Home Office

Annual Statistics of Scientific Procedures on Living Animals Great Britain 2022

HC 1540

Home Office

Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022

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Protected animals: Any living vertebrate, other than man, that has been born and any fish, amphibian or cephalopod once they become capable of independent feeding. Mammal, bird and reptile embryos after two-thirds of gestation or incubation period are protected but not counted in this publication.

Regulated procedures: Any procedure applied to a protected animal for an experimental or other scientific purpose, or for an educational purpose, that may have the effect of causing an animal 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.

'Number of procedures' is not 'number of animals': The number of procedures carried out in a year does not equal the number of animals that have been used in procedures that year. This is because some animals may be used more than once i.e. 're-used', in certain circumstances. These instances are counted as separate, additional, procedures. As a result, the number of procedures is usually slightly higher than the number of animals used.

Key results

- **2.76 million scientific procedures** involving living animals were carried out in Great Britain in 2022. This is a decrease of 10% on last year and lowest number since 2002
- **experimental procedures** have **decreased by 12%** and procedures for **creation and breeding** have **decreased by 6%** since 2021
- **experimental procedures made up 55% of all procedures in 2022**
- **the majority (96%) of procedures (both for experimental and breeding purposes) used mice, fish, birds or rats.** These species have been the most used for more than a decade
- **procedures on specially protected species (cats, dogs, horses and non-human primates) accounted for use in 0.97% of experimental procedures** in

2022. No specially protected species were used in procedures counted under creation and breeding of GA animals

Experimental procedures

These procedures involve using animals in scientific studies for purposes such as: basic research and the development of treatments, safety testing of pharmaceuticals and other substances, specific surgical training and education, environmental research and species protection.

- **1.51 million** procedures carried out for experimental purposes (55% of all procedures in 2022)
- **59%** of procedures used mice
- **14%** of procedures used fish
- **12%** of procedures used rats
- **8.9%** of procedures used birds
- **0.97%** of procedures used specially protected species (cats, dogs, horses and non-human primates)
- **5.35%** of procedures used other species
- **around half (53%) of experimental procedures were for basic research.** The top three research areas were the nervous system, the immune system and cancer (oncology)
- **96%** of all experimental procedures were assessed as **non-recovery, sub-threshold, mild, or moderate** in severity. The remaining 4% were assessed as **severe**

Creation and breeding of genetically altered animals

This refers to the breeding of animals whose genes have mutated or have been modified. These animals are used to produce GA offspring for use in experimental procedures but are not themselves used in experimental procedures.

- **1.25 million** procedures carried out for the creation and breeding of GA animals (45% of all procedures in 2022)
- **86%** were for the creation and breeding of mice
- **13%** were for the creation and breeding of fish
- **0.6%**, were for the creation and breeding of rats and birds
- **the majority (89%) of procedures in this category were for maintenance of already established GA lines**, with 11% of procedures for the creation of new lines

- **99%** of all procedures for creation and breeding were assessed as **non-recovery, sub-threshold, mild, or moderate** in severity. **1%** were assessed as **severe**

Introduction

Purpose of this release

This publication meets the requirements of section 2 of the 1986 Act to publish, and lay before Parliament, annual statistics on the use of **protected animals** in **regulated procedures**.

Coverage of this release

These statistics cover England, Scotland, and Wales. For Northern Ireland, the Department of Health separately collects and publishes information on NI regulated procedures under devolved arrangements.

'Number of procedures' is not 'number of animals'

The statistics in this release and the accompanying data tables relate to the number of procedures, not the number of animals used, unless specified (i.e. data tables 1.3, 2.1, 2.2 and 2.3 relate to the number of animals).

Severity of procedures

These statistics describe the nature and purpose of procedures including their actual severity. The experience of the animal at the time of death or killing is a factor in determining the actual severity and therefore the killing or death of animals is not reported separately. Further information regarding actual severity can be found here: Advisory notes on actual severity reporting(publishing.service.gov.uk)

Accompanying data tables and user guide

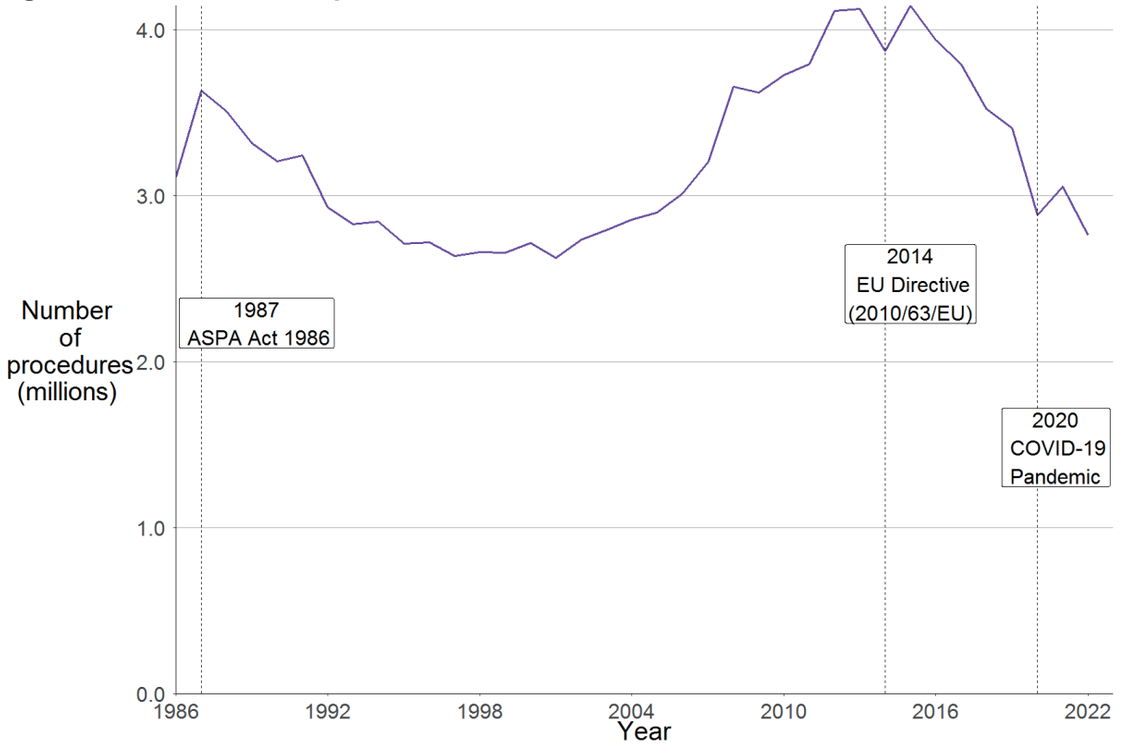
The accompanying data tables for this report can be found on the statistics of scientific procedures webpage. Since the 2018 publication, the principal data tables have been expanded to include data from 2014. To allow users to view and extract the data as they wish. Since the 2021 publication, tables 1.1 and 1.2 have been expanded to include country data from 2014. The tables that have been expanded include data from 2014 as not all data pre-2014 are comparable. See the accompanying user guide for further information.

Glossary

A full glossary of terms is available at the end of this publication.

Total procedures

Figure 1. Total scientific procedures in Great Britain, 1986 to 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 1.1. See the user guide for links to all data pre-2007.

As shown in Figure 1, the number of procedures carried out decreased from 1987 until 2001, to a low of 2.62 million. This was mainly due to a reduction in the use of rodents, rabbits and birds (although there was an increase in procedures involving fish). After 2001, procedures increased, reaching a peak of 4.14 million in 2015 and then started to decrease again to 2.88 million in 2020. This may be partly explained by national lockdowns in response to the COVID-19 pandemic, which may have affected the activity of the establishments. In 2021 there was an increase to 3.06 million.

In 2022 there was a decrease in procedures to 2.76 million - this is the lowest figure since 2002. See the Further information section for more details.

The number of procedures in England and Scotland fell by 10% and 7% respectively in the last year. The number of procedures undertaken in establishments in Wales increased by 1% compared with 2021. A similar trend to Great Britain is seen in the number of procedures for England and Scotland. England's number of procedures peaks at 3.51 million in 2015 and is lowest at 2.32 million in 2022. Scotland's peak was 573,000 in 2015 and low was 396,000 procedures in 2020. Whilst Wales also peaked in

2015 at 55,000 procedures, the number of procedures decreased to a low of 39,000 in 2021.

The number of procedures carried out on living animals is determined by several factors, including the focus of scientific and medical endeavours, the economic climate and global trends in new technologies or fields of research.

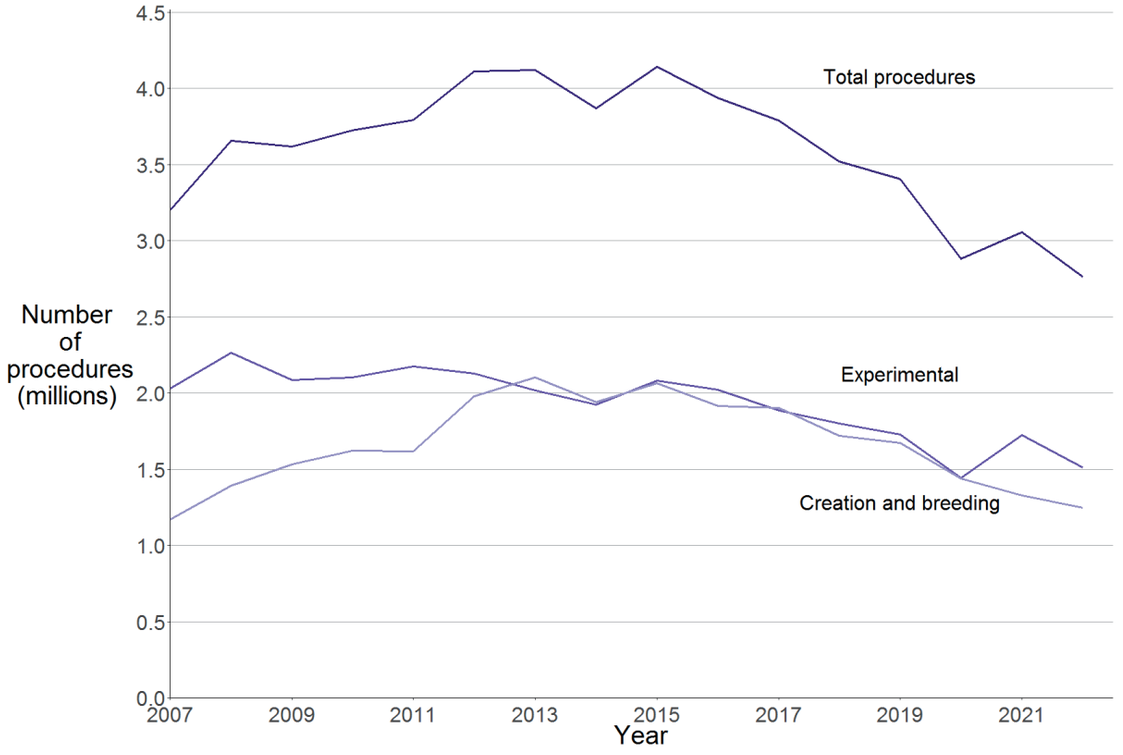
Prior to 1986, figures were recorded for the number of ‘experiments’ on living animals, under the Cruelty to Animals Act 1876. In 1986, the Animals (Scientific Procedures) Act was introduced, and required all ‘scientific procedures’ to be recorded. This new, broader term largely explains the initial increase in figures directly after 1986.

At the beginning of 2013, EU Directive 2010/63/EU came into effect, and as a result changed the way in which the data was collected under UK law from 2014 onwards. All figures for procedures (1986 onwards) are comparable, as the definition of a procedure is unchanged. As a result of the change in methodology, the 2014 data is subject to data quality issues (see the user guide for further information).

Experimental procedures involve using animals in scientific studies for purposes such as: basic research and the development of treatments, safety testing of pharmaceuticals and other substances, education, specific surgical training and education, environmental research and species protection.

Procedures for creation and breeding involve the breeding of animals whose genes have mutated or have been modified. These animals are used to produce genetically altered offspring for use in experimental procedures but are not themselves used in experimental procedures.

Figure 2. Total scientific procedures by type, 2007 to 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 1.2 and Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2017: time series tables, Table 1

As shown in Figure 2, the total number of procedures was rising prior to 2013, mainly due to the increase in procedures for the creation and breeding of GA animals. This increase in the earlier part of the decade can mainly be attributed to the availability of new technology which led to new research opportunities. However, more recently, the number of procedures for the creation and breeding of GA animals has been falling, with a decrease of 6% compared with last year.

In contrast, the number of experimental procedures remained relatively stable during the earlier part of the last decade but has decreased since 2015 similarly to procedures for creation and breeding of GA animals. This year there has been a decrease of 12% in experimental procedures compared with 2021.

Experimental procedures

The severity of a procedure is determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of a procedure. In 2022, **96%** of all experimental procedures were assessed as **non-recovery, sub-threshold, mild, or moderate** in severity, the remainder were **severe**.

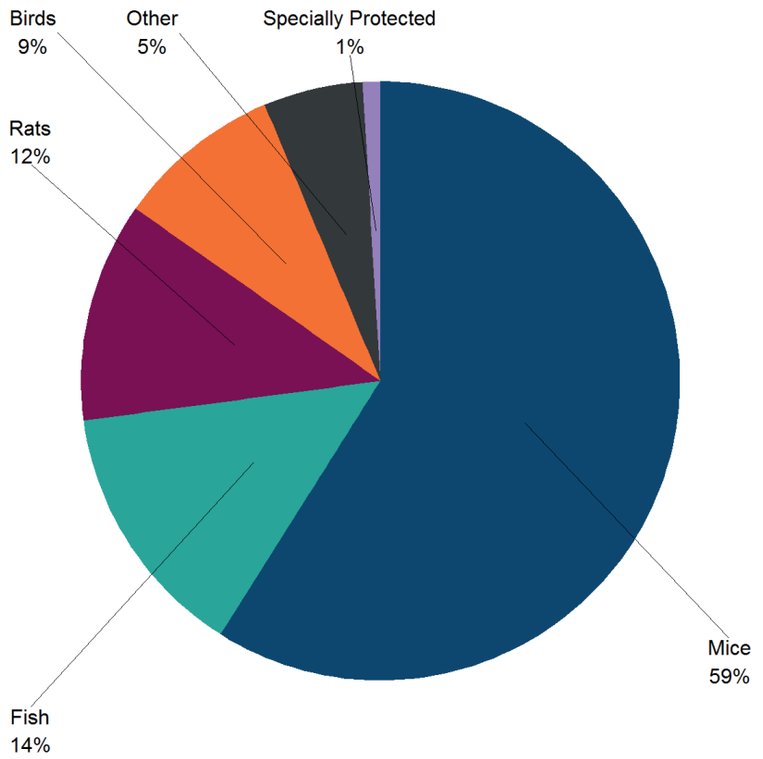
This section covers only experimental procedures. That is, procedures that involve using animals in scientific studies for purposes such as: basic biological research, medical studies and development of treatments, training and education, environmental research, preservation of species, and safety testing of pharmaceuticals and other substances. An experimental procedure may benefit people, animals, or the environment for any of the purposes stated above. The animals used in experimental procedures may be genetically altered.

Species

The proportions of species used for experimental procedures as shown in Figure 3, had remained similar from 2014 to 2022. From 2021 to 2022, the proportion of mice has increased from 54% to 59% and rats has increased from 11% to 12%. The proportion of fish and birds have decreased from 15% to 14% and 14% to 9% respectively from 2021 to 2022.

For most species, small year-on-year variations can be attributed to technological developments and changes in the types and stages of individual projects being carried out in any reporting year.

Figure 3. Experimental procedures by species, 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 1.2

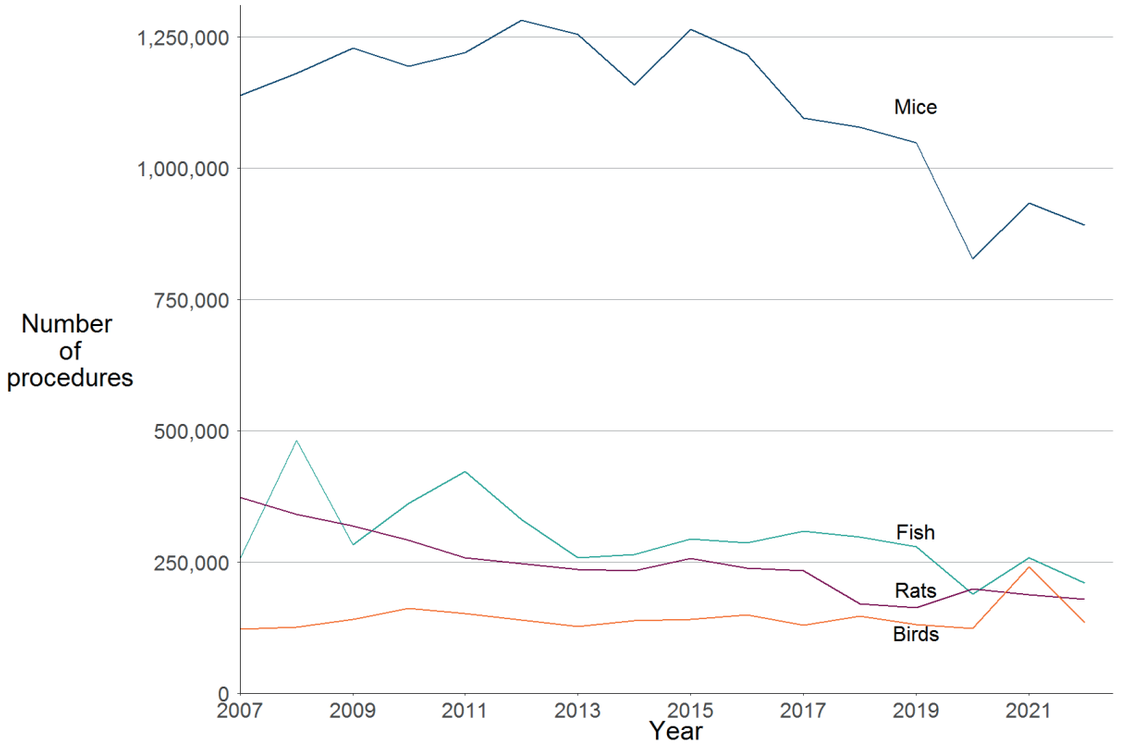
Notes: Specially protected species are cats, dogs, horses and primates.

Mice, fish, rats and birds in experimental procedures

The majority of experimental procedures used mice, fish, birds or rats; together these species were used in 94% of experimental procedures in 2022.

The Other category contains all other protected animals, including amphibians, cattle and reptiles.

Figure 4. Experimental procedures using mice, fish, birds and rats, 2007 to 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022 data tables: Table 1.2 and Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2017: time series tables, Table 2.2

As shown in Figure 4, there were decreases in the number of procedures using rats, mice, fish and birds (decreasing by 4%, 4%, 19% and 44% respectively)

In 2022, around two thirds of experimental procedures involving rats (69%) were for regulatory testing (e.g. tests evaluating the safety and efficacy of substances such as pharmaceuticals).

Around two thirds of experimental procedures involving mice in 2022 (68%) were for basic research. More specifically, the basic research areas of the immune system and the nervous system had the most mouse procedures.

Around two thirds of experimental procedures involving fish in 2022 (66%) were also for basic research. More specifically, the basic research areas of the nervous system and the developmental research had the most fish procedures.

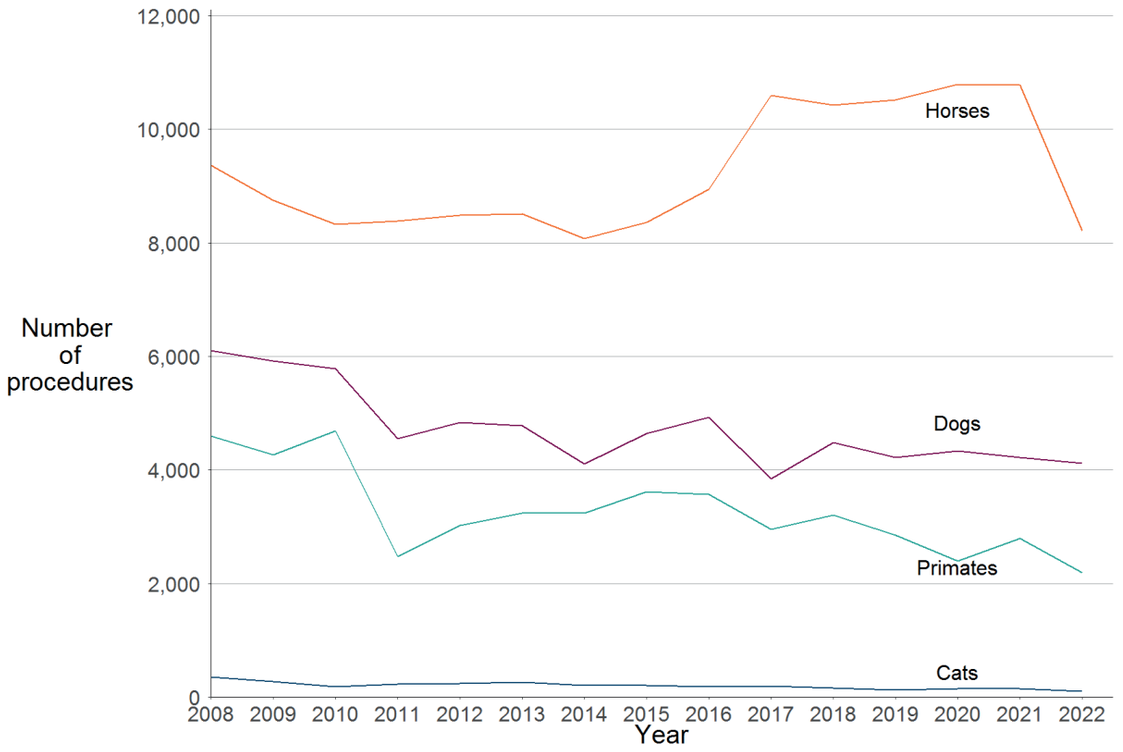
The majority of experimental procedures involving birds in 2022 (86%) were for applied research. More specifically, the applied research area of animal diseases and disorders had the most bird procedures.

Specially protected species in experimental procedures

Specially protected species refers to cats, dogs, horses, and non-human primates. These species were used in 0.97% of experimental procedures (~15,000) in 2022.

Cats, dogs, horses and primates are subject to additional protection under Section 5C of the 1986 Act. Licence holders using specially protected species must demonstrate that no other species are suitable for the purposes of the licence and must adhere to additional licence conditions.

Figure 5. Experimental procedures involving specially protected species, 2008 to 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022 data tables: Table 1.2 and Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2017: time series tables, Table 2.2.

The total number of procedures involving specially protected species has decreased over the past decade from around 17,000 in 2012 to around 15,000 in 2022.

The number of procedures involving horses had been decreasing from 2010 to 2014, with an increase in procedures between 2015 to 2017. From 2017 to 2021 the numbers remained relatively steady. This year there was a decrease of 23.8% in procedures compared with 2021. In 2022, the majority (71%) of experimental procedures that used horses were for regulatory procedures. The main regulatory procedure carried out on horses was for the routine production of blood-based products, which are used for a variety of diagnostic purposes.

The number of experimental procedures that used cats have decreased by 34% on last year. There were 102 experimental procedures that used cats in 2022, all of which were for basic research.

The species of primates that were used in experimental procedures in 2022 were cynomolgus monkeys (2,024 procedures), rhesus monkeys (101 procedures) and marmosets and tamarins (72 procedures). The total number of procedures (2,197 procedures) have decreased by 21% on last year to the lowest level since 2008. Rhesus and cynomolgus monkeys were used in regulatory procedures.

In 2022, the use of dogs in procedures decreased by 2%. There were 4,122 procedures that used dogs in 2022, mainly for regulatory procedures.

In 2022, the majority of experimental procedures that used primates and dogs were for regulatory procedures (86% and 70% respectively). These were mainly for testing the safety of products and devices for human medicine, dentistry and veterinary medicine.

Note: the figures in this section do not follow the rounding conventions as stated in the user guide.

Use of endangered species

Information was collected on whether any endangered species, as listed in Annex A of Council Regulation (EC) No 338/97, were used.

One endangered species was used in 2022, the Rock Dove (Columba livia), which was used for research for the research of the conservation of the species and the protection of the natural environment in the interests of the health or welfare of human beings or animals.

Place of birth of primates

Self-sustaining Colony

Marmosets, Tamarins, and other new-world primates A self-sustaining colony is a colony that contains no wild caught animals. Is kept in a way that ensures animals are used to humans and is sustained using animals from within or from other self-sustaining colonies.

Macaques and other old-world primates A self-sustaining colony is a colony that no longer sources animals from the wild (it may contain some existing wild caught animals) and is sustained using only captive bred animals.

Generation

f0 - wild caught

f1 - progeny of wild caught females

f2 - progeny of captive bred females

Of the 1,820 primates used for the first time in experimental procedures in 2022, all marmosets, tamarins and rhesus monkeys were born in the UK at a licensed establishment, whereas 97% of cynomolgus monkeys were born in either Africa or Asia. All primates used for the first time in experimental procedures in 2022, were from self-sustaining colonies.

The place of birth of primates used in experimental procedures for the first time can be found in Table 2.2 of the data tables. The place of birth of all other species used in experimental procedures for the first time in each year since 2014 can be found in Table 2.1 of the data tables.

Of the 1,820 primates used for the first time in experimental procedures in 2022, 541 (30%) were f1 generation and 1279 (70%) were f2 generation or greater. There were no f0 generation primates in 2022.

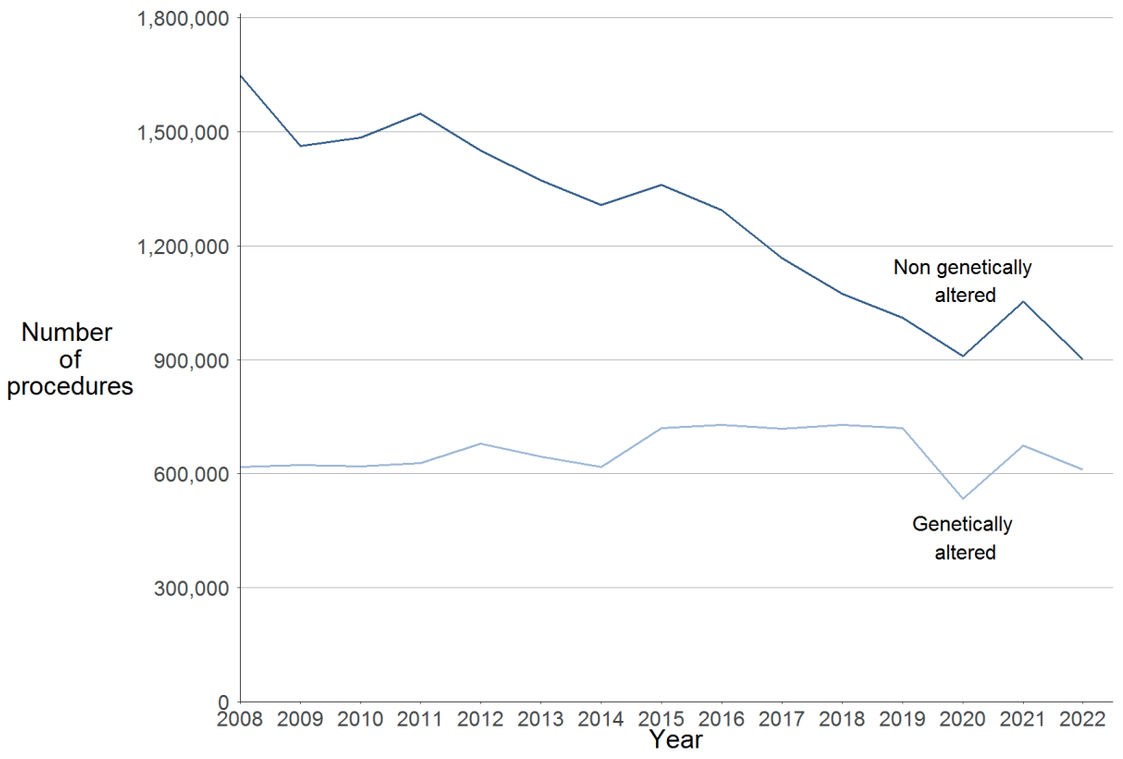
This publication uses definitions consistent with previous releases. In 2022, 'Ad hoc data on non-human primates used in experimental procedures for the first time' was published to provide assurance on the data used for non-human primates. These ad hoc statistics were produced following the Animal in Science Committee's report on non-human primates bred for use in scientific purposes which proposed alternate definitions for colony status and generation. These alternate definitions would classify some colonies as non self-sustaining due to containing wild old world primates even if new animals are no longer sourced from the wild and had not been for many years. Future change to the definitions used in annual data collection is under review.

Note: the figures on place of birth of primates do not follow the rounding conventions as stated in the user guide to provide additional detail.

Genetic status

Of the 1.51 million experimental procedures completed in 2022, 60% used animals that were not genetically altered.

Figure 6. Experimental procedures by genetic status, 2008 to 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 4 and Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2017: time series tables, Table 3.2

As shown in Figure 6, and in line with the overall decrease in experimental procedures in 2022, the number of experimental procedures involving non-GA animals has decreased by 14% in the last year and decreased by 38% over the last decade.

The use of GA animals was relatively stable from 2015 until 2019, before a decrease of 26% in 2020 which may be related to national lockdowns in response to the COVID-19 pandemic. In 2021 there was an increase, though still below the 2015-2019 level. In 2022 there was a 9% decrease.

Further information regarding the genetic status of GA animals used in experimental procedures in 2022 can be found in Table 4 of the data tables.

Purpose

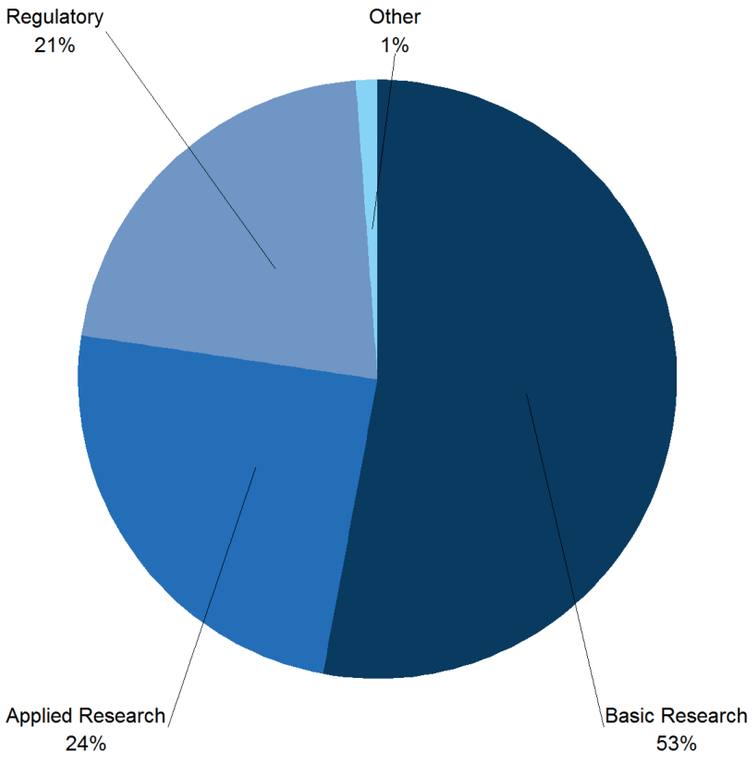
Basic research: aims to expand our knowledge of the structure, functioning and behaviour of living organisms and the environment.

Applied research: attempts to address diseases through prevention and development of treatments. Within the data tables, this is shown as 'Translational/Applied research'.

Regulatory testing: procedures carried out to satisfy legal requirements, including: ensuring substances are produced to legal specification; evaluating the safety or effectiveness of pharmaceuticals and other substances.

As shown in Figure 7, around half (53%) of the experimental procedures carried out in 2022 were for basic research. A further 24% for applied research and 21% conducted for regulatory testing purposes. Other (1%) includes experimental procedures carried out for higher education or training, preservation of species and for the protection of the natural environment.

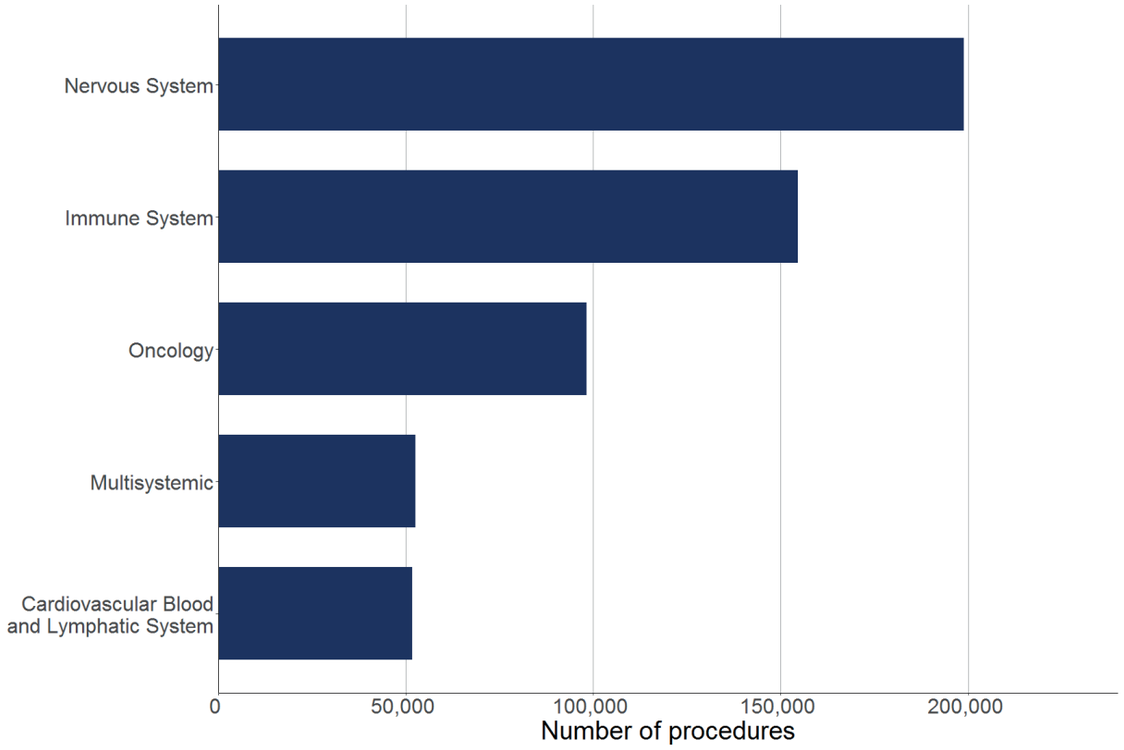
Figure 7. Experimental procedures by purpose, 2022



Basic Research

In 2022, ~800,000 experimental procedures were carried out for basic research purposes. The most common research areas, as shown in Figure 8, were: the nervous system (25%), immune system (19%) and oncology (12%).

Figure 8. Most common areas of focus in basic research in experimental procedures, 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 5

Notes: Research is classified as multisystemic when numerous body organs and systems are targeted.

The distribution of purposes for basic research has remained mostly similar since 2014. Studies into the immune system, the functioning and disease of the nervous system and cancer, including its development and control mechanisms (oncology) have been reported within the top five most common areas for basic research in each year since 2014.

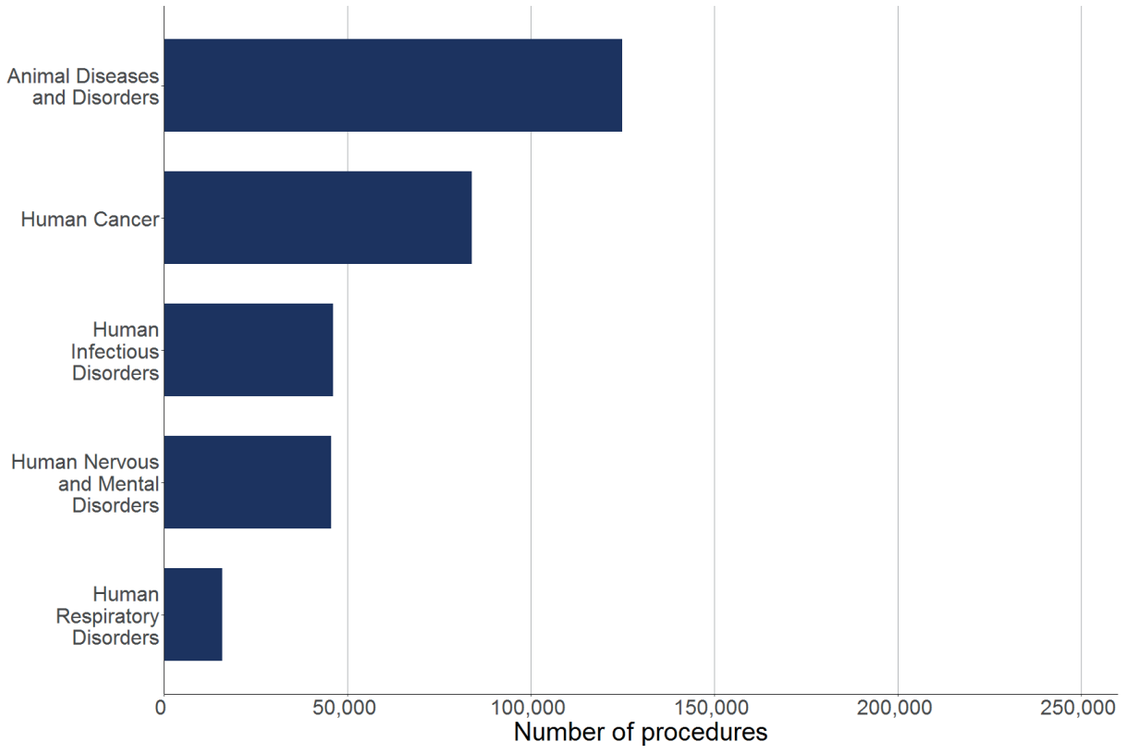
For data on all purposes for basic research by species, see Table 5 of the data tables.

Applied research

There were ~369,000 experimental procedures for applied research (24% of all experimental procedures) in 2022. Applied research attempts to address diseases through prevention and development of treatments, as shown in Figure 9. The most common areas of research were animal diseases and disorders (34%), human cancer (23%), and human infectious disorders and human nervous and mental disorders (12%).

The majority of procedures for animal diseases and disorders are conducted on fowl (91%). Almost all (99%) experimental procedures for applied research focusing on human cancer used mice; the remaining 1% of procedures involved rats and pigs.

Figure 9. Most common areas focused upon in experimental procedures for applied research, 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 6

Since 2014, human cancer, infectious disorders, and nervous and mental disorders have consistently been within the top five most common areas of applied research in each year.

For data on all purposes for applied research by species, see Table 6 of the data tables.

Regulatory

There were ~325,000 procedures carried out for regulatory purposes in 2022 (21% of all experimental procedures). Regulatory procedures are carried out to satisfy the legal requirements necessary to enable materials, products, and devices to be licensed for use. Regulatory procedures are usually carried out during the final stages of research and development and focuses on safety and efficacy. The most common procedure in 2022 was toxicity and other safety testing (55%).

Of the ~325,000 regulatory procedures in 2022, the most common legislative requirements were legislation on medicinal products for human use (45%) and veterinary use (26%). No procedures were carried out for cosmetics testing.

The majority (94%) of regulatory procedures were undertaken to satisfy UK and/or EU legislation.

Routine production: covers studies carried out for manufacturing processes requiring regulatory approval.

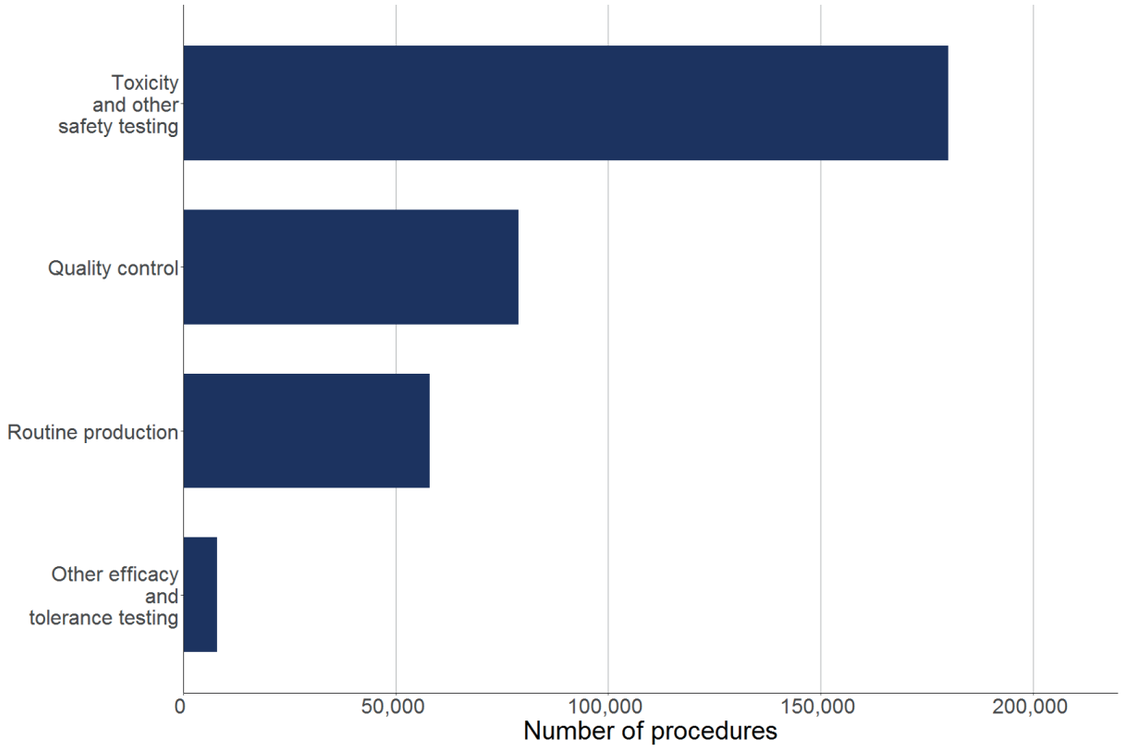
Toxicity and other safety testing: studies for safety evaluation of products and devices for human medicine, dentistry, veterinary medicine and other chemicals.

Quality control: the testing of quality control parameters of a product, and any controls carried out during the manufacturing process for registration purposes, to satisfy any other national or international requirements or to satisfy the in-house policy of the manufacturer.

Other efficacy and tolerance testing: efficacy testing of biocides and pesticides is covered under this category as well as the tolerance testing of additives in animal nutrition.

Figure 10 shows the proportion of each purpose of regulatory procedures carried out in 2022. With **toxicity and other safety testing**, **quality control** and **routine production** accounting for 55%, 24% and 18% respectively.

Figure 10. Experimental procedures for regulatory purposes by sub-purpose, 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 7.1

The most common species used in regulatory procedures were rats (38%; ~124,000). Of which, 99% were for toxicity and other safety testing including pharmacology. In contrast to their predominant use in experimental procedures for basic research and applied research, mice were used in around a third (33%) of all regulatory procedures, although they were still the second most commonly used species.

Cosmetic testing

Animal testing for consumer safety of cosmetics and their ingredients have been banned in the UK since 1998. Under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation, regulated procedures on animals to test chemicals that may be used as ingredients in cosmetics has been required as a last resort for worker and environmental safety. These procedures are recorded under the purpose of “Toxicity and other safety testing”, which also includes safety evaluation of products and devices for human medicine, dentistry, veterinary medicine and other chemicals.

The Government announced in May 2023 that no new licences will be issued for animal testing of chemicals used exclusively as cosmetic ingredients. The Government is engaging with holders of legacy licenses.

The Home Secretary issued a Written Ministerial Statement to members of Parliament which contains further details.

Techniques of special interest

Information was collected on whether any procedures were related to techniques of interest to the Home Office (i.e. areas related to Home Office policies). The areas of interest include testing of alcohol, tobacco, and household products.

In 2022, there were no experimental procedures involving the testing of household product ingredients.

There were no experimental procedures which involved the testing of products containing alcohol or tobacco.

An additional area of interest is ascites methods of monoclonal antibody production because a non-animal alternative exists. No ascites methods of monoclonal antibody production were used in 2022.

Note: these figures do not follow the rounding conventions as stated in the user guide.

Rodenticide trials

Rodenticides are a category of pest control chemicals intended to kill rodents. Rodenticide trials are field trials of such chemicals and are occasionally undertaken by commercial companies that produce them to assess how safe and effective they are when used.

Of the 2,913 returns, 2 reported that rodenticide trials occurred in 2022. Home Office ask data suppliers only to indicate whether field trials of rodenticide substances occurred, as these trials can be conducted in semi-field situations where the number of animals is not accurately known as the colonies are not intensively managed.

Severity

The severity (i.e. pain, distress or suffering) experienced by animals in procedures has been recorded since 2014. There are five severity assessments:

Sub-threshold: When a procedure was authorised under a project licence but did not actually cause suffering above the threshold of regulation, i.e. was less than the level of pain, suffering, distress or lasting harm that is caused by inserting a hypodermic needle according to good veterinary practice.

Non-recovery (under general anaesthesia): When the entire procedure was carried out under general anaesthesia from which the animal shall not recover consciousness. It includes unintended death of animals on recovery protocols while under anaesthesia,

provided that no regulated procedure had been carried out prior to the induction of anaesthesia.

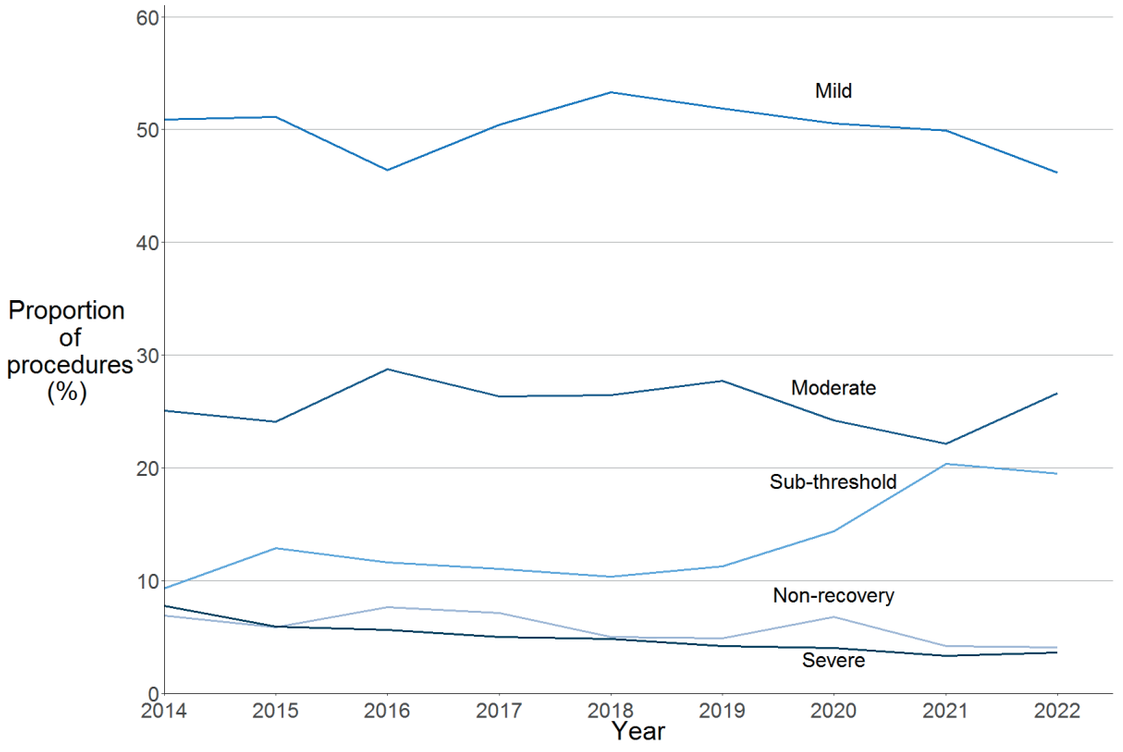
Mild: Any pain or suffering experienced by an animal was, at worst, only slight or transitory and minor so that the animal returns to its normal state within a short period of time.

Moderate: The procedure caused a significant and easily detectable disturbance to an animal's normal state, but this was not life threatening. Most surgical procedures carried out under general anaesthesia and with good post-operative analgesia (i.e. pain relief) would be classed as moderate.

Severe: The procedure caused a major departure from the animal's usual state of health and well-being. This would usually include long-term disease processes where assistance with normal activities such as feeding and drinking were required, or where significant deficits in behaviours/activities persist. It includes animals found dead unless an informed decision can be made that the animal did not suffer severely prior to death.

Severity assessments measure harms to an animal during a procedure and generally reflect the peak or cumulative severity of the entire procedure; they do not include harms caused to animals as a result of non-procedural events such as transport and housing.

Figure 11. Experimental procedures by severity, 2014 to 2022

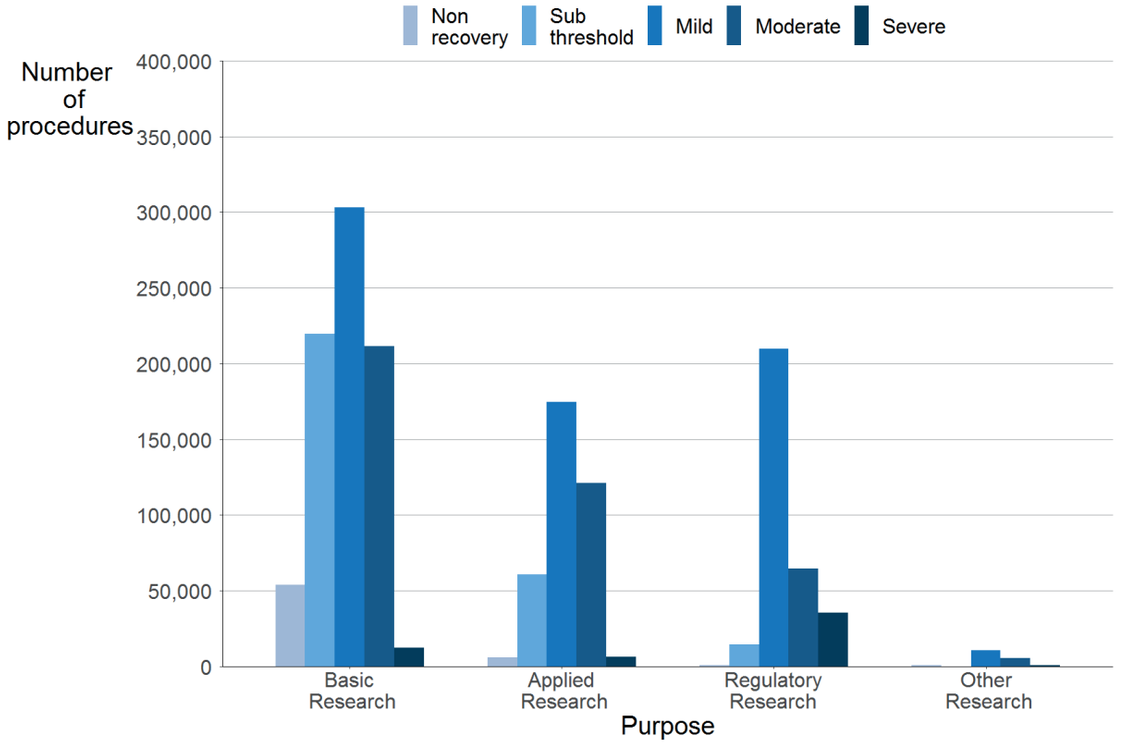


Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 3.1

The proportions of severity assessments for procedures reported were relatively similar from 2014 to 2019 as shown in Figure 11. From 2019 to 2021 the proportion of procedures with a moderate severity decreased to 22%, before increasing in 2022 to 27%. Almost half (46%) of experimental procedures in 2022 were mild. The proportion of non-recovery remained and sub-threshold severity assessments for procedures have remained at 4% and 20% respectively since last year. The proportion of severe increased slightly from 3.4% to 3.6% in 2022.

The severity assessment of experimental procedures varies according to the purpose. However, as shown in Figure 12, the most common severity assessment was mild for each purpose of experimental procedure.

Figure 12. Experimental procedures by severity and purpose, 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 3.1

Neuromuscular blocking agents and anaesthesia

Neuromuscular blocking agents (NMBA) are used for muscle relaxation during some types of experimental procedure such as nerve stimulation under anaesthesia. NMBAs

may be used only when given the authority to do so and with an appropriate level of anaesthesia and/or analgesia as determined in the project license.

The use of NMBA was recorded in 17 of the 2,913 returns. Of these, 16 returns reported that use of NMBA was whilst the animal was under general anaesthesia. The single return that reported the use of NMBA whilst the animal was not under general anaesthesia involved fish larvae.

Creation and breeding of genetically altered animals

This section covers only procedures performed for the purpose of creation and breeding of GA animals. That is, the breeding of animals whose genes have mutated or have been modified and have not been subsequently used in other procedures.

Species

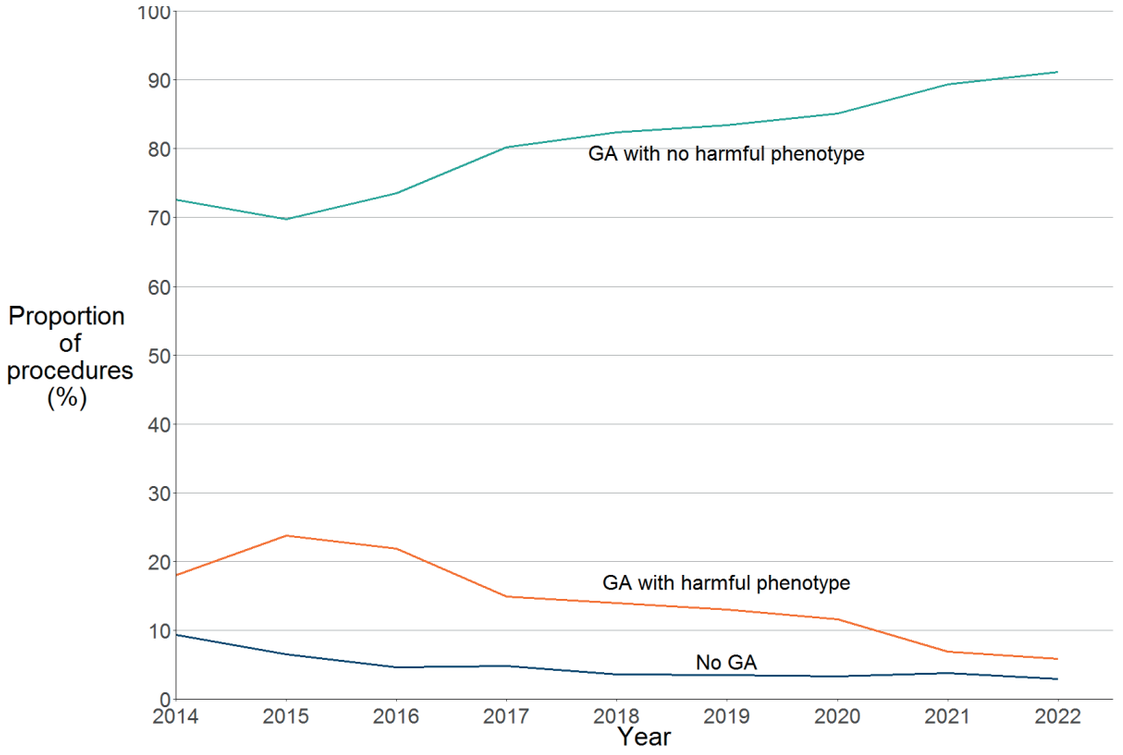
Almost all (over 99%) of the procedures for the creation and breeding of GA animals involved mice (86%), fish (13%), or rats (0.5%). The remaining 0.5% of procedures used domestic fowl, amphibians, sheep and pigs.

No specially protected species (horses, dogs, cats, or primates) were used in procedures counted under creation and breeding of GA animals.

Genetic status

Of the 1.25 million procedures for creation and breeding that used GA animals in 2022, 1.14 million (91%) used GA animals with no harmful phenotype (i.e. the animals did not appear or behave any differently from non-GA animals).

Figure 13. Creation and breeding of GA animals by type of genetic alteration, 2014 to 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 8

As shown in Figure 13, there has been an increase in the proportion of animals used for creation and breeding that are genetically altered without a harmful phenotype (increasing from 73% in 2014 to 91% in 2022).

There were some animals that were bred with the intention of producing GA animals, but resulted in non-GA animals being born. In addition, some animals used for the creation of a new genetic line will also have been genetically normal animals (e.g. those used for superovulation). 3% of procedures for creation and breeding involved non-GA animals in 2022.

Purpose

Of the total 1.25 million procedures for the creation and breeding of GA animals, 89% were for the maintenance of already established GA lines, with the remainder for the creation of new lines.

Of the ~143,000 procedures that were for the creation of new GA lines, the majority (91%) were to create new GA lines to be used in basic research. The most common areas within basic research were multisystemic research (~29,000 breeding

procedures), the nervous system (~29,000 breeding procedures), oncology (~13,000 breeding procedures) and cardiovascular blood and lymphatic system (~9,600 breeding procedures).

For data on all purposes for applied research by species, see Tables 8-10 of the data tables.

Creation: includes the natural breeding of different strains to produce a new strain and procedures that use standard techniques such as vasectomy for the generation of novel transgenic or mutant lines of GA animals. The birth of a GA animal counts as creation when the line is new and before is it 'established' (i.e. stable and characterised).

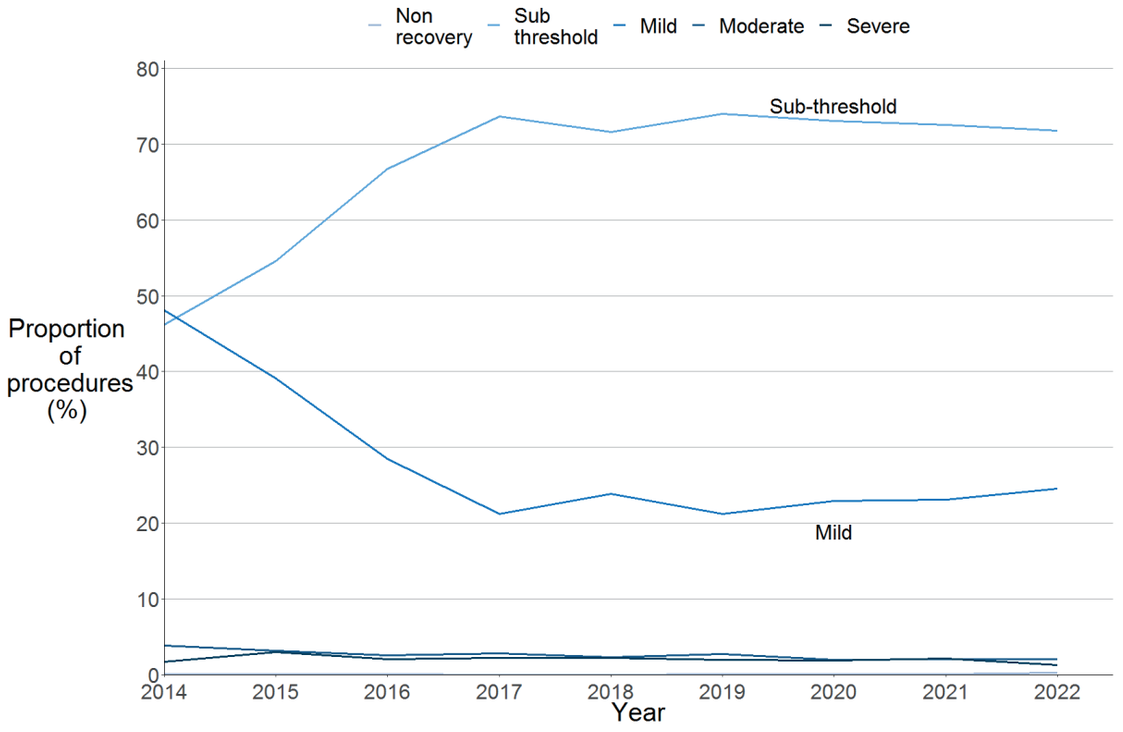
Breeding: the production of GA animals of an established line that has been bred for at least two generations. Breeding procedures also include other techniques applied to the animal after birth e.g. genotyping but not any techniques applied as part of an experiment or study.

Severity

Animals in this type of procedure were not used in regulated experimental procedures. As such, the severity experienced by GA animals created and bred are assessed as follows:

- the observable characteristics (phenotype) of the animals, e.g. development of congenital disease (i.e. diseases present at birth) or tumours
- in the case of animals that have no harmful phenotype but that have been biopsied (taking a sample of tissue) specifically for genotyping to determine the genetic make-up of an animal, the biopsy procedures will generally be assessed as mild
- the animals assessed as severe in this category are largely animals within breeding colonies that were found dead and where the death of the animal was either a result of its phenotype or, more commonly, unexplained (all animals found dead are reported as severe unless an informed decision can be made that the animal did not suffer severely prior to death)
- a small number of the animals used to create new lines of GA animals will have been subjected to surgical procedures (classed as moderate) or the injection of drugs (classed as mild)

Figure 14. Creation and breeding of GA animals by severity, 2014 to 2022



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2022: data tables, Table 8.

The severity assessments for creation and breeding in 2022 have remained stable since 2017, where sub-threshold procedures make up the majority (72%) and only 1% of creation and breeding procedures were assessed as severe. Mild procedures account for 25%, followed by moderate (2%) and non-recovery (0.3%).

As shown in Figure 14, up until 2017 there was an increase in proportion of sub-threshold and decrease in proportion of mild procedures. This change does not reflect a true change in the severity of creation/breeding procedures from 2014 to 2017. Home Office Inspectors believe that initially many creation/breeding procedures reported as ‘mild’ should have been reported as ‘sub-threshold’. Therefore, the changing severity assessment profile reflects data suppliers improved familiarity and understanding of severity assessments. Since 2017, the proportions of sub-threshold and mild have remained stable.

Establishment and project licences

All projects and establishments seeking to conduct regulated procedures on living animals must be licensed under Animals (Scientific Procedures) Act 1986 (ASPA).

During 2022, there were 139 establishment licences, 2 of which did not have any active project licences and 2,913 active project licences.

Information regarding establishment type is no longer collected in the return of procedures collection. Establishment type is not an indicator of the type of procedures carried out and often establishments could be categorised as more than one establishment type.

Further information

The data used in this release was extracted on the 8th June 2023.

Frequency of release: Annually

Forthcoming release: Home Office statistics release calendar

Home Office responsible statistician: Amy Baxter

This report contains statistics on regulated scientific procedures performed using living animals under the Animals (Scientific Procedures) Act 1986 (ASPA).

Accompanying user guide

See the accompanying user guide for information including:

- background information on the data collection
- uses of the statistics, and links to related statistics
- details on methodology and data quality issues

Data quality

The UK Statistics Authority has designated these statistics as National Statistics, in accordance with the Statistics and Registration Service Act 2007, signifying compliance with the Code of Practice for Statistics.

National Statistics status

National Statistics status means that our statistics meet the highest standards of trustworthiness, quality, and public value, and it is our responsibility to maintain compliance with these standards.

The designation of these statistics as National Statistics was confirmed in 2023 following a compliance check by the Office for Statistics Regulation. The statistics last underwent a full assessment of compliance against the Code of Practice in 2012. More information is available in the User Guide.

Revisions

It is standard practice across all Home Office statistical releases to incorporate revisions to previous years' data in the latest release. Corrections and revisions follow the Home Office's statement of compliance with the Code of Practice.

The time series data tables published in the 2022 statistical report include any revisions that have been made to previously published data for the years 2014 to 2021. Only data for 2021 has been affected. The following table shows major revisions or corrections:

What has changed	Number of procedures affected
Reduction in total procedures	1,143
Reduction in mice	410
Reduction in rats	130
Reduction in rabbits	632
Reduction in sheep	8
Reduction in goats	44
Reduction in other fish	15,111
Increase in zebrafish	15,192
Reduction in sub-purpose of "Routine production Monoclonal antibodies"	770
Increase in sub-purpose of "Routine production Blood based products"	86

The change in total procedures is partially due to a data processing error identified during this year's production process. This error was caused by uncommon circumstances affecting limited number of establishments and has now been rectified. The majority of change in zebrafish and other fish is from a species reclassification. Other changes can be due to amendments from project licence holders submitted after the data collection deadline.

The reduction in the production of monoclonal antibodies is due to an error with the data processing which incorrectly labelled polyclonal production as monoclonal. Monoclonal antibody production is notable as it is done by the ascites method. No monoclonal antibody production was conducted in 2021. 2021's data was corrected to the blood based products grouping. Blood based products has net increased from a combination of the reductions in procedures and this reclassification.

Other changes are due to minor amendments from the project licence holders.

Changes in legislation and definitions

Prior to 1986, figures were recorded for the number of 'experiments' on living animals, under the Cruelty to Animals Act 1876. In 1986, the Animals (Scientific Procedures) Act

was introduced, and required all 'scientific procedures' to be recorded. This new, broader term largely explains the increase in figures directly after 1986 (see Figure 1).

At the beginning of 2013, an EU Directive (2010/63/EU) came into effect, and as a result changed the way in which the data was collected under UK law from 2014 onwards. All figures for procedures (1986 onwards) are comparable as the definition of a procedure is unchanged. As a result of the change in methodology, the 2014 data is subject to data quality issues (see the user guide for further information).

Additional statistics for animal use in Great Britain

The annual statistics release covers regulated procedures on living animals, under the Animals (Scientific Procedures) Act (ASPA) 1986. This comprises of procedures carried out using animals for experimental purposes, and procedures counted under creation/breeding of genetically altered (GA) animals (i.e. the use of GA animals to create offspring for use in experimental procedures). The use of non-GA animals for breeding, to produce non-GA offspring for use in experimental procedures, is covered under the 1986 Act but is not included in the annual statistics. The annual statistics also do not include the use of other animals 'used' specifically in the support of the production and use of animals in experimental procedures or e.g. sentinel animals for the monitoring of disease within the facilities. This data on breeding and genotyping of animals for 2017 was published by the Home Office in November 2018 on GOV.UK.

Cross-Government ownership of animals in scientific procedures policy

The annual statistics on regulated procedures on living animals are released by the Home Office, however policies and legislation that influence the number and type of procedures are the responsibility of different government departments. The table below outlines organisations are their areas of responsibility.

Department	Areas of responsibility
Home Office	Regulation of the use of animals in science under ASPA, including licensing and compliance
Department for Science, Innovation and Technology	Policy on the development and validation of alternatives that cause less harm or do not use animals (under ASPA Section 20B), Government funding for alternatives (through UK Research and Innovation (UKRI) and the National Centre for the 3Rs (NC3Rs)), Basic research, Applied research, Public attitudes survey, Strategic support to the life sciences sector to promote research, innovation and the use of technology to improve health and care
Department for Environment, Food & Rural Affairs	Protection of the natural environment, Chemical regulation (REACH), Precision breeding, Animal welfare (excluding ASPA), health and preservation of species, Veterinary medicine
Department for Health and Social Care	Medicines and healthcare products policy and regulation, Higher education or training (primarily training for surgeons)

Department for Business and Trade	Consumer product safety including regulation of cosmetics
Food Standards Agency	Food safety regulation

Glossary

Applied research: attempts to address diseases through prevention and development of treatments. Within the data tables, this is shown as 'Translational/Applied research'.

Basic research: aims to expand our knowledge of the structure, functioning and behaviour of living organisms and the environment.

Breeding: the production of GA animals of an established line that has been bred for at least two generations. Breeding procedures also include other techniques applied to the animal after birth e.g. genotyping but not any techniques applied as part of an experiment or study.

Creation: includes the natural breeding of different strains to produce a new strain and procedures that use standard techniques such as vasectomy for the generation of novel transgenic or mutant lines of GA animals. The birth of a GA animal counts as creation when the line is new and before is it 'established' (i.e. stable and characterised).

Experimental procedures: involve using animals in scientific studies for purposes such as: basic research and the development of treatments, safety testing of pharmaceuticals and other substances, education, specific surgical training and education, environmental research and species protection.

Other efficacy and tolerance testing: efficacy testing of biocides and pesticides is covered under this category as well as the tolerance testing of additives in animal nutrition.

Procedures for creation and breeding: involve the breeding of animals whose genes have mutated or have been modified. These animals are used to produce genetically altered offspring for use in experimental procedures but are not themselves used in experimental procedures.

Protected animals: Any living vertebrate, other than man, that has been born and any fish, amphibian or cephalopod once they become capable of independent feeding. Mammal, bird and reptile embryos after two-thirds of gestation or incubation period are protected but not counted in this publication.

Quality control: the testing of quality control parameters of a product, and any controls carried out during the manufacturing process for registration purposes, to satisfy any other national or international requirements or to satisfy the in-house policy of the manufacturer.

Regulated procedures: Any procedure applied to a protected animal for an experimental or other scientific purpose, or for an educational purpose, that may have the effect of causing an animal 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.

Regulatory testing: procedures carried out to satisfy legal requirements, including: ensuring substances are produced to legal specification; evaluating the safety or effectiveness of pharmaceuticals and other substances.

Routine production: covers studies carried out for manufacturing processes requiring regulatory approval.

Self-sustaining Colony:

Marmosets, Tamarins, and other new-world primates A self-sustaining colony is a colony that contains no wild caught animals. Is kept in a way that ensures animals are used to humans and is sustained using animals from within or from other self-sustaining colonies.

Macaques and other old-world primates A self-sustaining colony is a colony that no longer sources animals from the wild (it may contain some existing wild caught animals) and is sustained using only captive bred animals.

Severity: The severity (i.e. pain, distress or suffering) experienced by animals in procedures has been recorded since 2014.

There are five severity assessments:

Sub-threshold: When a procedure was authorised under a project licence but did not actually cause suffering above the threshold of regulation, i.e. was less than the level of pain, suffering, distress or lasting harm that is caused by inserting a hypodermic needle according to good veterinary practice.

Non-recovery (under general anaesthesia): When the entire procedure was carried out under general anaesthesia from which the animal shall not recover consciousness. It includes unintended death of animals on recovery protocols while under anaesthesia, provided that no regulated procedure had been carried out prior to the induction of anaesthesia.

Mild: Any pain or suffering experienced by an animal was, at worst, only slight or transitory and minor so that the animal returns to its normal state within a short period of time.

Moderate: The procedure caused a significant and easily detectable disturbance to an animal's normal state, but this was not life threatening. Most surgical procedures carried

out under general anaesthesia and with good post-operative analgesia (i.e. pain relief) would be classed as moderate.

Severe: The procedure caused a major departure from the animal's usual state of health and well-being. This would usually include long-term disease processes where assistance with normal activities such as feeding and drinking were required, or where significant deficits in behaviours/activities persist. It includes animals found dead unless an informed decision can be made that the animal did not suffer severely prior to death.

Severity assessments measure harms to an animal during a procedure and generally reflect the peak or cumulative severity of the entire procedure; they do not include harms caused to animals as a result of non-procedural events such as transport and housing.

Specially protected species: Cats, dogs, horses and non-human primates.

Toxicity and other safety testing: studies for safety evaluation of products and devices for human medicine, dentistry, veterinary medicine and other chemicals.

Feedback and enquiries

Home Office statisticians welcome feedback on the annual statistics release. If you have any feedback or enquiries about this publication, please contact the Statistical Transformation Team, the Home Office Unit which produced the statistics.

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