status of animals

The Directive requires additional elements to be recorded related to the use of animals for scientific purposes, such as reuse and information on the genetic status of the animals.

IV.2.3.1. Reuses

In line with the principle of the Three Rs¹⁹, the total number of animals used in procedures can be reduced by performing procedures on animals more than once. However, this should only take place when this does not result in poor animal welfare and is evaluated on a case-by-case basis. Under Directive 2010/63/EU, reuse of animals in procedures is permitted only under specific conditions related to the actual level of severity the animal has experienced in a previous procedure, and the health and well-being of the animal, taking into account the lifetime experience of the individual animal. A reuse cannot be authorised for a procedure, in which the animal may reach ‘severe’ level of pain, suffering or distress. Also, an animal may be reused following a severe procedure only in exceptional circumstances and after a veterinary examination of that animal.

In 2019, the proportion of reuses remained stable at 2% (Table 28).

2019	
No	98% (10,401,673)
Yes	2% (207,091)
Total	100% (10,608,764)

Table 28: Reuses of animals used for research, testing, routine production and educational purposes

IV.2.3.2.1. Animal species reused

In absolute numbers, the main species reused for scientific purposes in 2018 were mice, sheep, rats, rabbits, horses, donkeys and cross-breeds.

In proportions, large mammals are more often reused such as horses, donkeys and cross-breeds (89%), sheep (69%), cats (41%), dogs (37%) and non-human primates.

Reptiles (76%) and xenopus (26%) amongst amphibians were also often reused (Table 29).

	Total number of uses	Number of reuses	Proportion of reuses
Mice	5,515,089	55,656	1%
Rats	992,667	14,362	1%
Guinea-Pigs	125,295	808	1%
Hamsters (Syrian)	12,136	5	<1%
Mongolian gerbil	4,111	8	<1%
Other rodents	34,885	222	1%
Rabbits	364,400	10,569	3%
Cats	3,708	1,528	41%
Dogs	20,641	7,565	37%

¹⁹ To Replace, Reduce and Refine the use of animals in scientific procedures

Ferrets	1,929	46	2%
Other carnivores	5,056	330	7%
Horses, donkeys and cross-breeds	13,399	11,968	89%
Pigs	87,116	4,297	5%
Goats	2,372	1,170	49%
Sheep	72,974	51,232	69%
Cattle	35,361	10,112	29%
Prosimians	249	55	22%
Marmoset and tamarins	382	160	42%
Cynomolgus monkey	9,030	2,282	25%
Rhesus monkey	440	189	43%
Vervets Chlorocebus spp.	36	11	31%
Other species of Old World Monkeys (Cercopithecoidea)	33	31	94%
Other mammals	5,787	442	8%
Domestic fowl	522,800	3,504	1%
Other birds	124,546	1,555	1%
Reptiles	8,249	6,237	76%
Rana	6,321	4	<1%
Xenopus	26,593	6,795	26%
Other amphibians	21,262	601	3%
Zebra fish	525,170	7,977	2%
Other fish	2,049,687	7,348	<1%
Cephalopods	16,990	22	<1%

Table 29: Reuses by type of species in 2019

IV.2.3.2.2. Reuse by purposes of procedures

In 2019, education or training for the acquisition, maintenance or improvement of vocational skills (11%) and routine production (10%) had the largest proportion of reuses mainly for blood-based products. The second most common use purpose for which animals have been reused was higher education and training (Table 30).

	Total number of uses	Number of re-uses	Proportion
Basic research	4,771,386	59,354	1%
Translational and applied research	2,833,086	26,385	1%
Regulatory use	1,788,779	40,181	2%
Routine production	591,885	57,585	10%
Higher education or training for the acquisition, maintenance or improvement of vocational skills	163,047	17,405	11%
Protection of the natural environment in the interests of the health or welfare of human beings or animals	234,707	5,729	2%
Preservation of species	225,484	452	<1%

Forensic enquiries	390	0	<1%
Total	10,608,764	207,091	2%

Table 30: Reuses by purposes in 2019

IV.2.3.2.3. Severity of reuse

According to the Directive, reuse of an animal is not allowed in a procedure classified prospectively as severe. In 2019, most of the reuses, the actual reported severities were mild (82%) or moderate (17%) (Figure 30).

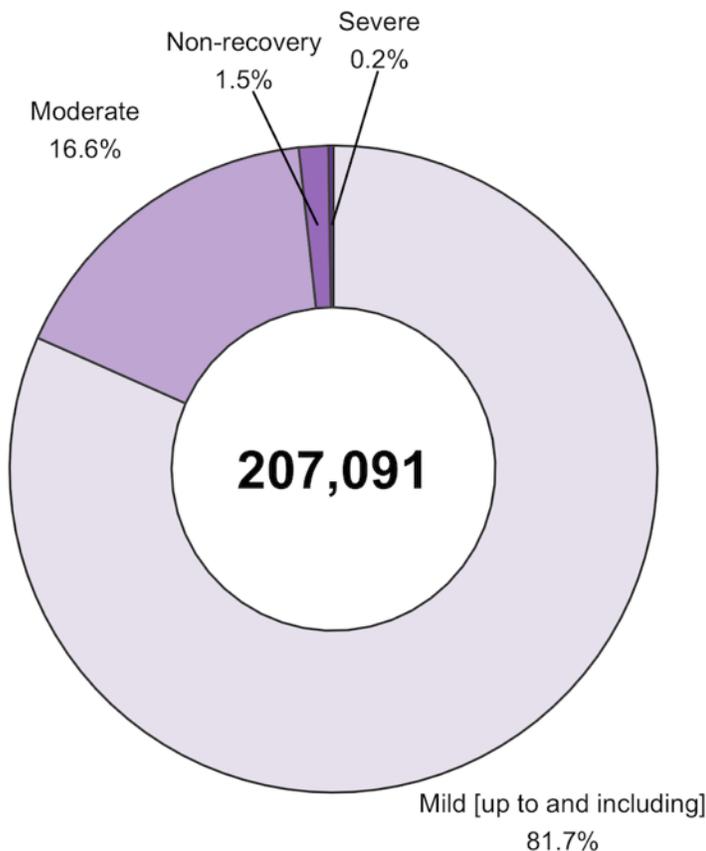


Figure 30: Reuses by severity in 2019

However, in some cases, even if the procedure is prospectively classified in a lower severity category, an individual animal may reach severity category "severe" due to unforeseen events occurring during the procedure. Only a very small number of such cases (<1 %) was reported, with an increase of 392 uses compared to 2018.

These 508 cases should be investigated by the authorities to eliminate any recurrence of any repetitive unforeseen adverse effects. Furthermore, these events, if recurring, may suggest a need for a revision of the prospective classification for future uses.

	2019
Non-recovery	1% (3,042)

Mild [up to and including]	82% (169,093)
Moderate	17% (34,448)
Severe	0% (508)
Total	100% (207,091)

Table 31: Severity classification of reuse procedures

IV.2.3.2. Use of genetically altered animals

Some of the animals used in procedures for purposes of research, testing, routine production and education are genetically altered. This section presents the types of genetic alteration reported. A welfare assessment is required to be performed on a newly created genetically altered animal line to establish whether the line is expected to have an intended non-harmful or harmful phenotype.

Intended non-harmful phenotypes include animal models where no adverse effects are noted during development, breeding and maintenance under conventional laboratory animal conditions. In addition, non-harmful phenotype lines include inducible and cre-lox lines, which require an active intervention for the harmful phenotype to be expressed.

Intended harmful phenotypes include animal models where gene alteration induces a specific genetic disorder or disease, or increases incidence of / susceptibility to for example tumour development. Other examples of harmful phenotype lines include those that require a specific bio-secure environment (for example, special housing arrangements to protect animals that are particularly sensitive to infection as a consequence of the gene alteration) or additional care beyond that required for conventional animals to maintain their health and well-being.

IV.2.3.2.1. Type of genetic alteration

In 2019, 2.66 million uses for the purposes of research were carried out on animals that were genetically altered. Of these, 17% were of a harmful phenotypic alteration.

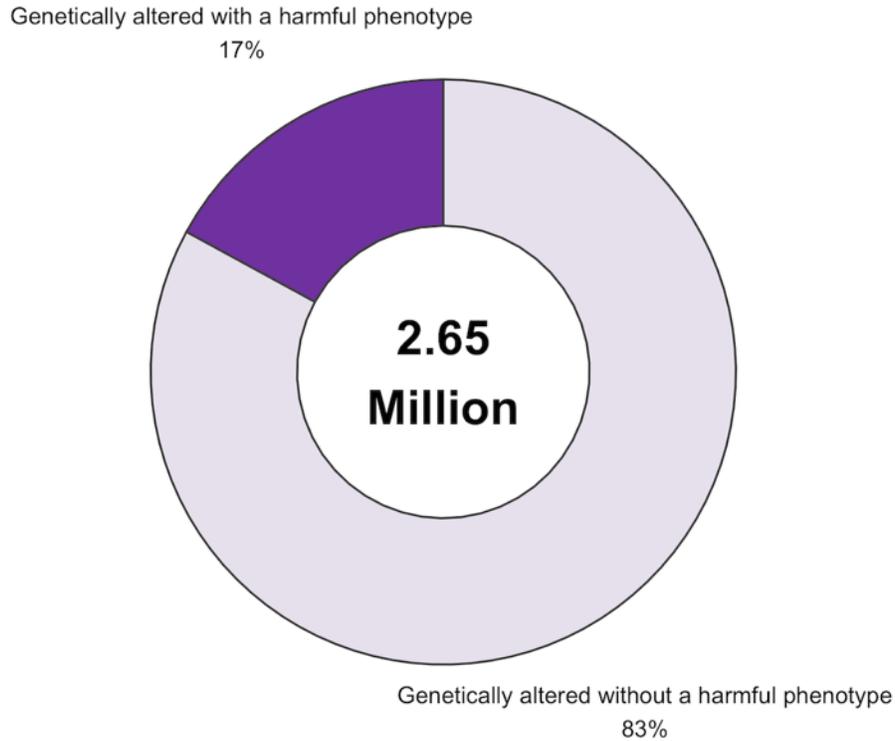


Figure 31: Uses of animals by type of genetic alteration in 2019

In 2019, the proportion of the uses of genetically altered animals for scientific purposes decreased slightly. The percentage of the uses of such animals with a harmful phenotype remained stable at 4%, and the uses of such animals without a harmful phenotype increased from 20% to 21%.

	2019
Genetically altered with a harmful phenotype	4% (452,106)
Genetically altered without a harmful phenotype	21% (2,199,664)
Not genetically altered	75% (7,956,994)
Total	100% (10,608,764)

Table 32: Genetic status of animals used

IV.2.3.2.2. Genetically altered animals by species

Amongst the species, which have been genetically altered, uses of mice accounted for the highest numbers, followed by zebra fish and rats.

Even if mice account for the most animals being genetically altered, in proportion, 61% of zebra fish was genetically altered, followed by mice (41%), while only 3% of rats were genetically altered used in procedures for purposes of research, testing, routine production in 2019 (Table 33).

	Total number of uses	Uses of genetically altered animals	Proportion
Zebra fish	525,170	322,391	61%
Mice	5,515,089	2,264,180	41%
Other amphibians	21,262	3,734	18%
Xenopus	26,593	3,549	13%
Rabbits	364,400	21,882	6%
Hamsters (Syrian)	12,136	553	5%
Rats	992,667	30,843	3%
Pigs	87,116	691	1%
Ferrets	1,929	10	1%
Dogs	20,641	60	<1%
Other fish	2,049,687	3,415	<1%
Other rodents	34,885	41	<1%
Domestic fowl	522,800	417	<1%
Other birds	124,546	4	<1%

Table 33: Genetically altered animals by species in 2019

This situation is mainly explained by the fact that genetically altered animals are used almost exclusively for research purposes. In 2019, basic research accounted for 77% of uses of genetically altered animals and translational and applied research for 19% (Table 34).

	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total
Basic research	57% (2,732,346)	36% (1,726,630)	7% (312,410)	100% (4,771,386)
Translational and applied research	81% (2,300,346)	14% (396,396)	5% (136,344)	100% (2,833,086)
Regulatory use	98% (1,759,115)	2% (27,702)	<1% (1,962)	100% (1,788,779)
Routine production	96% (568,386)	4% (23,499)	<1% (0)	100% (591,885)
Higher education or training for the acquisition, maintenance or improvement of vocational skills	90% (146,244)	10% (16,204)	<1% (599)	100% (163,047)
Preservation of species	97% (219,354)	2% (5,347)	<1% (783)	100% (225,484)
Protection of the natural environment in the interests of the health or welfare of human beings or animals	98% (230,821)	2% (3,886)	<1% (0)	100% (234,707)
Forensic enquiries	98% (382)	<1% (0)	2% (8)	100% (390)

Table 34: Genetic status of animals by use purposes in 2019

IV.3. Numbers and uses of animals for the creation and maintenance of genetically altered animals in the EU

In the context of Directive 2010/63/EU, Member States are also required to report the animals used in procedures for the creation of new genetically altered animal lines and the maintenance of colonies of established genetically altered animal lines to support the research needs in the Union.

Diagram in part IV.3 provides further understanding of the reporting requirements for both creation and maintenance of genetically altered animal lines.

IV.3.1. Numbers of animals used for the creation and maintenance of genetically altered animals

In 2019, 1.21 million animals were used for the provision of genetically altered animals for the purposes of scientific research.

This included 508,525 animals used for the first time for the creation of new genetically altered animal lines (Table 35), which represents a decrease of 14% from 2018.

699,985 animals were used for the first time for the maintenance of colonies of established genetically altered animal lines (Table 3.8). In comparison to 2018, this represents a decrease of 24%. It is important to note in this context that the reporting requirements for the maintenance of colonies of established genetically altered animal lines are particularly complex. This is the likely to be the greatest single contributing factor for such significant year to year fluctuations. The Commission, Member States and key stakeholder organisations have been working to provide more guidance to the users. A guidance document on genetically altered animals was endorsed by Member State National Contact Points responsible for the implementation of the Directive in their meeting in November 2021. More information is provided under section IV.3.3 below.

IV.3.2. All uses of animals for the creation of new genetic altered animal lines

The creation of a new genetic altered animal line is reported under the research purpose category for which the line is being created for. The reporting covers all animals carrying the genetic alteration. In addition, those used for superovulation, vasectomy and embryo implantation are equally reported (these may or may not be genetically altered themselves). Genetically normal animals (wild type offspring) produced as a result of creation of a new genetically altered line are not reported in the annual statistics. (Diagram in Part IV.4).

Counting all uses, the main species that were used for the creation of new genetic altered animal lines were mice and zebra fish, 73% and 25% respectively. Other species, although in small numbers, include rats, other species of fish, xenopus, domestic fowl, rabbits, other species of amphibians and pigs.

In 2019, the creation of new genetic lines decreased by 14% (Table 35).

	2019
Mice	370,912
Zebra fish	126,566
Rats	3,655
Other fish	3,169
Xenopus	1,787
Domestic fowl	1,166
Rabbits	305
Other amphibians	271
Pigs	265
Hamsters (Syrian)	116
Marmoset and tamarins	43
Sheep	41
Other mammals	13
Other birds	10
Cattle	1
Total	508,320

Table 35: Uses of animals for the creation of new genetically altered animal lines by species

IV.3.2.1. Creation of new genetically altered animal lines by genetic status

Animals that are not genetically altered but reported under the category creation of a new genetically altered animal lines include, for example, genetically normal parent animals or a part of the offspring that does not carry the genetic alteration. Of those that were genetically altered, over 85% were of a non-harmful phenotype.

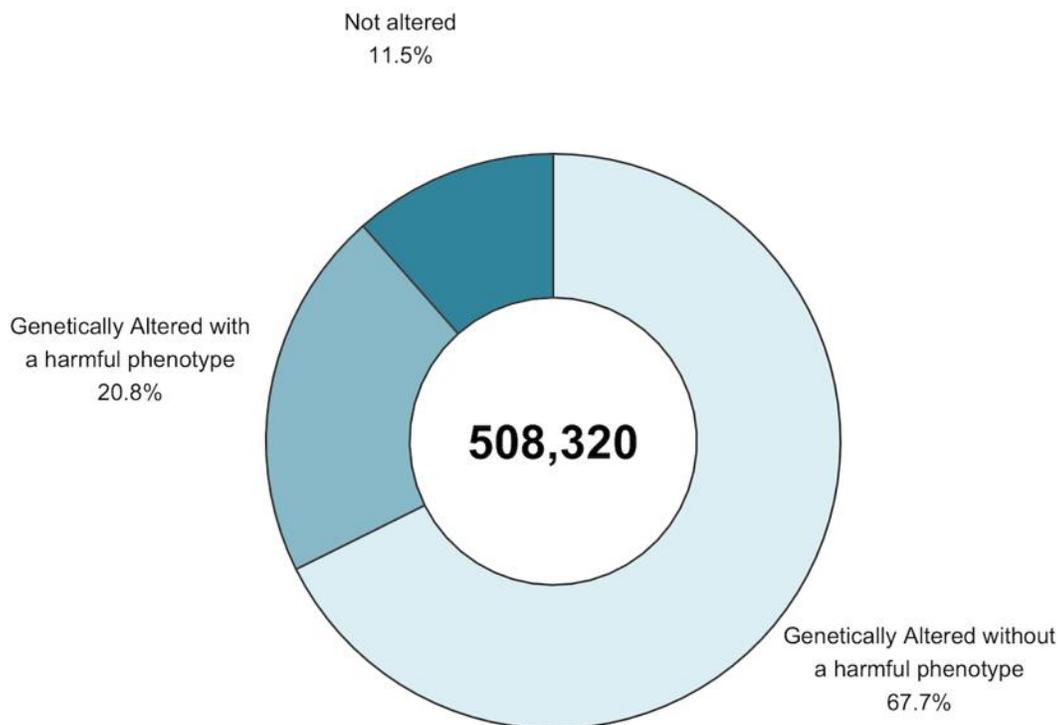


Figure 32: Creation of new genetically altered animal lines: genetic types of animal used in 2019

	2019
Not genetically altered	11% (105,871)
Genetically altered without a harmful phenotype	68% (343,905)
Genetically altered with a harmful phenotype	21% (58,544)
Total	100% (508,320)

Table 36: Creation of new genetically altered animal lines: genetic types of animal used

IV.3.2.2. Creation of new genetically altered animal lines by scientific purposes

The creation of new genetic lines is only carried out for research purposes. In 2019, 511,348 uses (first and any subsequent reuses) were reported for the purposes of creating new genetically altered animal lines.

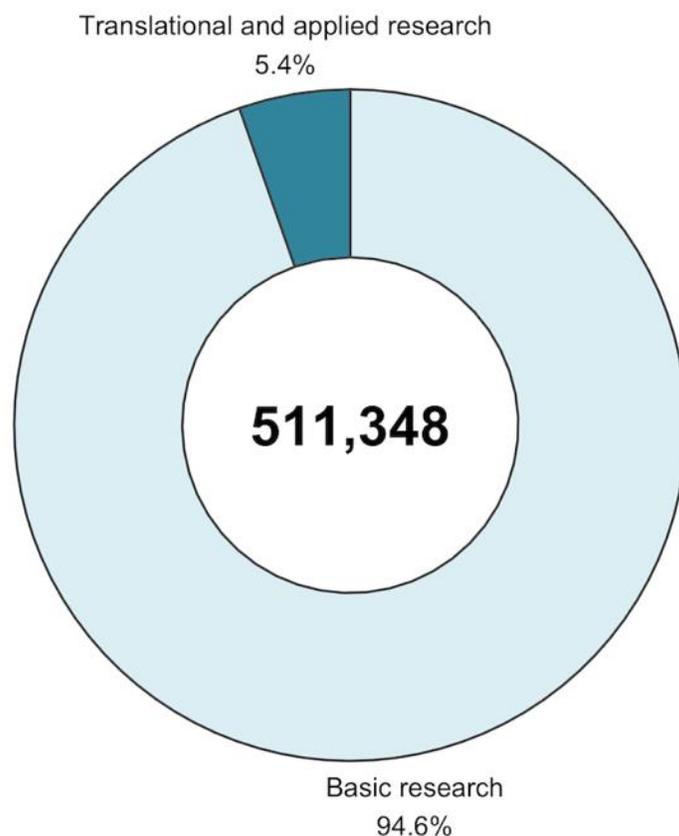


Figure 33: Creation of new genetically altered animal lines: uses for research purposes in 2019

95% of the new genetically altered lines were created for purposes covered under basic research. The table below presents all sub-categories from both basic and translational and applied research together.

In 2019, for basic research purposes, 18% concerned the multisystemic research (where more than one body system is the primary interest of the research, such as in some infectious diseases), 17% nervous system, 14% oncology and 13% immune system (Table 37).

The most important sub-category under translational and applied research for which new genetically altered animal lines were created was human cancer (2%). Due to the relatively low number of uses for the creation of new genetically altered animal lines for the applied and translational research purposes, Table 37 combines all research purposes both from basic, and translational and applied research.

	2019
Multisystemic	94,451
Nervous System	85,183
Oncology	68,848
Immune System	66,085
Cardiovascular Blood and Lymphatic System	50,629
Other basic research	37,757
Urogenital/Reproductive System	23,484
Gastrointestinal System including Liver	16,298
Endocrine System/Metabolism	15,371
Sensory Organs (skin, eyes and ears)	13,976
Human Cancer	9,617
Musculoskeletal System	9,255
Animal Diseases and Disorders	3,566
Other Human Disorders	3,018
Human Endocrine/Metabolism Disorders	2,682
Human Nervous and Mental Disorders	2,533
Ethology / Animal Behaviour /Animal Biology	1,874
Human Cardiovascular Disorders	1,844
Human Infectious Disorders	1,447
Human Immune Disorders	1,029
Respiratory System	766
Human Sensory Organ Disorders (skin, eyes and ears)	734
Human Gastrointestinal Disorders including Liver	355
Human Musculoskeletal Disorders	217
Human Respiratory Disorders	144
Human Urogenital/Reproductive Disorders	137
Non-regulatory toxicology and ecotoxicology	28
Diagnosis of diseases	20
Total	511,348

Table 37: Uses of animals for the creation of new genetically altered animal lines by type of research

IV.3.2.3. Creation of new genetically altered animal lines by severity

Severities reported under the creation of new genetically altered animal lines include impacts from surgical techniques used during creation (embryo transfer; vasectomy), tissue sampling (using an invasive method for genotyping) and effects caused by the phenotype of the genetic alteration.

	2019
Non-recovery	4% (19,644)
Mild [up to and including]	77% (393,000)
Moderate	18% (93,451)
Severe	1% (5,253)
Total	100% (511,348)

Table 38: Uses of animals for the creation of new genetically altered animal lines by severities

IV.3.2.4. Reuses

In 2019, the number of reuses for the creation of new genetic lines fell below 1%, and concerned mostly mice and zebra fish.

	2019
Yes	1% (3,028)
No	99% (508,320)
Total	100% (511,348)

Table 39: Reuse of animals used for the creation of new genetically altered animal lines

IV.3.3. All uses of animals for the maintenance of colonies of established genetically altered animal lines

Directive 2010/63/EU requires Member States to report animals used for the maintenance of colonies for genetically altered animals. This category contains animals required for the maintenance of colonies of genetically altered animals of established lines *with an intended harmful phenotype* and which *have exhibited pain, suffering, distress or lasting harm as a consequence of the harmful genotype* before being killed.

This category also includes genetically altered animals of an established line, irrespective of whether the line is of non-harmful or harmful phenotype, and

- for which the genotype has been confirmed using an invasive method (tissue sampling/genotyping), which was not carried out for the purposes of marking of the animal, and the animal is killed without further use;
- that are of unsuitable genotype, confirmed using an invasive method, which was not carried out for the purposes of marking of the animal.

Given the complexity of the reporting obligations, errors in the reporting of uses under maintenance of colonies continued to be detected. The new guidance document on genetically altered animals under the Directive, finalised in November 2021, is expected to improve consistency and accuracy of reporting.

IV.3.3.1. Maintenance of colonies of established genetically altered animal lines by genetic status

In 2019, 699,985 first uses were reported under the maintenance of colonies of established genetically altered animal lines. Amongst these uses, 78% were genetically altered without a harmful phenotype, 17% with a harmful phenotype and 5% without genetic alteration (Figure 33). This seems to suggest that

the majority of uses reported under maintenance of colonies of established genetically altered animal lines concern animals that have been genotyped using an invasive method. Those reported with a harmful phenotype are likely to be a mix of those that were genotyped and those having exhibited the harmful phenotype before being killed.

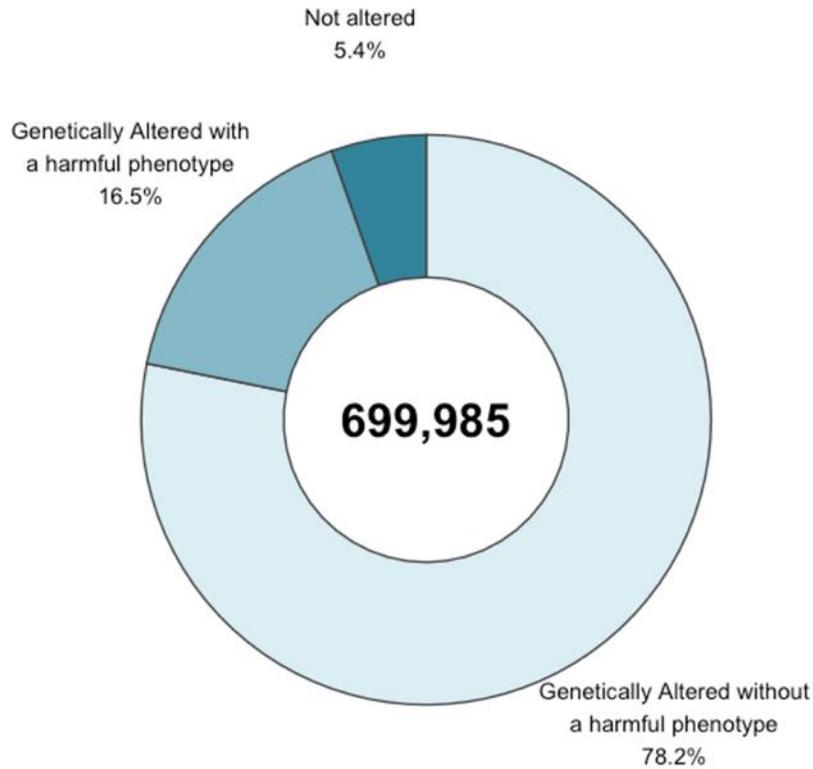


Figure 34: Genetic status of animals used for the maintenance of colonies of established genetically altered animal lines in 2019

IV.3.3.2. Maintenance of colonies of established genetically altered animal lines by severity

In 2019, in 82% of the uses the severities remained at mild (and up to mild) level (Table 41). Drawing from the previous figure 33 in which it was stated that 83% percent of animals were of non-harmful phenotype, the severities seem to relate to the effects of tissue sampling (invasive genotyping). For those classed as having a harmful-phenotype, the severities can be linked to the phenotype and invasive tissue sampling. Where animals are found dead with no clear reason, this results in reporting these as ‘severe’.

	2019
Non-recovery	<1% (1,353)
Mild [up to and including]	82% (580,931)

Moderate	11% (75,272)
Severe	7% (50,018)
Total	100% (707,574)

Table 40: Uses of animals for the maintenance of colonies of genetically altered animal lines by severity in 2019

IV.3.3.2. Maintenance of colonies of established genetically altered animal lines by species

Mice and zebra fish are the most common genetically altered animals used for scientific purposes and are therefore the main species also used for the maintenance of colonies.

	2019
Mice	620,099
Zebra fish	75,262
Rats	9,627
Other fish	1,811
Domestic fowl	405
Xenopus	360
Dogs	10
Total	707,574

Table 41: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species

IV.3.3.3. Reuses

These reuses involved mainly three types of species: mice, zebra fish and xenopus.

	Yes	No
Mice	6,177	613,922
Rats	0	9,627
Dogs	0	10
Domestic fowl	0	405
Xenopus	171	189
Zebra fish	1,241	74,021
Other fish	0	1,811
Total	7,589	699,985

Table 42: Reuses by species for the maintenance of colonies of established genetically altered animal lines

IV.4. Glossary of terms

Species of animals

The Directive applies to live non-human vertebrate animals, including independently feeding larval forms and foetal forms of mammals as from the last third of their normal development, and live cephalopods.

Larval forms and cephalopods are reported in the statistics when they become capable of independent feeding. Due to the small size of many larval forms of fish and cephalopod species, the count for these animals may be done on the basis of estimation.

Procedure

"Procedure" means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition but excludes the killing of animals solely for the use of their organs or tissues.

Use and reuse

The "use" of an animal within a project extends from the time the procedure (or first procedure/technique in a series) is applied to it, to the time when the observations, or the collection of data (or other products) for a particular scientific purpose (usually a single experiment or test), are completed.

"Reuse" is a term to indicate any subsequent use of an animal, which has already completed a procedure (or series of procedures/techniques) for a particular scientific purpose. Article 16 of the Directive on reuse defines it as a use when a different animal on which no procedure has previously been carried out could also be used. Article 16 also defines the conditions under which an animal may be reused.

Reporting of actual severity experienced by the animals

The impact on animal welfare is reported by assigning an animal's experience to a 'severity' category – "mild", "moderate" or "severe". There is a further category termed "non-recovery" which relates to where animals are placed under general anesthesia before they are used and are killed afterwards before regaining consciousness.

The reported severity reflects the highest degree of pain, suffering, distress or lasting harm observed to be actually experienced by the animal during the course of its use. Further guidance on severity assessment can be found at

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_Severity_Assessment.pdf.

- i. **Non-recovery** - Animals which have undergone a procedure that has been performed entirely under general anaesthesia from which the animal has not recovered consciousness shall be reported as Non-recovery.
- ii. **Mild (up to and including)** - Animals which have undergone a procedure as a result of which the animals have experienced short-term mild pain, suffering or distress, as well as when there has been no significant impairment of the well-being or general condition of the animals shall be reported as Mild.

This category also includes any animals used in an authorised project, but which have ultimately *not* been observed to have experienced a level of pain, suffering, distress or lasting harm above the minimum threshold (equivalent to that caused by the introduction of a needle in accordance with good veterinary practice) for example untreated control animals (“up to mild”). However, animals required for the maintenance of colonies of genetically altered animals of established lines *with an intended harmful phenotype and which have not exhibited* pain, suffering, distress or lasting harm as a consequence of the harmful genotype are not reported in annual statistics.

- iii. **Moderate** - Animals which have undergone a procedure as a result of which the animals have experienced short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that have caused moderate impairment of the well-being or general condition of the animals shall be reported as Moderate.
- iv. **Severe** - Animals which have undergone a procedure as a result of which the animals have experienced severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as procedures, that have caused severe impairment of the well-being or general condition of the animals shall be reported as Severe.

In the exceptional circumstances where, under the safeguard clause, the Severe classification is exceeded these animals and their use will be reported under Severe. Should this occur, further explanation on the circumstances of this use is provided in the respective Member State narrative.

Genetically altered animals

For the purposes of statistical reporting, "genetically altered animals" refer to either of the following:

- genetically modified (such as transgenic, knock-out and other forms of genetic alteration) and induced mutant animals (irrespective of the type of mutation);
- animals with spontaneous deleterious mutations maintained for research for that specific genotype.

Genetically altered animals are reported either

- a) When used for the creation of a new animal line;
- b) When used for the maintenance of an established line with an intended **and** exhibited harmful phenotype; This category also includes genetically altered animals during maintenance of an established line, irrespective of whether the line is of intended non-harmful or harmful phenotype, that have been subject to invasive genotyping (genetic characterisation/tissue sampling);
- c) When used in other (scientific) procedures (i.e. not for the creation or the maintenance of a line).

The reporting of genetically altered animals is summarised in the above table.

Creation

All animals *carrying a genetic alteration* are reported during the creation of a new line. Also, those used for superovulation, vasectomy and embryo implantation are reported (these may or may not be genetically altered).

Genetically normal animals (*wild-type offspring*) produced as a result of the creation of a new genetically altered line are not reported, unless these have been subjected to a procedure, for example an invasive method for the sole purposes of genotyping.

Establishment and maintenance of breeding colonies

A new strain or line of genetically altered animals is considered to be “established” when transmission of the genetic alteration is stable, which will be a minimum of two generations, and a welfare assessment has been completed. This marks the transition from "creation" to "breeding".

The welfare assessment determines if the newly established line is expected to have an *intended harmful phenotype (characteristic/trait)* i.e. an effect of genetic alteration that impacts negatively on an animal’s health or welfare, such as muscle weakness, diabetes, tumour development.

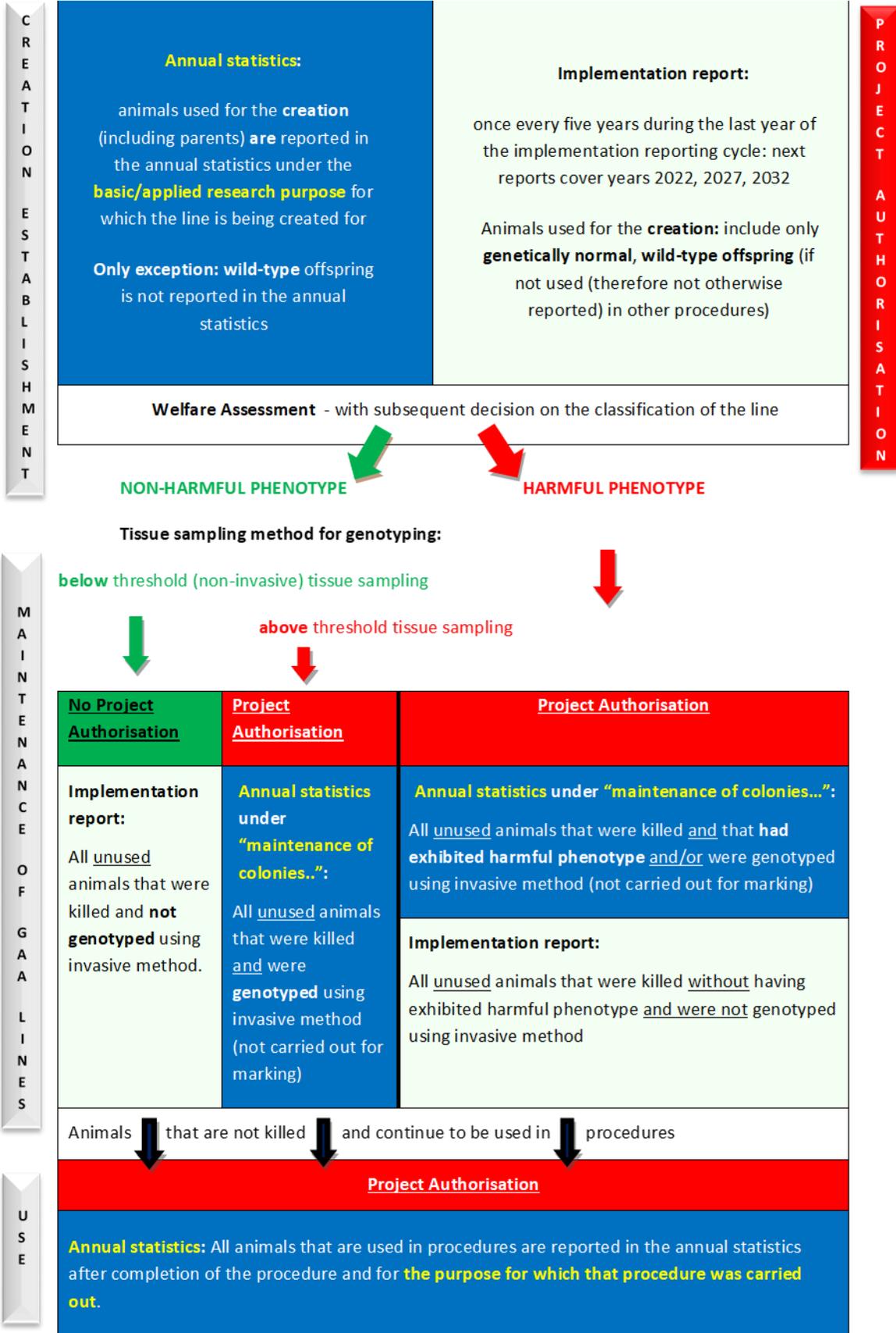
If the welfare assessment concludes that the line is *not* expected to have a harmful phenotype, its breeding falls outside the scope of a procedure and is not reported in the annual statistics.

If the welfare assessment concludes that the line *is* expected to have a harmful phenotype, its breeding falls within the scope of a procedure. If this is the case, and if the animal is not used in other procedures and it has exhibited, before being killed, pain, suffering, distress or lasting harm as a result of the harmful phenotype, it is reported under the category *Maintenance of colonies of established genetically altered animals, not used in other procedures*.

Use in procedures (other than creation or maintenance of a genetically altered line)

All genetically altered animals which are used in procedures (not for the creation or maintenance of a genetically altered line) are reported under their respective purposes they were used for. These animals may or may not exhibit a harmful phenotype.

Diagram for the reporting of the creation, maintenance and use of genetically altered animals



Main categories of purposes of uses for research, testing, routine production and education (including training)

Basic research

Basic research includes studies of a fundamental nature including physiology. Studies that are designed to add knowledge about normal and abnormal structure, functioning and behaviour of living organisms and environment, this includes fundamental studies in toxicology. Investigation and analysis focused on a better or fuller understanding of a subject, phenomenon, or a basic law of nature instead of on a specific practical application of the results.

Translational and applied research

Translational and applied research includes animals used for purposes as described in Article 5(b) and (c) of the Directive, that is to say,

“(b) translational or applied research with any of the following aims:

- (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;*
- (ii) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or*
- (iii) the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;*

(c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;”

This category also includes discovery toxicology and investigations to *prepare* for the regulatory submission and method development. This does not include studies *required* for regulatory submissions.

Regulatory use

Regulatory uses cover the use of animals in procedures with a view to satisfying regulatory requirements, that is to say, for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed. It also includes tests carried out in respect of products/substances for which a regulatory submission was foreseen but ultimately not made, for instance because these were deemed unsuitable for the market by the developer and thus fail to reach the end of the development process.

Routine production

Routine production includes animals used in the manufacturing process of products such as antibodies and blood products including polyclonal antisera by established methods.

Protection of the natural environment in the interests of the health or welfare of human beings or animals

This category includes studies aimed at investigating and understanding phenomena such as environmental pollution, loss of biodiversity, and epidemiology studies in wild animals. This excludes any regulatory use of animals for ecotoxicology purposes.

Preservation of species

Studies aimed at conserving species, often those at risk of extinction, for example to investigate improved breeding strategies or preservation of habitats.

Higher education or training

This category covers the use of animals for the purposes of education for delivering theoretical knowledge within a higher education programme and also for the acquisition, maintenance or improvement of vocational skills.

Forensic enquiries

Studies to assist the investigation of forensic enquiries.

PART B: EU DATA IN 2019

V. Detailed EU tables 2019

This section presents the basic consolidated tables used for the conclusions at Union level.

Part 1: Numbers of animals used for research, testing, routine production and educational purposes in the EU

Table 1: Numbers of animals used for the first time by species (2019)

	Number of animals	%
Mammals		
Rodents		
Mice	5,459,433	52.5
Rats	978,305	9.4
Guinea-Pigs	124,487	1.2
Hamsters (Syrian)	12,131	0.1
Hamsters (Chinese)	17	0
Mongolian gerbil	4,103	0
Other rodents	34,663	0.3
Rabbits		
Rabbits	353,831	3.4
Carnivores		
Cats	2,180	0
Dogs	13,076	0.1
Ferrets	1,883	0
Other carnivores	4,726	0
Farm animals		
Horses, donkeys and cross-breeds	1,431	0
Pigs	82,819	0.8
Goats	1,202	0
Sheep	21,742	0.2
Cattle	25,249	0.2
Non-human primates		
Prosimians	194	0
Marmoset and tamarins	222	0
Cynomolgus monkey	6,748	0.1
Rhesus monkey	251	0
Vervets Chlorocebus spp.	25	0
Baboons	33	0
Other species of old world monkeys (Cercopithecoidea)	2	0
Other mammals		
Other mammals	5,345	0.1
Birds		
Domestic fowl	519,296	5
Other birds	122,991	1.2
Reptiles		
Reptiles	2,012	0
Amphibians		
Rana	6,317	0.1
Xenopus	19,798	0.2
Other amphibians	20,661	0.2
Fish		
Zebra fish	517,193	5
Other fish	2,042,339	19.6
Cephalopods		
Cephalopods	16,968	0.2
Totals		
Total	10,401,673	100
%	100	

Table 2: Place of birth by species (other than non-human primates) (2019)

	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	Animals born in rest of world	Total	%
Mammals						
Rodents						
Mice	5,231,364	170,682	11,969	45,418	5,459,433	52.5
Rats	953,220	19,316	937	4,832	978,305	9.4
Guinea-Pigs	121,385	3,102	0	0	124,487	1.2
Hamsters (Syrian)	10,117	27	0	1,987	12,131	0.1
Hamsters (Chinese)	17	0	0	0	17	0
Mongolian gerbil	3,851	252	0	0	4,103	0
Other rodents	10,588	23,920	66	89	34,663	0.3
Rabbits						
Rabbits	346,498	5,290	32	2,011	353,831	3.4
Carnivores						
Cats	821	1,098	17	244	2,180	0
Dogs	4,875	3,580	185	4,436	13,076	0.1
Ferrets	1,611	98	0	174	1,883	0
Other carnivores	518	4,195	2	11	4,726	0
Farm animals						
Horses, donkeys and cross-breeds	451	980	0	0	1,431	0
Pigs	37,031	45,755	0	33	82,819	0.8
Goats	710	492	0	0	1,202	0
Sheep	13,388	8,340	14	0	21,742	0.2
Cattle	9,848	15,248	153	0	25,249	0.2
Other mammals	489	4,599	78	179	5,345	0.1
Birds						
Domestic fowl	368,592	150,704	0	0	519,296	5
Other birds	45,687	74,438	751	2,115	122,991	1.2
Reptiles						
Reptiles	74	1,725	162	51	2,012	0
Amphibians						
Rana	5,080	1,237	0	0	6,317	0.1
Xenopus	9,111	8,426	0	2,261	19,798	0.2
Other amphibians	7,230	13,421	0	10	20,661	0.2
Fish						
Zebra fish	493,591	22,017	0	1,585	517,193	5
Other fish	1,298,675	681,803	53,242	8,619	2,042,339	19.6
Cephalopods						
Cephalopods	15,917	1,051	0	0	16,968	0.2
Totals						
Total	8,990,739	1,261,796	67,608	74,055	10,394,198	100
%	86.5	12.1	0.7	0.7	100	

Table 3: Source of non-human primates by species (2019)

	Animals born at a registered breeder within EU	Animals born in Asia	Animals born in America	Animals born in Africa	Animals born elsewhere	Total	%
Non-human primates							
New World Monkeys							
Prosimians	194	0	0	0	0	194	2.6
Marmoset and tamarins	222	0	0	0	0	222	3
Old World Monkeys							
Cynomolgus monkey	226	3,175	0	3,071	276	6,748	90.3
Rhesus monkey	222	23	0	0	6	251	3.4
Vervets Chlorocebus spp.	7	0	18	0	0	25	0.3
Baboons	33	0	0	0	0	33	0.4
Other species of old world monkeys (Cercopithecoidea)	0	2	0	0	0	2	0
Totals							
Total	904	3,200	18	3,071	282	7,475	100
%	12.1	42.8	0.2	41.1	3.8	100	

Table 4: Generation of non-human primates by species (2019)

	F1	F2 or greater	Self-sustaining colony	Total	%
Non-human primates					
New World Monkeys					
Prosimians	0	11	183	194	2.6
Marmoset and tamarins	4	86	132	222	3
Old World Monkeys					
Cynomolgus monkey	1,054	3,323	2,371	6,748	90.3
Rhesus monkey	10	44	197	251	3.4
Vervets Chlorocebus spp.	7	18	0	25	0.3
Baboons	0	33	0	33	0.4
Other species of old world monkeys (Cercopithecoidea)	2	0	0	2	0
Totals					
Total	1,077	3,515	2,883	7,475	100
%	14.4	47	38.6	100	

Part 2: Details of all uses of animals for research, testing, routine production and educational purposes in the EU

Table 5: Uses of animals by species, main categories of scientific purposes and severities (2019)

	Severity	Basic research	Translational and applied research	Regulatory use	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	Total	%
Mice	Non-recovery	255,002	43,428	3,707	18,250	0	151	13,742	0	334,280	6.1
	Mild	1,366,777	460,613	412,803	5,289	766	2,422	41,429	280	2,290,379	41.5
	Moderate	1,209,088	760,798	179,474	66,940	68	4,672	21,865	0	2,242,905	40.7
	Severe	252,777	156,834	202,920	34,648	29	78	239	0	647,525	11.7
	Total	3,083,644	1,421,673	798,904	125,127	863	7,323	77,275	280	5,515,089	100.0
Rats	Non-recovery	48,950	13,981	15,163	2,269	35	0	23,098	0	103,496	10.4
	Mild	74,617	71,158	331,614	4,794	268	32	12,975	73	495,531	49.9
	Moderate	115,680	96,643	111,176	86	138	667	5,180	0	329,570	33.2
	Severe	37,391	17,766	8,585	115	169	0	44	0	64,070	6.5
	Total	276,638	199,548	466,538	7,264	610	699	41,297	73	992,667	100.0
Guinea-Pigs	Non-recovery	845	793	297	8,222	0	0	256	0	10,413	8.3
	Mild	1,277	4,983	42,493	776	11	0	921	0	50,461	40.3
	Moderate	1,836	1,502	43,923	53	0	0	980	0	48,294	38.5
	Severe	7	880	15,240	0	0	0	0	0	16,127	12.9
	Total	3,965	8,158	101,953	9,051	11	0	2,157	0	125,295	100.0
Hamsters (Syrian)	Non-recovery	372	30	0	0	0	0	6	0	408	3.4
	Mild	466	406	3,099	0	0	0	116	0	4,087	33.7
	Moderate	998	2,645	1,786	0	0	0	35	0	5,464	45.0
	Severe	14	352	1,675	136	0	0	0	0	2,177	17.9
	Total	1,850	3,433	6,560	136	0	0	157	0	12,136	100.0
Hamsters (Chinese)	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	0	0	0	0	0	0	0	0	0	0.0
	Moderate	17	0	0	0	0	0	0	0	17	100.0
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	17	0	0	0	0	0	0	0	17	100.0
Mongolian gerbil	Non-recovery	394	16	0	0	0	0	4	0	414	10.1
	Mild	732	674	47	59	0	0	43	0	1,555	37.8
	Moderate	792	1,153	100	24	0	0	6	0	2,075	50.5
	Severe	10	33	24	0	0	0	0	0	67	1.6
	Total	1,928	1,876	171	83	0	0	53	0	4,111	100.0
Other rodents	Non-recovery	690	0	36	0	590	0	0	0	1,316	3.8
	Mild	14,184	658	9,856	40	380	202	540	0	25,860	74.1
	Moderate	6,279	439	59	0	528	124	0	0	7,429	21.3
	Severe	119	34	24	0	103	0	0	0	280	0.8
	Total	21,272	1,131	9,975	40	1,601	326	540	0	34,885	100.0
Rabbits	Non-recovery	2,134	1,104	6,139	27,721	0	0	660	0	37,758	10.4
	Mild	9,255	2,613	50,955	129,181	0	0	951	0	192,955	53.0
	Moderate	5,548	5,649	29,756	86,337	0	0	61	0	127,351	34.9
	Severe	798	660	1,351	3,525	0	0	2	0	6,336	1.7
	Total	17,735	10,026	88,201	246,764	0	0	1,674	0	364,400	100.0
Cats	Non-recovery	35	0	13	0	0	0	0	0	48	1.3
	Mild	1,008	1,172	845	40	0	0	64	0	3,129	84.4
	Moderate	74	63	375	0	0	0	0	0	512	13.8
	Severe	10	4	5	0	0	0	0	0	19	0.5
	Total	1,127	1,239	1,238	40	0	0	64	0	3,708	100.0
Dogs	Non-recovery	18	49	96	18	0	0	112	0	293	1.4
	Mild	1,678	5,716	6,287	385	82	0	970	0	15,118	73.2
	Moderate	201	921	3,848	19	0	0	9	0	4,998	24.2
	Severe	2	60	167	3	0	0	0	0	232	1.1
	Total	1,899	6,746	10,398	425	82	0	1,091	0	20,641	100.0
Ferrets	Non-recovery	70	2	0	1	0	0	9	0	82	4.3
	Mild	78	448	235	48	0	0	35	0	844	43.8
	Moderate	100	566	182	10	0	0	17	0	875	45.4
	Severe	2	126	0	0	0	0	0	0	128	6.6
	Total	250	1,142	417	59	0	0	61	0	1,929	100.0
Other carnivores	Non-recovery	6	3	0	0	0	9	0	0	18	0.4
	Mild	3,912	111	50	0	235	69	20	0	4,397	87.0
	Moderate	70	165	283	0	65	33	0	0	616	12.2
	Severe	0	0	0	0	25	0	0	0	25	0.5
	Total	3,988	279	333	0	325	111	20	0	5,056	100.0
Horses, donkeys and cross-breeds	Non-recovery	0	16	0	0	0	0	49	0	65	0.5
	Mild	1,571	765	149	8,187	1,647	54	403	0	12,776	95.4
	Moderate	254	202	12	38	0	0	37	0	543	4.1
	Severe	0	3	10	2	0	0	0	0	15	0.1
	Total	1,825	986	171	8,227	1,647	54	489	0	13,399	100.0

	Severity	Basic research	Translational and applied research	Regulatory use	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	Total	%
Pigs	Non-recovery	1,585	3,034	319	36	40	0	9,023	0	14,037	16.1
	Mild	13,033	25,048	7,574	222	719	9	2,083	2	48,690	55.9
	Moderate	4,782	10,465	3,455	31	176	0	2,583	0	21,492	24.7
	Severe	588	1,724	585	0	0	0	0	0	2,897	3.3
	Total	19,988	40,271	11,933	289	935	9	13,689	2	87,116	100.0
Goats	Non-recovery	0	2	0	0	0	0	6	0	8	0.3
	Mild	1,097	190	50	145	0	0	299	0	1,781	75.1
	Moderate	346	183	15	5	2	0	3	0	554	23.4
	Severe	0	26	3	0	0	0	0	0	29	1.2
	Total	1,443	401	68	150	2	0	308	0	2,372	100.0
Sheep	Non-recovery	185	251	0	2	0	0	568	0	1,006	1.4
	Mild	9,974	4,339	988	47,109	3,415	0	724	33	66,582	91.2
	Moderate	1,392	2,462	134	278	45	0	169	0	4,480	6.1
	Severe	486	263	136	0	21	0	0	0	906	1.2
	Total	12,037	7,315	1,258	47,389	3,481	0	1,461	33	72,974	100.0
Cattle	Non-recovery	1	7	0	0	0	0	7	0	15	0.0
	Mild	8,633	12,924	2,385	102	1,726	0	4,388	2	30,160	85.3
	Moderate	1,201	1,250	547	4	28	0	1,984	0	5,014	14.2
	Severe	43	57	67	0	5	0	0	0	172	0.5
	Total	9,878	14,238	2,999	106	1,759	0	6,379	2	35,361	100.0
Prosimians	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	151	0	0	0	0	0	0	0	151	60.6
	Moderate	92	0	0	0	0	0	0	0	92	36.9
	Severe	6	0	0	0	0	0	0	0	6	2.4
	Total	249	0	0	0	0	0	0	0	249	100.0
Marmoset and tamarins	Non-recovery	6	4	0	0	0	0	0	0	10	2.6
	Mild	59	54	36	85	0	0	0	0	234	61.3
	Moderate	50	37	40	0	0	0	0	0	127	33.2
	Severe	1	6	4	0	0	0	0	0	11	2.9
	Total	116	101	80	85	0	0	0	0	382	100.0
Cynomolgus monkey	Non-recovery	3	44	4	0	0	0	0	0	51	0.6
	Mild	222	623	3,913	831	0	0	0	0	5,589	61.9
	Moderate	80	383	2,814	0	0	0	0	0	3,277	36.3
	Severe	1	71	41	0	0	0	0	0	113	1.3
	Total	306	1,121	6,772	831	0	0	0	0	9,030	100.0
Rhesus monkey	Non-recovery	6	6	0	0	0	0	0	0	12	2.7
	Mild	75	101	0	29	0	0	0	0	205	46.6
	Moderate	109	107	0	0	0	0	0	0	216	49.1
	Severe	5	2	0	0	0	0	0	0	7	1.6
	Total	195	216	0	29	0	0	0	0	440	100.0
Vervets Chlorocebus spp	Non-recovery	0	0	0	8	0	0	0	0	8	22.2
	Mild	0	12	0	3	0	0	0	0	15	41.7
	Moderate	0	3	0	0	0	0	0	0	3	8.3
	Severe	0	10	0	0	0	0	0	0	10	27.8
	Total	0	25	0	11	0	0	0	0	36	100.0
Baboons	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	0	8	0	0	0	0	0	0	8	24.2
	Moderate	0	19	0	0	0	0	0	0	19	57.6
	Severe	0	6	0	0	0	0	0	0	6	18.2
	Total	0	33	0	0	0	0	0	0	33	100.0
Other species of old world monkeys (Cercopithecoidea)	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	18	13	0	0	0	0	0	0	31	93.9
	Moderate	2	0	0	0	0	0	0	0	2	6.1
	Severe	0	0	0	0	0	0	0	0	0	0.0
	Total	20	13	0	0	0	0	0	0	33	100.0
Other mammals	Non-recovery	12	12	0	0	0	3	0	0	27	0.5
	Mild	3,547	488	0	15	166	259	185	0	4,660	80.5
	Moderate	953	71	0	12	0	6	0	0	1,042	18.0
	Severe	26	26	0	4	2	0	0	0	58	1.0
	Total	4,538	597	0	31	168	268	185	0	5,787	100.0
Domestic fowl	Non-recovery	439	597	710	1,252	384	0	186	0	3,568	0.7
	Mild	96,582	79,440	93,615	99,228	3,352	439	1,781	0	374,437	71.6
	Moderate	44,032	40,796	25,619	15,094	572	0	409	0	126,522	24.2
	Severe	1,094	9,188	7,494	432	65	0	0	0	18,273	3.5
	Total	142,147	130,021	127,438	116,006	4,373	439	2,376	0	522,800	100.0
Other birds	Non-recovery	2,419	3,080	0	682	288	0	121	0	6,590	5.3
	Mild	58,741	1,839	3,823	261	2,138	1,868	710	0	69,380	55.7
	Moderate	13,821	651	2,798	27,399	1,082	68	64	0	45,883	36.8
	Severe	271	1,030	1,389	0	0	0	3	0	2,693	2.2
	Total	75,252	6,600	8,010	28,342	3,508	1,936	898	0	124,546	100.0

	Severity	Basic research	Translational and applied research	Regulatory use	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	Total	%
Reptiles	Non-recovery	0	0	0	0	0	0	0	0	0	0.0
	Mild	3,928	8	0	0	0	624	36	0	4,596	55.7
	Moderate	3,651	0	0	0	0	0	0	0	3,651	44.3
	Severe	2	0	0	0	0	0	0	0	2	0.0
	Total	7,581	8	0	0	0	624	36	0	8,249	100.0
Rana	Non-recovery	0	0	0	0	0	0	930	0	930	14.7
	Mild	803	0	0	0	0	0	3,840	0	4,643	73.5
	Moderate	0	0	0	0	0	0	600	0	600	9.5
	Severe	148	0	0	0	0	0	0	0	148	2.3
	Total	951	0	0	0	0	0	5,370	0	6,321	100.0
Xenopus	Non-recovery	589	0	0	0	0	0	50	0	639	2.4
	Mild	12,753	2,702	1,300	0	137	0	225	0	17,117	64.4
	Moderate	1,177	9	40	0	200	0	29	0	1,455	5.5
	Severe	562	0	6,820	0	0	0	0	0	7,382	27.8
	Total	15,081	2,711	8,160	0	337	0	304	0	26,593	100.0
Other amphibians	Non-recovery	112	0	0	0	2,400	55	86	0	2,653	12.5
	Mild	4,222	6	0	0	212	6,585	1,395	0	12,420	58.4
	Moderate	2,900	0	0	0	0	0	3	0	2,903	13.7
	Severe	3,282	0	0	0	0	4	0	0	3,286	15.5
	Total	10,516	6	0	0	2,612	6,644	1,484	0	21,262	100.0
Zebra fish	Non-recovery	26,396	0	184	0	0	0	268	0	26,848	5.1
	Mild	255,774	73,562	13,965	0	5,572	0	1,806	0	350,679	66.8
	Moderate	78,269	31,627	11,359	0	1,294	0	0	0	122,549	23.3
	Severe	13,149	3,069	8,874	0	2	0	0	0	25,094	4.8
	Total	373,588	108,258	34,382	0	6,868	0	2,074	0	525,170	100.0
Other fish	Non-recovery	16,421	4,040	0	0	1,463	2,091	1,457	0	25,472	1.2
	Mild	480,742	660,815	43,713	1,400	51,254	183,021	1,838	0	1,422,783	69.4
	Moderate	149,388	66,194	23,355	0	139,363	21,729	303	0	400,332	19.5
	Severe	33,764	118,137	35,752	0	13,237	210	0	0	201,100	9.8
	Total	680,315	849,186	102,820	1,400	205,317	207,051	3,598	0	2,049,687	100.0
Cephalopods	Non-recovery	806	15,100	0	0	0	0	2	0	15,908	93.6
	Mild	207	628	0	0	41	0	5	0	881	5.2
	Moderate	10	0	0	0	121	0	0	0	131	0.8
	Severe	24	0	0	0	46	0	0	0	70	0.4
	Total	1,047	15,728	0	0	208	0	7	0	16,990	100.0
All Species	Non-recovery	357,496	85,599	26,668	58,461	5,200	2,309	50,640	0	586,373	5.5
	Mild	2,426,116	1,412,117	1,029,795	298,229	72,121	195,584	77,782	390	5,512,134	52.0
	Moderate	1,643,192	1,025,003	441,150	196,330	143,682	27,299	34,337	0	3,510,993	33.1
	Severe	344,582	310,367	291,166	38,865	13,704	292	288	0	999,264	9.4
	Total	4,771,386	2,833,086	1,788,779	591,885	234,707	225,484	163,047	390	10,608,764	100.0

Table 6: Uses of animals in all sub-categories of research and testing by severities (2019)

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total	%
Basic research						
Oncology	12,082	208,319	337,374	52,574	610,349	5.8
Cardiovascular Blood and Lymphatic System	51,843	142,394	101,523	16,895	312,655	2.9
Nervous System	111,780	383,870	397,572	104,164	997,386	9.4
Respiratory System	8,252	25,235	25,193	5,956	64,636	0.6
Gastrointestinal System including Liver	14,513	66,029	65,410	15,815	161,767	1.5
Musculoskeletal System	8,313	54,854	31,349	20,283	114,799	1.1
Immune System	40,275	372,862	255,815	77,654	746,606	7
Urogenital/Reproductive System	11,218	69,370	27,878	1,294	109,760	1
Sensory Organs (skin, eyes and ears)	14,964	36,373	19,681	5,858	76,876	0.7
Endocrine System/Metabolism	11,307	100,372	95,302	9,138	216,119	2
Multisystemic	10,992	193,135	55,355	9,923	269,405	2.5
Ethology / Animal Behaviour /Animal Biology	13,510	584,528	179,815	10,379	788,232	7.4
Other basic research	48,447	188,775	50,925	14,649	302,796	2.9
Translational and applied research						
Human Cancer	5,868	123,491	356,183	41,484	527,026	5
Human Infectious Disorders	7,356	144,945	100,214	39,710	292,225	2.8
Human Cardiovascular Disorders	11,913	19,863	25,790	7,462	65,028	0.6
Human Nervous and Mental Disorders	14,955	115,273	145,772	29,177	305,177	2.9
Human Respiratory Disorders	3,574	21,432	25,405	5,694	56,105	0.5
Human Gastrointestinal Disorders including Liver	2,054	14,287	24,707	4,885	45,933	0.4
Human Musculoskeletal Disorders	740	11,940	16,451	7,547	36,678	0.3
Human Immune Disorders	2,577	26,191	35,391	9,844	74,003	0.7
Human Urogenital/Reproductive Disorders	1,214	6,239	10,051	1,959	19,463	0.2
Human Sensory Organ Disorders (skin, eyes and ears)	779	20,352	21,721	2,006	44,858	0.4
Human Endocrine/Metabolism Disorders	4,575	39,838	84,286	2,620	131,319	1.2
Other Human Disorders	2,397	11,950	14,728	2,504	31,579	0.3
Animal Diseases and Disorders	3,715	631,807	94,795	132,695	863,012	8.1
Animal Welfare	20,029	164,572	23,476	6,031	214,108	2
Diagnosis of diseases	1,632	21,404	13,810	13,878	50,724	0.5
Plant diseases	0	108	0	0	108	0
Non-regulatory toxicology and ecotoxicology	2,221	38,425	32,223	2,871	75,740	0.7
Regulatory use						
Quality control (incl batch safety and potency testing)						
Batch safety testing	1,331	127,200	18,892	3,554	150,977	1.4
Pyrogenicity testing	30	10,318	20,296	268	30,912	0.3
Batch potency testing	18,022	347,840	163,113	215,735	744,710	7
Other quality controls	452	17,977	12,040	3,144	33,613	0.3
Toxicity and other safety testing including pharmacology						
Acute and sub-acute toxicity testing methods						
LD50, LC50	0	21,211	1,217	9,226	31,654	0.3
Other lethal methods	0	118	191	347	656	0
Non lethal methods	3	12,677	11,161	973	24,814	0.2
Skin irritation/corrosion	0	1,651	1,506	110	3,267	0
Skin sensitisation	0	14,291	24,351	1,791	40,433	0.4
Eye irritation/corrosion	0	119	261	94	474	0
Repeated dose toxicity						
up to 28 days	21	33,351	17,984	1,458	52,814	0.5
29 - 90 days	0	19,288	12,914	783	32,985	0.3
> 90 days	120	12,408	7,397	332	20,257	0.2
Carcinogenicity	20	4,274	3,353	446	8,093	0.1
Genotoxicity	6	7,936	1,488	377	9,807	0.1
Reproductive toxicity	169	71,115	24,594	1,255	97,133	0.9
Developmental toxicity	2	68,293	14,531	1,088	83,914	0.8
Neurotoxicity	0	999	219	4	1,222	0
Kinetics	900	36,190	21,718	672	59,480	0.6
Pharmacodynamics (incl safety pharmacology)	4,447	45,437	24,883	1,492	76,259	0.7
Phototoxicity	0	371	42	1	414	0
Ecotoxicity						
Acute toxicity	60	25,338	8,235	21,419	55,052	0.5
Chronic toxicity	0	16,352	14,741	5,846	36,939	0.3
Reproductive ecotoxicity	156	0	0	68	224	0
Endocrine activity	0	2,756	40	6,820	9,616	0.1
Bioaccumulation	0	4,157	661	0	4,818	0
Other ecotoxicity	0	3,431	14	321	3,766	0
Safety testing in food and feed area	0	30,545	948	6,545	38,038	0.4
Target animal safety	0	4,588	731	19	5,338	0.1
Other toxicity/safety testing	74	15,385	6,707	222	22,388	0.2
Other efficacy and tolerance testing						
Other efficacy and tolerance testing	855	74,179	26,922	6,756	108,712	1

	Non-recovery	Mild [up to and including]	Moderate	Severe	Total	%
Routine production						
Blood based products	29,980	168,117	86,091	389	284,577	2.7
Monoclonal antibody by mouse ascites method	7	1,612	1,665	34,193	37,477	0.4
Other product types	28,474	128,500	108,574	4,283	269,831	2.5
Other						
Protection of the natural environment in the interests of the health or welfare of human beings or animals	5,200	72,121	143,682	13,704	234,707	2.2
Preservation of species	2,309	195,584	27,299	292	225,484	2.1
Higher education or training for the acquisition, maintenance or improvement of vocational skills	50,640	77,782	34,337	288	163,047	1.5
Forensic enquiries	0	390	0	0	390	0
Total	586,373	5,512,134	3,510,993	999,264	10,608,764	100
%	5.5	52	33.1	9.4	100	

Table 7: Basic research related uses by species and type of research (2019)

	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	%
Mammals															
Rodents															
Mice	575,229	233,957	695,616	55,995	124,168	81,104	666,310	78,319	59,876	151,890	194,547	15,650	150,983	3,083,644	64.6
Rats	4,211	32,931	141,383	4,578	10,601	7,068	7,707	4,919	5,900	17,555	15,748	13,822	10,215	276,638	5.8
Guinea-Pigs	34	217	105	1,168	32	0	232	18	686	584	292	109	488	3,965	0.1
Hamsters	51	542	681	0	3	0	106	192	0	0	50	20	205	1,850	0
Hamsters (Syrian)	0	0	0	0	0	0	0	0	0	0	0	17	0	17	0
Mongolian gerbil	0	0	834	0	12	0	193	0	390	0	335	17	147	1,928	0
Other rodents	61	0	635	0	524	4	887	138	234	27	298	16,566	1,898	21,272	0.4
Rabbits															
Rabbits	124	1,227	641	929	673	433	511	539	449	53	220	6,260	5,676	17,735	0.4
Carnivores															
Cats	4	0	89	0	40	27	109	31	13	344	176	11	283	1,127	0
Dogs	55	131	40	86	203	115	186	86	10	63	126	108	690	1,899	0
Ferrets	0	0	152	65	0	0	0	0	0	0	12	4	17	250	0
Other carnivores	0	0	0	0	666	0	0	0	0	0	0	3,288	34	3,988	0.1
Farm animals															
Horses, donkeys and cross-breeds	0	30	0	21	10	38	659	215	29	404	184	80	155	1,825	0
Pigs	166	1,724	348	366	2,700	672	1,205	686	93	2,292	3,478	2,818	3,440	19,988	0.4
Goats	0	0	5	0	71	0	151	83	0	114	58	718	243	1,443	0
Sheep	6	825	241	8	335	1,026	989	586	21	1,234	3,507	2,537	722	12,037	0.3
Cattle	12	15	0	37	915	0	835	736	0	905	432	4,682	1,309	9,878	0.2
Non-human primates															
Prosimians	0	0	61	0	0	0	0	0	0	48	0	140	0	249	0
Marmoset and tamarins	0	0	58	0	0	0	0	4	0	9	4	41	0	116	0
Cynomolgus monkey	0	3	45	0	0	0	39	0	0	7	0	7	205	306	0
Rhesus monkey	0	55	140	0	0	0	0	0	0	0	0	0	0	195	0
Other species of old world monkeys (Cercopithecoidea)	0	2	0	0	0	0	0	0	0	0	0	18	0	20	0
Other mammals															
Other mammals	0	372	117	0	0	0	3	18	11	10	28	3,485	494	4,538	0.1
Birds															
Domestic fowl	0	94	5,832	0	12,002	348	1,801	1	204	14,179	1,264	93,133	13,289	142,147	3
Other birds	5,232	142	391	0	200	33	2,188	200	36	1,248	208	60,751	4,623	75,252	1.6
Reptiles															
Reptiles	0	19	116	36	0	24	0	0	14	110	235	6,992	35	7,581	0.2
Amphibians															
Rana	0	0	0	0	0	0	0	0	4	448	0	408	91	951	0
Xenopus	913	101	3,300	20	0	547	0	1,103	57	562	1,648	502	6,328	15,081	0.3
Other amphibians	0	354	1,028	0	0	3,858	0	0	10	6	347	4,145	768	10,516	0.2
Fish															
Zebra fish	23,928	38,822	139,479	0	5,680	17,713	23,426	7,476	7,434	11,777	35,064	21,258	41,531	373,588	7.8
Other fish	323	1,092	6,022	1,327	2,932	1,765	39,069	14,404	1,405	12,250	11,144	529,735	58,847	680,315	14.3
Cephalopods															
Cephalopods	0	0	27	0	0	24	0	6	0	0	0	910	80	1,047	0
Totals															
Total	610,349	312,655	997,386	64,636	161,767	114,799	746,606	109,760	76,876	216,119	269,405	788,232	302,796	4,771,386	100
%	12.8	6.6	20.9	1.4	3.4	2.4	15.6	2.3	1.6	4.5	5.6	16.5	6.3	100	

Table 8.1: Translational and applied research related uses by species and type of research (Part 1) (2019)

	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
Mammals									
Rodents									
Mice	518,838	246,448	44,804	190,407	44,261	31,994	25,403	68,207	12,250
Rats	5,682	5,005	14,680	80,947	6,178	9,250	8,877	4,859	6,561
Guinea-Pigs	20	1,175	479	335	4,097	34	2	191	0
Hamsters (Syrian)	180	1,584	99	399	0	122	0	12	0
Mongolian gerbil	0	1,115	0	0	0	0	0	0	0
Other rodents	0	265	0	120	4	0	0	0	0
Rabbits									
Rabbits	1,859	629	1,056	369	857	23	972	409	82
Carnivores									
Cats	0	0	0	0	0	0	0	0	0
Dogs	49	23	172	123	74	80	50	48	9
Ferrets	0	915	0	2	0	59	0	0	0
Other carnivores	0	6	0	0	0	0	0	0	0
Farm animals									
Horses, donkeys and cross-breeds	0	0	0	0	0	0	0	2	0
Pigs	304	275	3,035	400	532	765	533	90	447
Goats	0	14	45	0	0	0	42	0	5
Sheep	24	434	476	107	62	0	418	2	90
Cattle	0	62	7	0	0	0	0	0	18
Non-human primates									
Marmoset and tamarins	0	58	0	35	0	0	0	0	0
Cynomolgus monkey	9	375	23	143	32	0	0	118	1
Rhesus monkey	4	159	9	12	0	0	0	15	0
Vervets Chlorocebus spp.	0	25	0	0	0	0	0	0	0
Baboons	0	24	6	3	0	0	0	0	0
Other mammals									
Other species of old world monkeys (Cercopithecoidea)	0	13	0	0	0	0	0	0	0
Birds									
Other mammals	57	28	2	0	8	0	0	4	0
Domestic fowl	0	128	0	0	0	0	0	40	0
Reptiles									
Other birds	0	276	0	0	0	0	0	6	0
Amphibians									
Reptiles	0	0	0	0	0	0	0	0	0
Xenopus	0	0	0	0	0	0	0	0	0
Other amphibians	0	0	0	0	0	0	0	0	0
Fish									
Zebra fish	0	33,189	135	31,775	0	3,506	381	0	0
Other fish	0	0	0	0	0	100	0	0	0
Cephalopods									
Cephalopods	0	0	0	0	0	0	0	0	0
Totals									
Total	527,026	292,225	65,028	305,177	56,105	45,933	36,678	74,003	19,463
%	18.6	10.3	2.3	10.8	2	1.6	1.3	2.6	0.7

Table 8.2: Translational and applied research related uses by species and type of research (Part 2) (2019)

	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	%
Mammals										
Rodents										
Mice	32,013	102,655	21,627	29,962	1,446	37,566	66	13,726	1,421,673	50.2
Rats	6,226	20,444	6,742	1,972	219	4,595	0	17,311	199,548	7
Guinea-Pigs	254	3	65	667	0	226	0	610	8,158	0.3
Hamsters (Syrian)	0	699	0	338	0	0	0	0	3,433	0.1
Mongolian gerbil	113	0	0	648	0	0	0	0	1,876	0.1
Other rodents	0	0	0	417	10	220	0	95	1,131	0
Rabbits										
Rabbits	706	194	214	1,277	121	753	39	466	10,026	0.4
Carnivores										
Cats	0	0	0	1,208	16	15	0	0	1,239	0
Dogs	20	37	18	4,701	37	29	0	1,276	6,746	0.2
Ferrets	0	0	0	95	0	27	0	44	1,142	0
Other carnivores	0	0	0	81	192	0	0	0	279	0
Farm animals										
Horses, donkeys and cross-breeds	10	0	0	797	110	67	0	0	986	0
Pigs	169	1,010	238	20,037	11,638	487	0	311	40,271	1.4
Goats	0	0	0	240	10	32	0	13	401	0
Sheep	31	52	6	3,217	1,283	1,109	0	4	7,315	0.3
Cattle	0	194	0	7,031	6,416	502	0	8	14,238	0.5
Non-human primates										
Marmoset and tamarins	8	0	0	0	0	0	0	0	101	0
Cynomolgus monkey	56	24	98	0	3	0	0	239	1,121	0
Rhesus monkey	1	0	16	0	0	0	0	0	216	0
Vervets Chlorocebus spp.	0	0	0	0	0	0	0	0	25	0
Baboons	0	0	0	0	0	0	0	0	33	0
Other mammals										
Other species of old world monkeys (Cercopithecoidea)	0	0	0	0	0	0	0	0	13	0
Birds										
Other mammals	0	4	0	374	101	19	0	0	597	0
Domestic fowl	0	0	3	77,214	45,906	3,720	3	3,007	130,021	4.6
Reptiles										
Other birds	0	0	2	2,274	3,581	263	0	198	6,600	0.2
Amphibians										
Reptiles	0	0	0	0	8	0	0	0	8	0
Xenopus	0	29	0	0	0	9	0	2,673	2,711	0.1
Other amphibians	0	0	6	0	0	0	0	0	6	0
Fish										
Zebra fish	5,251	5,830	2,544	636	1,858	760	0	22,393	108,258	3.8
Other fish	0	144	0	709,198	126,053	325	0	13,366	849,186	30
Cephalopods										
Cephalopods	0	0	0	628	15,100	0	0	0	15,728	0.6
Totals										
Total	44,858	131,319	31,579	863,012	214,108	50,724	108	75,740	2,833,086	100
%	1.6	4.6	1.1	30.5	7.6	1.8	0	2.7	100	

Table 9: Regulatory uses by species and type of use (2019)

	Quality				Toxicity	Other	Total	%
	Quality: Batch safety testing	Quality: Pyrogenicity testing	Quality: Batch potency testing	Quality: Other quality controls	Toxicity and other safety testing including pharmacology	Other efficacy and tolerance testing		
Mammals								
Rodents								
Mice	81,096	270	420,998	26,316	212,569	57,655	798,904	44.7
Rats	11,774	0	157,268	1,009	291,028	5,459	466,538	26.1
Guinea-Pigs	14,179	140	55,006	672	30,245	1,711	101,953	5.7
Hamsters (Syrian)	52	0	3,888	448	1,573	599	6,560	0.4
Mongolian gerbil	0	0	121	0	50	0	171	0
Other rodents	0	0	0	0	9,895	80	9,975	0.6
Rabbits								
Rabbits	1,216	30,502	18,476	116	35,115	2,776	88,201	4.9
Carnivores								
Cats	174	0	23	67	613	361	1,238	0.1
Dogs	543	0	18	61	8,988	788	10,398	0.6
Ferrets	225	0	146	0	10	36	417	0
Other carnivores	42	0	151	0	0	140	333	0
Farm animals								
Horses, donkeys and cross-breeds	0	0	23	0	74	74	171	0
Pigs	2,103	0	859	302	4,594	4,075	11,933	0.7
Goats	0	0	8	0	57	3	68	0
Sheep	258	0	492	19	362	127	1,258	0.1
Cattle	333	0	1,031	0	783	852	2,999	0.2
Non-human primates								
Marmoset and tamarins	0	0	0	0	80	0	80	0
Cynomolgus monkey	0	0	0	0	6,695	77	6,772	0.4
Birds								
Domestic fowl	37,821	0	46,687	4,125	10,832	27,973	127,438	7.1
Other birds	542	0	458	0	1,084	5,926	8,010	0.4
Amphibians								
Xenopus	0	0	0	0	8,160	0	8,160	0.5
Fish								
Zebra fish	0	0	0	84	34,298	0	34,382	1.9
Other fish	619	0	39,057	394	62,750	0	102,820	5.7
Totals								
Total	150,977	30,912	744,710	33,613	719,855	108,712	1,788,779	100
%	8.4	1.7	41.6	1.9	40.2	6.1	100	

Table 10.1: Toxicity and other safety testing including pharmacology by species and type of use (Part 1) (2019)

	Acute				Repeated Dose					Carcinogenicity	Genotoxicity	Reproductive toxicity	Developmental toxicity	Safety testing in food and feed area
	LDS0, LC50	Other lethal methods	Non lethal methods	Skin irritation / corrosion	Skin sensitisation	Eye irritation / corrosion	up to 28 days	29 - 90 days	> 90 days					
Mammals														
Rodents														
Mice	25,292	84	13,032	0	12,226	0	13,191	6,302	3,603	3,855	1,704	2,895	2,039	31,965
Rats	2,352	572	9,415	44	10	0	33,104	22,927	13,420	3,497	92,905	6,890	58,529	34
Guinea-Pigs	1,155	0	511	0	27,983	0	10	0	0	0	0	0	0	0
Hamsters (Syrian)	0	0	298	111	18	0	0	0	0	741	0	0	0	0
Mongolian gerbil	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other rodents	0	0	0	0	0	0	32	0	0	0	0	0	0	0
Rabbits														
Rabbits	0	0	379	3,106	160	474	1,095	632	310	0	2,423	12	22,754	0
Carnivores														
Cats	0	0	0	0	0	0	36	0	0	0	0	0	0	0
Dogs	0	0	465	0	36	0	2,646	1,341	1,378	0	66	10	12	0
Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Farm animals														
Horses, donkeys and cross-breeds	0	0	0	0	0	0	0	0	0	0	0	0	0	32
Pigs	0	0	156	6	0	0	778	263	295	0	35	0	0	762
Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	62
Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	82
Non-human primates														
Marmoset and tamarins	0	0	0	0	0	0	36	0	32	0	0	0	0	0
Cynomolgus monkey	0	0	116	0	0	0	1,886	1,520	1,219	0	0	0	260	0
Birds														
Domestic fowl	558	0	0	0	0	0	0	0	0	0	0	0	0	4,650
Other birds	94	0	10	0	0	0	0	0	0	0	0	0	0	0
Amphibians														
Xenopus	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fish														
Zebra fish	1,292	0	432	0	0	0	0	0	0	0	0	0	0	0
Other fish	911	0	0	0	0	0	0	0	0	0	0	0	320	450
Totals														
Total	31,654	656	24,814	3,267	40,433	474	52,814	32,985	20,257	8,093	97,133	9,807	83,914	38,038
%	4.4	0.1	3.4	0.5	5.6	0.1	7.3	4.6	2.8	1.1	13.5	1.4	11.7	5.3

Table 10.2: Toxicity and other safety testing including pharmacology by species and type of use (Part 2) (2019)

	LD50, LC50	Other lethal methods	Non lethal methods	Skin irritation / corrosion	Skin sensitisation	EcoToxicity					Carcinogenicity	Genotoxicity	Reproductive toxicity	Developmental toxicity	Safety testing in food and feed area
						Eye irritation / corrosion	up to 28 days	29 - 90 days	> 90 days						
Mammals															
Rodents															
Mice	380	214	38,462	46,506	396	6,207	20	0	0	0	0	4,196	212,569	29.5	
Rats	24	1,008	15,268	26,461	0	861	1,056	0	0	0	0	2,651	291,028	40.4	
Guinea-Pigs	0	0	49	507	18	0	0	0	0	0	0	12	30,245	4.2	
Hamsters (Syrian)	0	0	0	9	0	0	0	0	0	0	0	396	1,573	0.2	
Mongolian gerbil	0	0	0	50	0	0	0	0	0	0	0	0	50	0	
Other rodents	767	0	0	0	0	0	0	0	0	0	0	9,096	9,895	1.4	
Rabbits															
Rabbits	161	0	199	889	0	40	158	0	0	0	6	2,317	35,115	4.9	
Carnivores															
Cats	83	0	427	67	0	0	0	0	0	0	0	0	613	0.1	
Dogs	268	0	1,711	883	0	0	0	0	0	0	0	172	8,988	1.2	
Ferrets	10	0	0	0	0	0	0	0	0	0	0	0	10	0	
Farm animals															
Horses, donkeys and cross-breeds	4	0	38	0	0	0	0	0	0	0	0	0	74	0	
Pigs	930	0	829	447	0	0	0	0	0	12	20	61	4,594	0.6	
Goats	0	0	56	0	0	0	0	0	0	0	0	0	57	0	
Sheep	74	0	214	0	0	0	6	0	0	0	0	6	362	0.1	
Cattle	93	0	499	61	0	0	0	0	0	22	12	14	783	0.1	
Non-human primates															
Marmoset and tamarins	0	0	4	0	0	0	0	0	0	0	0	8	80	0	
Cynomolgus monkey	0	0	878	132	0	0	0	0	0	0	0	684	6,695	0.9	
Birds															
Domestic fowl	2,026	0	807	247	0	0	0	0	0	0	0	2,544	10,832	1.5	
Other birds	105	0	39	0	0	592	10	0	0	0	54	180	1,084	0.2	
Amphibians															
Xenopus	0	0	0	0	0	0	0	0	8,160	0	0	0	8,160	1.1	
Fish															
Zebra fish	0	0	0	0	0	12,735	15,893	224	312	1,409	1,950	51	34,298	4.8	
Other fish	413	0	0	0	0	34,617	19,796	0	1,144	3,375	1,724	0	62,750	8.7	
Totals															
Total	5,338	1,222	59,480	76,259	414	55,052	36,939	224	9,616	4,818	3,766	22,388	719,855	100	
%	0.7	0.2	8.3	10.6	0.1	7.6	5.1	0	1.3	0.7	0.5	3.1	100		

Table 11: Regulatory uses by species and type of legislation (2019)

	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	Other legislation	Total	%
Mammals											
Rodents											
Mice	638,995	98,986	15,896	5,490	5,232	962	32,331	145	867	798,904	44.7
Rats	308,690	8,951	4,109	110,461	28,816	814	4,180	0	517	466,538	26.1
Guinea-Pigs	58,188	17,082	25,446	1,036	24	102	0	0	75	101,953	5.7
Hamsters (Syrian)	1,572	4,466	522	0	0	0	0	0	0	6,560	0.4
Mongolian gerbil	121	50	0	0	0	0	0	0	0	171	0
Other rodents	32	0	0	0	9,863	0	0	0	80	9,975	0.6
Rabbits											
Rabbits	50,655	12,242	6,197	14,304	2,477	460	6	298	1,562	88,201	4.9
Carnivores											
Cats	13	1,158	0	0	0	0	67	0	0	1,238	0.1
Dogs	8,122	2,032	23	0	160	0	61	0	0	10,398	0.6
Ferrets	407	10	0	0	0	0	0	0	0	417	0
Other carnivores	0	333	0	0	0	0	0	0	0	333	0
Farm animals											
Horses, donkeys and cross-breeds	56	83	0	0	0	0	0	32	0	171	0
Pigs	2,481	8,003	187	0	0	0	13	1,176	73	11,933	0.7
Goats	8	42	3	0	15	0	0	0	0	68	0
Sheep	14	1,006	159	0	0	0	52	27	0	1,258	0.1
Cattle	0	2,926	0	0	44	0	0	17	12	2,999	0.2
Non-human primates											
Marmoset and tamarins	80	0	0	0	0	0	0	0	0	80	0
Cynomolgus monkey	6,772	0	0	0	0	0	0	0	0	6,772	0.4
Birds											
Domestic fowl	2,419	110,459	0	0	223	0	0	14,317	20	127,438	7.1
Other birds	20	7,242	0	0	740	0	8	0	0	8,010	0.4
Amphibians											
Xenopus	0	0	0	50	8,110	0	0	0	0	8,160	0.5
Fish											
Zebra fish	6,541	88	931	10,589	5,528	119	0	0	10,586	34,382	1.9
Other fish	8,644	41,206	240	12,467	7,631	0	0	450	32,182	102,820	5.7
Totals											
Total	1,093,830	316,365	53,713	154,397	68,863	2,457	36,718	16,462	45,974	1,788,779	100
%	61.1	17.7	3	8.6	3.8	0.1	2.1	0.9	2.6	100	

Table 12: Regulatory uses by species and origin of regulatory requirement (2019)

	Legislation satisfying EU requirements	Legislation satisfying national requirements only [within EU]	Legislation satisfying Non-EU requirements only	Total	%
Mammals					
Rodents					
Mice	744,097	8,564	46,243	798,904	44.7
Rats	463,111	1,131	2,296	466,538	26.1
Guinea-Pigs	94,895	1,396	5,662	101,953	5.7
Hamsters (Syrian)	5,878	298	384	6,560	0.4
Mongolian gerbil	171	0	0	171	0
Other rodents	9,895	80	0	9,975	0.6
Rabbits					
Rabbits	84,618	134	3,449	88,201	4.9
Carnivores					
Cats	1,234	0	4	1,238	0.1
Dogs	10,339	10	49	10,398	0.6
Ferrets	417	0	0	417	0
Other carnivores	333	0	0	333	0
Farm animals					
Horses, donkeys and cross-breeds	171	0	0	171	0
Pigs	10,157	5	1,771	11,933	0.7
Goats	68	0	0	68	0
Sheep	1,110	106	42	1,258	0.1
Cattle	2,976	17	6	2,999	0.2
Non-human primates					
Marmoset and tamarins	80	0	0	80	0
Cynomolgus monkey	6,761	0	11	6,772	0.4
Birds					
Domestic fowl	118,438	0	9,000	127,438	7.1
Other birds	8,009	1	0	8,010	0.4
Amphibians					
Xenopus	8,160	0	0	8,160	0.5
Fish					
Zebra fish	32,882	1,270	230	34,382	1.9
Other fish	74,278	26,892	1,650	102,820	5.7
Totals					
Total	1,678,078	39,904	70,797	1,788,779	100
%	93.8	2.2	4	100	

Table 13: Routine production uses by species and product type (2019)

	Blood based products	Other product types	Monoclonal antibody by mouse ascites method	Total	%
Mammals					
Rodents					
Mice	2,800	85,598	36,729	125,127	21.1
Rats	1,169	6,093	2	7,264	1.2
Guinea-Pigs	1,306	7,745	0	9,051	1.5
Hamsters (Syrian)	136	0	0	136	0
Mongolian gerbil	0	83	0	83	0
Other rodents	0	40	0	40	0
Rabbits					
Rabbits	219,291	26,744	729	246,764	41.7
Carnivores					
Cats	25	15	0	40	0
Dogs	405	20	0	425	0.1
Ferrets	59	0	0	59	0
Horses, donkeys and cross-breeds	8,227	0	0	8,227	1.4
Farm animals					
Pigs	237	52	0	289	0
Goats	61	89	0	150	0
Sheep	47,349	40	0	47,389	8
Cattle	71	35	0	106	0
Marmoset and tamarins	85	0	0	85	0
Non-human primates					
Cynomolgus monkey	614	217	0	831	0.1
Rhesus monkey	29	0	0	29	0
Birds					
Vervets Chlorocebus spp.	3	8	0	11	0
Other mammals	0	14	17	31	0
Amphibians					
Domestic fowl	2,679	113,327	0	116,006	19.6
Fish					
Other birds	31	28,311	0	28,342	4.8
Other fish	0	1,400	0	1,400	0.2
Totals					
Total	284,577	269,831	37,477	591,885	100
%	48.1	45.6	6.3	100	

Table 14: Reuses of animals by species and main categories of scientific purposes in research, testing routine production and education (2019)

	Reuse	Basic research	Translational and applied research	Regulatory use	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	Total	%
Mice	Yes	19,441	10,486	18,249	570	0	249	6,661	0	55,656	
	No	3,064,203	1,411,187	780,655	124,557	863	7,074	70,614	280	5,459,433	99.0
	Total	3,083,644	1,421,673	798,904	125,127	863	7,323	77,275	280	5,515,089	100.0
Rats	Yes	4,328	4,298	2,545	130	0	38	3,023	0	14,362	1.4
	No	272,310	195,250	463,993	7,134	610	661	38,274	73	978,305	98.6
	Total	276,638	199,548	466,538	7,264	610	699	41,297	73	992,667	100.0
Guinea-Pigs	Yes	8	68	364	168	11	0	189	0	808	0.6
	No	3,957	8,090	101,589	8,883	0	0	1,968	0	124,487	99.4
	Total	3,965	8,158	101,953	9,051	11	0	2,157	0	125,295	100.0
Hamsters (Syrian)	Yes	0	0	0	0	0	0	5	0	5	0.0
	No	1,850	3,433	6,560	136	0	0	152	0	12,131	100.0
	Total	1,850	3,433	6,560	136	0	0	157	0	12,136	100.0
Hamsters (Chinese)	Yes	0	0	0	0	0	0	0	0	0	0.0
	No	17	0	0	0	0	0	0	0	17	100.0
	Total	17	0	0	0	0	0	0	0	17	100.0
Mongolian gerbil	Yes	4	4	0	0	0	0	0	0	8	0.2
	No	1,924	1,872	171	83	0	0	53	0	4,103	99.8
	Total	1,928	1,876	171	83	0	0	53	0	4,111	100.0
Other rodents	Yes	212	10	0	0	0	0	0	0	222	0.6
	No	21,060	1,121	9,975	40	1,601	326	540	0	34,663	99.4
	Total	21,272	1,131	9,975	40	1,601	326	540	0	34,885	100.0
Rabbits	Yes	46	348	9,042	818	0	0	315	0	10,569	2.9
	No	17,689	9,678	79,159	245,946	0	0	1,359	0	353,831	97.1
	Total	17,735	10,026	88,201	246,764	0	0	1,674	0	364,400	100.0
Cats	Yes	695	158	587	25	0	0	63	0	1,528	41.2
	No	432	1,081	651	15	0	0	1	0	2,180	58.8
	Total	1,127	1,239	1,238	40	0	0	64	0	3,708	100.0
Dogs	Yes	1,136	2,051	3,156	366	0	0	856	0	7,565	36.7
	No	763	4,695	7,242	59	82	0	235	0	13,076	63.3
	Total	1,899	6,746	10,398	425	82	0	1,091	0	20,641	100.0
Ferrets	Yes	0	22	0	0	0	0	24	0	46	2.4
	No	250	1,120	417	59	0	0	37	0	1,883	97.6
	Total	250	1,142	417	59	0	0	61	0	1,929	100.0
Other carnivores	Yes	250	30	0	0	50	0	0	0	330	6.5
	No	3,738	249	333	0	275	111	20	0	4,726	93.5
	Total	3,988	279	333	0	325	111	20	0	5,056	100.0
Horses, donkeys and cross-breeds	Yes	1,337	427	6	8,187	1,647	54	310	0	11,968	89.3
	No	488	559	165	40	0	0	179	0	1,431	10.7
	Total	1,825	986	171	8,227	1,647	54	489	0	13,399	100.0
Pigs	Yes	652	1,882	446	10	0	0	1,307	0	4,297	4.9
	No	19,336	38,389	11,487	279	935	9	12,382	2	82,819	95.1
	Total	19,988	40,271	11,933	289	935	9	13,689	2	87,116	100.0
Goats	Yes	795	14	5	109	0	0	247	0	1,170	49.3
	No	648	387	63	41	2	0	61	0	1,202	50.7
	Total	1,443	401	68	150	2	0	308	0	2,372	100.0
Sheep	Yes	1,705	716	152	44,884	3,282	0	493	0	51,232	70.2
	No	10,332	6,599	1,106	2,505	199	0	968	33	21,742	29.8
	Total	12,037	7,315	1,258	47,389	3,481	0	1,461	33	72,974	100.0
Cattle	Yes	3,230	3,125	242	9	167	0	3,339	0	10,112	28.6
	No	6,648	11,113	2,757	97	1,592	0	3,040	2	25,249	71.4
	Total	9,878	14,238	2,999	106	1,759	0	6,379	2	35,361	100.0
Prosimians	Yes	55	0	0	0	0	0	0	0	55	22.1
	No	194	0	0	0	0	0	0	0	194	77.9
	Total	249	0	0	0	0	0	0	0	249	100.0
	Yes	48	19	8	85	0	0	0	0	160	41.9

		Reuse	Basic research	Translational and applied research	Regulatory use	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	Total	%
Marmoset and tamarins	No		68	82	72	0	0	0	0	0	222	58.1
	Total		116	101	80	85	0	0	0	0	382	100.0
Cynomolgus monkey	Yes		29	416	1,122	715	0	0	0	0	2,282	25.3
	No		277	705	5,650	116	0	0	0	0	6,748	74.7
	Total		306	1,121	6,772	831	0	0	0	0	9,030	100.0
Rhesus monkey	Yes		134	26	0	29	0	0	0	0	189	43.0
	No		61	190	0	0	0	0	0	0	251	57.0
	Total		195	216	0	29	0	0	0	0	440	100.0
Vervets Chlorocebus spp	Yes		0	8	0	3	0	0	0	0	11	30.6
	No		0	17	0	8	0	0	0	0	25	69.4
	Total		0	25	0	11	0	0	0	0	36	100.0
Baboons	Yes		0	0	0	0	0	0	0	0	0	0.0
	No		0	33	0	0	0	0	0	0	33	100.0
	Total		0	33	0	0	0	0	0	0	33	100.0
Other species of old world monkeys (Cercopithecoidea)	Yes		18	13	0	0	0	0	0	0	31	93.9
	No		2	0	0	0	0	0	0	0	2	6.1
	Total		20	13	0	0	0	0	0	0	33	100.0
Other mammals	Yes		258	76	0	0	1	104	3	0	442	7.6
	No		4,280	521	0	31	167	164	182	0	5,345	92.4
	Total		4,538	597	0	31	168	268	185	0	5,787	100.0
Domestic fowl	Yes		731	176	2,312	71	0	0	214	0	3,504	0.7
	No		141,416	129,845	125,126	115,935	4,373	439	2,162	0	519,296	99.3
	Total		142,147	130,021	127,438	116,006	4,373	439	2,376	0	522,800	100.0
Other birds	Yes		950	176	202	6	0	0	221	0	1,555	1.2
	No		74,302	6,424	7,808	28,336	3,508	1,936	677	0	122,991	98.8
	Total		75,252	6,600	8,010	28,342	3,508	1,936	898	0	124,546	100.0
Reptiles	Yes		6,219	8	0	0	0	0	10	0	6,237	75.6
	No		1,362	0	0	0	0	624	26	0	2,012	24.4
	Total		7,581	8	0	0	0	624	36	0	8,249	100.0
Rana	Yes		4	0	0	0	0	0	0	0	4	0.1
	No		947	0	0	0	0	0	5,370	0	6,317	99.9
	Total		951	0	0	0	0	0	5,370	0	6,321	100.0
Xenopus	Yes		5,566	1,204	0	0	0	0	25	0	6,795	25.6
	No		9,515	1,507	8,160	0	337	0	279	0	19,798	74.4
	Total		15,081	2,711	8,160	0	337	0	304	0	26,593	100.0
Other amphibians	Yes		395	6	0	0	200	0	0	0	601	2.8
	No		10,121	0	0	0	2,412	6,644	1,484	0	20,661	97.2
	Total		10,516	6	0	0	2,612	6,644	1,484	0	21,262	100.0
Zebra fish	Yes		5,830	536	1,603	0	0	0	8	0	7,977	1.5
	No		367,758	107,722	32,779	0	6,868	0	2,066	0	517,193	98.5
	Total		373,588	108,258	34,382	0	6,868	0	2,074	0	525,170	100.0
Other fish	Yes		5,256	82	140	1,400	371	7	92	0	7,348	0.4
	No		675,059	849,104	102,680	0	204,946	207,044	3,506	0	2,042,339	99.6
	Total		680,315	849,186	102,820	1,400	205,317	207,051	3,598	0	2,049,687	100.0
Cephalopods	Yes		22	0	0	0	0	0	0	0	22	0.1
	No		1,025	15,728	0	0	208	0	7	0	16,968	99.9
	Total		1,047	15,728	0	0	208	0	7	0	16,990	100.0
All Species	Yes		59,354	26,385	40,181	57,585	5,729	452	17,405	0	207,091	2.0
	No		4,712,032	2,806,701	1,748,598	534,300	228,978	225,032	145,642	390	10,401,673	98.0
	Total		4,771,386	2,833,086	1,788,779	591,885	234,707	225,484	163,047	390	10,608,764	100.0

Table 15: Genetic status of animals used by species and main categories of scientific purposes (2019)

	Genetic status	Basic research	Translational and applied research	Regulatory use	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	Total	%
Mice	Not altered	1,335,922	955,387	771,289	123,726	863	1,838	61,612	272	3,250,909	58.9
	Non harmful	1,454,217	346,189	26,162	1,401	0	5,347	15,103	0	1,848,419	33.5
	Harmful	293,505	120,097	1,453	0	0	138	560	8	415,761	7.5
	Total	3,083,644	1,421,673	798,904	125,127	863	7,323	77,275	280	5,515,089	100.0
Rats	Not altered	258,057	190,847	464,792	6,815	610	54	40,576	73	961,824	96.9
	Non harmful	14,707	5,189	1,527	449	0	0	692	0	22,564	2.3
	Harmful	3,874	3,512	219	0	0	645	29	0	8,279	0.8
	Total	276,638	199,548	466,538	7,264	610	699	41,297	73	992,667	100.0
Guinea-Pigs	Not altered	3,965	8,158	101,953	9,051	11	0	2,157	0	125,295	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	3,965	8,158	101,953	9,051	11	0	2,157	0	125,295	100.0
Hamsters (Syrian)	Not altered	1,688	3,042	6,560	136	0	0	157	0	11,583	95.4
	Non harmful	162	0	0	0	0	0	0	0	162	1.3
	Harmful	0	391	0	0	0	0	0	0	391	3.2
	Total	1,850	3,433	6,560	136	0	0	157	0	12,136	100.0
Hamsters (Chinese)	Not altered	17	0	0	0	0	0	0	0	17	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	17	0	0	0	0	0	0	0	17	100.0
Mongolian gerbil	Not altered	1,928	1,876	171	83	0	0	53	0	4,111	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	1,928	1,876	171	83	0	0	53	0	4,111	100.0
Other rodents	Not altered	21,231	1,131	9,975	40	1,601	326	540	0	34,844	99.9
	Non harmful	41	0	0	0	0	0	0	0	41	0.1
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	21,272	1,131	9,975	40	1,601	326	540	0	34,885	100.0
Rabbits	Not altered	17,605	9,923	88,201	225,115	0	0	1,674	0	342,518	94.0
	Non harmful	95	103	0	21,649	0	0	0	0	21,847	6.0
	Harmful	35	0	0	0	0	0	0	0	35	0.0
	Total	17,735	10,026	88,201	246,764	0	0	1,674	0	364,400	100.0
Cats	Not altered	1,127	1,239	1,238	40	0	0	64	0	3,708	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	1,127	1,239	1,238	40	0	0	64	0	3,708	100.0
Dogs	Not altered	1,867	6,718	10,398	425	82	0	1,091	0	20,581	99.7
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	32	28	0	0	0	0	0	0	60	0.3
	Total	1,899	6,746	10,398	425	82	0	1,091	0	20,641	100.0
Ferrets	Not altered	240	1,142	417	59	0	0	61	0	1,919	99.5
	Non harmful	10	0	0	0	0	0	0	0	10	0.5
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	250	1,142	417	59	0	0	61	0	1,929	100.0
Other carnivores	Not altered	3,988	279	333	0	325	111	20	0	5,056	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	3,988	279	333	0	325	111	20	0	5,056	100.0
Horses, donkeys and cross-breeds	Not altered	1,825	986	171	8,227	1,647	54	489	0	13,399	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	1,825	986	171	8,227	1,647	54	489	0	13,399	100.0
Pigs	Not altered	19,798	39,791	11,920	289	935	9	13,681	2	86,425	99.2
	Non harmful	165	334	13	0	0	0	6	0	518	0.6
	Harmful	25	146	0	0	0	0	2	0	173	0.2
	Total	19,988	40,271	11,933	289	935	9	13,689	2	87,116	100.0
Goats	Not altered	1,443	401	68	150	2	0	308	0	2,372	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	1,443	401	68	150	2	0	308	0	2,372	100.0

	Genetic status	Basic research	Translational and applied research	Regulatory use	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	Total	%
Sheep	Not altered	12,037	7,315	1,258	47,389	3,481	0	1,461	33	72,974	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	12,037	7,315	1,258	47,389	3,481	0	1,461	33	72,974	100.0
Cattle	Not altered	9,878	14,238	2,999	106	1,759	0	6,379	2	35,361	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	9,878	14,238	2,999	106	1,759	0	6,379	2	35,361	100.0
Prosimians	Not altered	249	0	0	0	0	0	0	0	249	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	249	0	0	0	0	0	0	0	249	100.0
Marmoset and tamarins	Not altered	116	101	80	85	0	0	0	0	382	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	116	101	80	85	0	0	0	0	382	100.0
Cynomolgus monkey	Not altered	306	1,121	6,772	831	0	0	0	0	9,030	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	306	1,121	6,772	831	0	0	0	0	9,030	100.0
Rhesus monkey	Not altered	195	216	0	29	0	0	0	0	440	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	195	216	0	29	0	0	0	0	440	100.0
Vervets Chlorocebus spp	Not altered	0	25	0	11	0	0	0	0	36	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	0	25	0	11	0	0	0	0	36	100.0
Baboons	Not altered	0	33	0	0	0	0	0	0	33	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	0	33	0	0	0	0	0	0	33	100.0
Other species of old world monkeys (Cercopithecoidea)	Not altered	20	13	0	0	0	0	0	0	33	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	20	13	0	0	0	0	0	0	33	100.0
Other mammals	Not altered	4,538	597	0	31	168	268	185	0	5,787	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	4,538	597	0	31	168	268	185	0	5,787	100.0
Domestic fowl	Not altered	141,730	130,021	127,438	116,006	4,373	439	2,376	0	522,383	99.9
	Non harmful	392	0	0	0	0	0	0	0	392	0.1
	Harmful	25	0	0	0	0	0	0	0	25	0.0
	Total	142,147	130,021	127,438	116,006	4,373	439	2,376	0	522,800	100.0
Other birds	Not altered	75,252	6,600	8,010	28,342	3,508	1,936	894	0	124,542	100.0
	Non harmful	0	0	0	0	0	0	4	0	4	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	75,252	6,600	8,010	28,342	3,508	1,936	898	0	124,546	100.0
Reptiles	Not altered	7,581	8	0	0	0	624	36	0	8,249	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	7,581	8	0	0	0	624	36	0	8,249	100.0
Rana	Not altered	951	0	0	0	0	0	5,370	0	6,321	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	951	0	0	0	0	0	5,370	0	6,321	100.0
Xenopus	Not altered	12,038	2,205	8,160	0	337	0	304	0	23,044	86.7
	Non harmful	3,043	506	0	0	0	0	0	0	3,549	13.3
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	15,081	2,711	8,160	0	337	0	304	0	26,593	100.0
Other amphibians	Not altered	6,993	6	0	0	2,612	6,644	1,273	0	17,528	82.4
	Non harmful	3,523	0	0	0	0	0	211	0	3,734	17.6
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	10,516	6	0	0	2,612	6,644	1,484	0	21,262	100.0
Zebra fish	Not altered	111,814	52,013	34,092	0	2,982	0	1,878	0	202,779	38.6

	Genetic status	Basic research	Translational and applied research	Regulatory use	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	Total	%
	Non harmful	247,043	44,075	0	0	3,886	0	188	0	295,192	56.2
	Harmful	14,731	12,170	290	0	0	0	8	0	27,199	5.2
	Total	373,588	108,258	34,382	0	6,868	0	2,074	0	525,170	100.0
Other fish	Not altered	676,900	849,186	102,820	1,400	205,317	207,051	3,598	0	2,046,272	99.8
	Non harmful	3,232	0	0	0	0	0	0	0	3,232	0.2
	Harmful	183	0	0	0	0	0	0	0	183	0.0
	Total	680,315	849,186	102,820	1,400	205,317	207,051	3,598	0	2,049,687	100.0
Cephalopods	Not altered	1,047	15,728	0	0	208	0	7	0	16,990	100.0
	Non harmful	0	0	0	0	0	0	0	0	0	0.0
	Harmful	0	0	0	0	0	0	0	0	0	0.0
	Total	1,047	15,728	0	0	208	0	7	0	16,990	100.0
All Species	Harmful	312,410	136,344	1,962	0	0	783	599	8	452,106	4.3
	Non harmful	1,726,630	396,396	27,702	23,499	3,886	5,347	16,204	0	2,199,664	20.7
	Not altered	2,732,346	2,300,346	1,759,115	568,386	230,821	219,354	146,244	382	7,956,994	75.0
	Total	4,771,386	2,833,086	1,788,779	591,885	234,707	225,484	163,047	390	10,608,764	100.0

Part 3: Numbers and uses of animals for the creation and maintenance of genetically altered animals in the EU

Table 16: Use of animals for the creation of new genetically altered animal lines by research type species and severity (2019)

	Severity	Basic research	Translational and applied research	Total	%
Mice	Non-recovery	15,878	1,384	17,262	4.6
	Mild	266,780	13,949	280,729	75.5
	Moderate	61,064	8,393	69,457	18.7
	Severe	4,275	236	4,511	1.2
	Total	347,997	23,962	371,959	100.0
Rats	Non-recovery	21	9	30	0.8
	Mild	1,094	40	1,134	31.0
	Moderate	2,031	39	2,070	56.6
	Severe	421	0	421	11.5
	Total	3,567	88	3,655	100.0
Hamsters (Syrian)	Non-recovery	36	0	36	31.0
	Mild	80	0	80	69.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	116	0	116	100.0
Rabbits	Non-recovery	0	0	0	0.0
	Mild	21	168	189	62.0
	Moderate	16	100	116	38.0
	Severe	0	0	0	0.0
	Total	37	268	305	100.0
Pigs	Non-recovery	0	0	0	0.0
	Mild	145	34	179	66.5
	Moderate	19	60	79	29.4
	Severe	0	11	11	4.1
	Total	164	105	269	100.0
Sheep	Non-recovery	0	0	0	0.0
	Mild	32	0	32	78.0
	Moderate	9	0	9	22.0
	Severe	0	0	0	0.0
	Total	41	0	41	100.0
Cattle	Non-recovery	0	0	0	0.0
	Mild	1	0	1	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	1	0	1	100.0
Marmoset and tamarins	Non-recovery	0	0	0	0.0
	Mild	47	0	47	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	47	0	47	100.0
Other mammals	Non-recovery	8	0	8	61.5
	Mild	4	0	4	30.8
	Moderate	1	0	1	7.7
	Severe	0	0	0	0.0
	Total	13	0	13	100.0
Domestic fowl	Non-recovery	0	0	0	0.0
	Mild	1,000	54	1,054	90.4
	Moderate	67	45	112	9.6
	Severe	0	0	0	0.0
	Total	1,067	99	1,166	100.0
Other birds	Non-recovery	0	0	0	0.0
	Mild	10	0	10	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	10	0	10	100.0
Xenopus	Non-recovery	0	0	0	0.0
	Mild	1,787	0	1,787	100.0
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	1,787	0	1,787	100.0
Other amphibians	Non-recovery	15	0	15	5.5

	Severity	Basic research	Translational and applied research	Total	%
	Mild	256	0	256	94.5
	Moderate	0	0	0	0.0
	Severe	0	0	0	0.0
	Total	271	0	271	100.0
Zebra fish	Non-recovery	2,265	28	2,293	1.8
	Mild	101,514	2,821	104,335	81.2
	Moderate	21,606	0	21,606	16.8
	Severe	305	0	305	0.2
	Total	125,690	2,849	128,539	100.0
Other fish	Non-recovery	0	0	0	0.0
	Mild	3,163	0	3,163	99.8
	Moderate	1	0	1	0.0
	Severe	5	0	5	0.2
	Total	3,169	0	3,169	100.0
All Species	Non-recovery	18,223	1,421	19,644	3.8
	Mild	375,934	17,066	393,000	76.9
	Moderate	84,814	8,637	93,451	18.3
	Severe	5,006	247	5,253	1.0
	Total	483,977	27,371	511,348	100.0

Table 17: Use of animals for the creation of new genetically altered animal lines by research type species and severity (2019)

	Reuse	Basic research	Translational and applied research	Total	%
Mice	Yes	1,047	0	1,047	0.3
	No	346,950	23,962	370,912	99.7
	Total	347,997	23,962	371,959	100.0
Rats	Yes	0	0	0	0.0
	No	3,567	88	3,655	100.0
	Total	3,567	88	3,655	100.0
Hamsters (Syrian)	Yes	0	0	0	0.0
	No	116	0	116	100.0
	Total	116	0	116	100.0
Rabbits	Yes	0	0	0	0.0
	No	37	268	305	100.0
	Total	37	268	305	100.0
Pigs	Yes	0	4	4	1.5
	No	164	101	265	98.5
	Total	164	105	269	100.0
Sheep	Yes	0	0	0	0.0
	No	41	0	41	100.0
	Total	41	0	41	100.0
Cattle	Yes	0	0	0	0.0
	No	1	0	1	100.0
	Total	1	0	1	100.0
Marmoset and tamarins	Yes	4	0	4	8.5
	No	43	0	43	91.5
	Total	47	0	47	100.0
Other mammals	Yes	0	0	0	0.0
	No	13	0	13	100.0
	Total	13	0	13	100.0
Domestic fowl	Yes	0	0	0	0.0
	No	1,067	99	1,166	100.0
	Total	1,067	99	1,166	100.0
Other birds	Yes	0	0	0	0.0
	No	10	0	10	100.0
	Total	10	0	10	100.0
Xenopus	Yes	0	0	0	0.0
	No	1,787	0	1,787	100.0
	Total	1,787	0	1,787	100.0
Other amphibians	Yes	0	0	0	0.0
	No	271	0	271	100.0
	Total	271	0	271	100.0
Zebra fish	Yes	1,973	0	1,973	1.5
	No	123,717	2,849	126,566	98.5
	Total	125,690	2,849	128,539	100.0
Other fish	Yes	0	0	0	0.0
	No	3,169	0	3,169	100.0
	Total	3,169	0	3,169	100.0
All Species	Yes	3,024	4	3,028	0.6
	No	480,953	27,367	508,320	99.4
	Total	483,977	27,371	511,348	100.0

Table 18: Uses of animals for the creation of new genetically altered animal lines in basic research by species and type of research (2019)

	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	%
Mammals															
Rodents															
Mice	63,422	17,412	39,989	726	13,169	5,363	57,887	18,775	8,696	12,389	80,496	72	29,601	347,997	71.9
Rats	0	1,064	534	0	0	0	820	0	0	0	870	0	279	3,567	0.7
Hamsters (Syrian)	0	0	0	0	0	0	80	36	0	0	0	0	0	116	0
Rabbits															
Rabbits	0	16	0	0	0	0	0	21	0	0	0	0	0	37	0
Farm animals															
Pigs	0	19	0	38	0	0	107	0	0	0	0	0	0	164	0
Sheep	0	0	39	2	0	0	0	0	0	0	0	0	0	41	0
Cattle	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Non-human primates															
Marmoset and tamarins	0	0	0	0	0	0	0	32	0	0	15	0	0	47	0
Other mammals															
Other mammals	0	0	0	0	0	0	0	1	0	0	12	0	0	13	0
Birds															
Domestic fowl	45	0	0	0	0	0	274	301	0	0	447	0	0	1,067	0.2
Other birds	0	0	0	0	0	0	0	0	0	0	0	10	0	10	0
Amphibians															
Xenopus	0	0	89	0	0	0	0	1,665	0	0	26	0	7	1,787	0.4
Other amphibians	0	0	0	0	0	0	0	0	0	0	0	0	271	271	0.1
Fish															
Zebra fish	5,381	32,067	44,500	0	3,129	3,892	6,917	2,253	3,901	2,982	11,477	1,792	7,399	125,690	26
Other fish	0	50	32	0	0	0	0	400	1,379	0	1,108	0	200	3,169	0.7
Totals															
Total	68,848	50,629	85,183	766	16,298	9,255	66,085	23,484	13,976	15,371	94,451	1,874	37,757	483,977	100
%	14.2	10.5	17.6	0.2	3.4	1.9	13.7	4.9	2.9	3.2	19.5	0.4	7.8	100	

Table 19.1: Uses of animals for the creation of new genetically altered animal lines in basic, translational and applied research by species and type of research (Part 1) (2019)

	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
Mammals								
Rodents								
Mice	9,567	84	923	2,533	116	344	171	1,029
Rats	11	0	0	0	28	11	38	0
Rabbits								
Rabbits	0	0	0	0	0	0	0	0
Farm animals								
Pigs	39	0	21	0	0	0	8	0
Birds								
Domestic fowl	0	0	0	0	0	0	0	0
Fish								
Zebra fish	0	1,363	900	0	0	0	0	0
Totals								
Total	9,617	1,447	1,844	2,533	144	355	217	1,029
%	35.2	5.3	6.7	9.3	0.5	1.3	0.8	3.8

Table 19.2: Uses of animals for the creation of new genetically altered animal lines in basic translational and applied research by species and type of research (Part 2) (2019)

	Human Urogenital/Reproductive Disorders	Human Sensory Organ Disorders (skin, eyes and ears)	Human Endocrine/Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Diagnosis of diseases	Non-regulatory toxicology and ecotoxicology	Total	%
Mammals									
Rodents									
Mice	137	274	2,319	2,978	3,467	20	0	23,962	87.5
Rats	0	0	0	0	0	0	0	88	0.3
Rabbits									
Rabbits	0	0	268	0	0	0	0	268	1
Farm animals									
Pigs	0	17	20	0	0	0	0	105	0.4
Birds									
Domestic fowl	0	0	0	0	99	0	0	99	0.4
Fish									
Zebra fish	0	443	75	40	0	0	28	2,849	10.4
Totals									
Total	137	734	2,682	3,018	3,566	20	28	27,371	100
%	0.5	2.7	9.8	11	13	0.1	0.1	100	

Table 20: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, severity and genetic status (2019)

	Severity	Genetically altered with a harmful phenotype	Genetically altered without a harmful phenotype	Not genetically altered	Total	%
Mice	Non-recovery	133	417	178	728	0.1
	Mild	53,951	431,416	24,833	510,200	82.3
	Moderate	27,297	25,972	8,123	61,392	9.9
	Severe	24,463	23,229	87	47,779	7.7
	Total	105,844	481,034	33,221	620,099	100.0
Rats	Non-recovery	0	0	0	0	0.0
	Mild	1,201	5,196	285	6,682	69.4
	Moderate	583	830	732	2,145	22.3
	Severe	671	129	0	800	8.3
Total	2,455	6,155	1,017	9,627	100.0	
Dogs	Non-recovery	0	0	0	0	0.0
	Mild	0	0	0	0	0.0
	Moderate	0	0	0	0	0.0
	Severe	10	0	0	10	100.0
	Total	10	0	0	10	100.0
Domestic fowl	Non-recovery	0	0	0	0	0.0
	Mild	0	133	229	362	89.4
	Moderate	21	0	0	21	5.2
	Severe	22	0	0	22	5.4
	Total	43	133	229	405	100.0
Xenopus	Non-recovery	0	0	0	0	0.0
	Mild	0	212	143	355	98.6
	Moderate	0	0	3	3	0.8
	Severe	0	1	1	2	0.6
	Total	0	213	147	360	100.0
Zebra fish	Non-recovery	0	146	479	625	0.8
	Mild	2,973	56,425	2,794	62,192	82.6
	Moderate	3,539	7,501	0	11,040	14.7
	Severe	369	1,017	19	1,405	1.9
	Total	6,881	65,089	3,292	75,262	100.0
Other fish	Non-recovery	0	0	0	0	0.0
	Mild	0	1,140	0	1,140	62.9
	Moderate	0	671	0	671	37.1
	Severe	0	0	0	0	0.0
	Total	0	1,811	0	1,811	100.0
All Species	Non-recovery	133	563	657	1,353	0.2
	Mild	58,125	494,522	28,284	580,931	82.1
	Moderate	31,440	34,974	8,858	75,272	10.6
	Severe	25,535	24,376	107	50,018	7.1
	Total	115,233	554,435	37,906	707,574	100.0

Table 21: Uses of animals for the maintenance of colonies of established genetically altered animal lines by species, reuse and genetic status (2019)

		Reuse	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	%
Mice	Yes		0	6,177	0	6,177	1.0
	No		33,221	474,857	105,844	613,922	99.0
	Total		33,221	481,034	105,844	620,099	100.0
Rats	Yes		0	0	0	0	0.0
	No		1,017	6,155	2,455	9,627	100.0
	Total		1,017	6,155	2,455	9,627	100.0
Dogs	Yes		0	0	0	0	0.0
	No		0	0	10	10	100.0
	Total		0	0	10	10	100.0
Domestic fowl	Yes		0	0	0	0	0.0
	No		229	133	43	405	100.0
	Total		229	133	43	405	100.0
Xenopus	Yes		136	35	0	171	47.5
	No		11	178	0	189	52.5
	Total		147	213	0	360	100.0
Zebra fish	Yes		132	1,081	28	1,241	1.6
	No		3,160	64,008	6,853	74,021	98.4
	Total		3,292	65,089	6,881	75,262	100.0
Other fish	Yes		0	0	0	0	0.0
	No		0	1,811	0	1,811	100.0
	Total		0	1,811	0	1,811	100.0
All Species	Yes		268	7,293	28	7,589	1.1
	No		37,638	547,142	115,205	699,985	98.9
	Total		37,906	554,435	115,233	707,574	100.0