

Annual Statistics of Scientific Procedures on Living Animals Great Britain 2018



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Presented to Parliament pursuant to section 21(7) and 21A(1) of the Animals (Scientific Procedures) Act 1986

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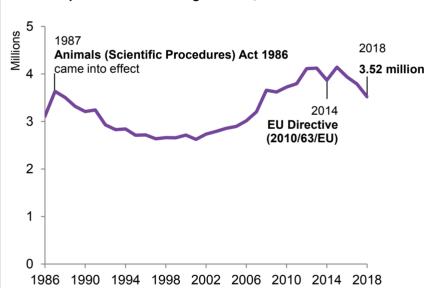
Annual Statistics of Scientific Procedures on Living Animals, Great Britain, 2018

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

Key results

In 2018, 3.52 million procedures were carried out in Great Britain involving living animals. This is a decrease of 7% on last year, and the lowest number of procedures since 2007.

Scientific procedures on living animals, 1986-2018.



Half of all procedures were experimental procedures (1.80 million), whilst the other half were for the creation and breeding of genetically altered (GA) animals (1.72 million).

The majority (93%) of procedures (both for experimental and breeding purposes) used mice, fish and rats. These species have been the most used for the past decade.

Over half (56%) of experimental procedures were for the purpose of basic research, most commonly focusing on the the immune system, the nervous system, and cancer.

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Home Office responsible statistician: Amy Baxter

Press enquires: pressoffice@homeoffice.gov.uk
020 7035 3535

Public enquires:

FLPOAU@homeoffice.gov.uk

3.52 million

procedures were carried out in Great Britain involving living animals in 2018

Experimental procedures

1.80 million

procedures carried out for experimental purposes.



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.

Creation and breeding of GA animals

1.72 million

procedures for the creation and breeding of GA 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.

60% of procedures used mice



Species

17% of procedures used fish



9% of procedures used rats



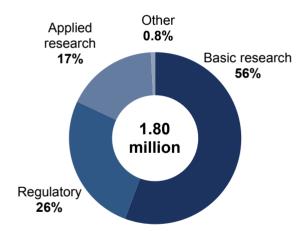
87% were for creation/breeding of mice



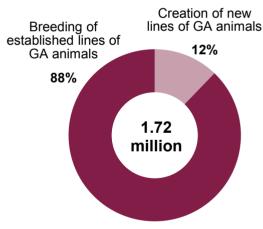
13% were for creation/breeding of fish



0.4% were for creation/breeding of rats



Over half of experimental procedures were for basic research. The top three areas targeted in this research were the immune system, the nervous system and oncology (cancer).



Most procedures in this category were for maintenance of already established GA lines, with 12% of procedures for the creation of new lines.



90% of all experimental procedures were assessed as sub-threshold, mild or moderate in severity.

5% were assessed as severe and 5% were non-recovery.



98% of all procedures for creation and breeding were assessed as sub-threshold, mild or moderate in severity.

2% were assessed as severe and 0.03% were non-recovery.

Purpose of procedures

Introduction 2

Purpose of this release

This publication meets the requirements of the 1986 Act to publish, and lay before Parliament. annual statistics on the use of protected animals in regulated procedures¹.

Coverage of this release

These statistics cover England, Scotland and Wales. For Northern Ireland, the Department of Health separately collects and publishes information on regulated procedures under devolved arrangements².

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

The number of procedures carried out in a year

does not always correspond with the number of animals that have been used in procedures that year. This is because some animals may be

Protected animals

Any living vertebrate, other than man, and any living cephalopod.

This includes embryos after two thirds of gestation (although these are not included as countable procedures), and fish and amphibian larvae after they become capable of free feeding.

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.

're-used'. 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.

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).

Accompanying data tables and user guide

The accompanying data tables for this report can be found here: https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-livinganimals-great-britain-2018.

This year, the data tables have been published online only (except for Table 1.2). The principal data tables have been expanded to include previous year's data (from 2014) and filters have been added to allow users to view and extract the data as they wish. This is part of a wider programme of work to promote transparency and to improve and modernise our statistical releases. Within the notes section for the data tables you will find further instructions on how to use the filters. The tables that have been expanded include data from 2014 as not all data pre-2014 are comparable.

See the accompanying user guide³ for further information.

¹ Section 2 of the 1986 Act.

² https://www.health-ni.gov.uk/publications/statistics-scientific-procedures-living-animals-northern-ireland.

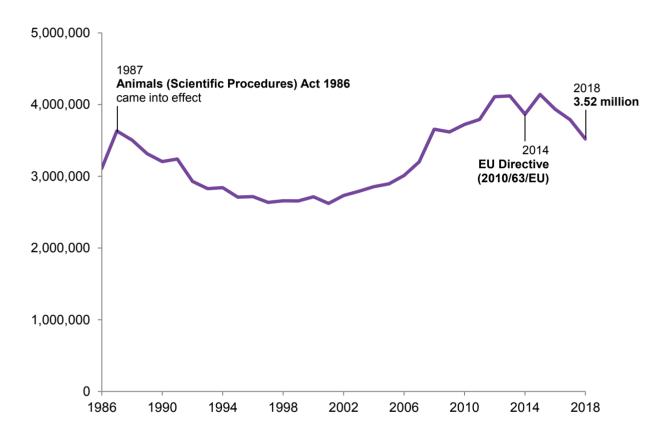
³ https://www.gov.uk/government/publications/user-guide-to-home-office-statistics-of-scientific-procedures-onliving-animals.

3 Total procedures

Key results

- In 2018, there were 3.52 million procedures completed on living animals in Great Britain. This is a decrease of 7% from last year, and the lowest number of procedures since 2007.
- Procedures for creation and breeding have decreased by 10% and experimental procedures have decreased by 4%.

Figure 1. Total scientific procedures in Great Britain, 1986 to 2018



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data tables, Table 1.1. See the user guide for links to all data pre-2007.

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.

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, but has decreased since to 3.52 million in 2018. This is the lowest number of procedures carried out in a single year since 2007.

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.

5,000,000 Percentage change Total procedures from from 4,000,000 last year 10 years ago 3% 3,000,000 Experimental 2,000,000 Creation and breeding of GA animals 1,000,000 0 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018

Figure 2. Total scientific procedures by type, 2009 to 2018

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: 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 decreasing, with a decrease of 10% compared to last year.

In contrast, the number of experimental procedures remained stable during the earlier part of the last decade but has decreased since 2015 similarly to procedures for creation and breeding of GA animals.

4 Experimental procedures

Key results

- Of the 1.80 million experimental procedures, the majority (86%; 1.55 million) used mice, fish and rats.
- Over half (56%) of all experimental procedures were carried out for basic research purposes (1.00 million procedures). The most common areas focused on in this research were: the immune system (22%), the nervous system (21%), and cancer (oncology;12%).
- In 2018, 90% of all experimental procedures were assessed as sub-threshold, mild or moderate in severity.

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. The animals used in experimental procedures may be genetically altered.

4.1 Species

The proportions of species used for experimental procedures as shown in Figure 3 have remained mostly stable for the past decade. However, while the total number of experimental procedures has declined in the last year, the use of certain species in experimental procedures has increased, such as the use of birds (from 130,000 procedures in 2017 to 147,000 in 2018).

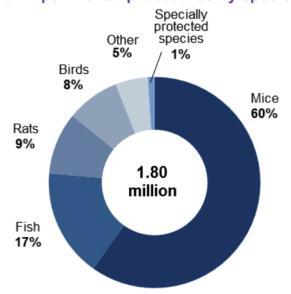


Figure 3. Experimental procedures by species, 2018

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data

tables, Table 1.2

Notes: Specially protected species are Cats, Dogs, Horses and Primates.

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

Mice, fish and rats in experimental procedures

The majority of experimental procedures used mice, fish and rats; together these species were used in 86% of experimental procedures in 2018.

Percentage change 1,400,000 from from last year 10 years ago 1,200,000 12% 1% 1,000,000 Mice 000,008 600,000 Fish 400,000 200,000 Rats 0 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018

Figure 4. Experimental procedures using mice, fish and rats, 2009 to 2018

Source: Home Office, Statistics of Scientific Procedures on Living Animals, Great Britain 2018 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, in line with the overall decrease in experimental procedures, the use of mice, fish and rats has decreased since 2017. The use of rats in experimental procedures has decreased by 27% since 2017 and has almost halved compared to their use 10 years ago. In 2018, over half of experimental procedures involving rats (53%) were for regulatory testing (e.g. tests evaluating the safety and efficacy of substances such as pharmaceuticals).

The majority of experimental procedures involving mice and fish in 2018 (68% and 65% respectively) were for basic research. More specifically, most of the basic research that involved the use of mice focused on the immune system, the nervous system and oncology (cancer). Most basic research that involved the use of fish focused on animal behaviour/biology and the nervous system.

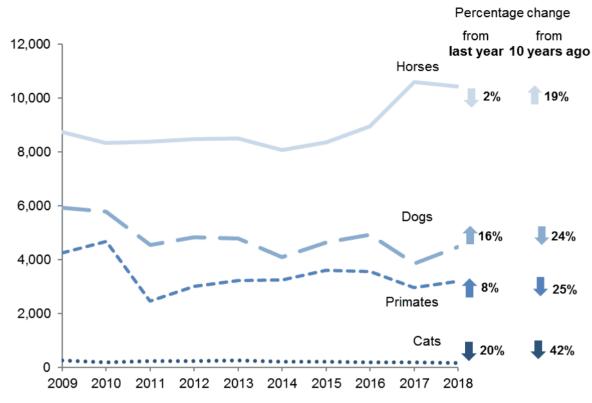
Specially protected species in experimental procedures

'Specially protected species' refers to cats, dogs, horses and primates. These species were used in 1% of experimental procedures (18,000) in 2018.

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, 2009 to 2018



Source: Home Office, Statistics of Scientific Procedures on Living Animals, Great Britain 2018 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 19,000 in 2009 to 18,000 in 2018. Most notable is the decrease in procedures involving primates and dogs; both of which have decreased by a quarter over the past decade, although the use of both species has increased in the last year. In 2018, the majority (81% and 71% respectively) of experimental procedures that used primates and dogs were for regulatory procedures, mainly for testing the safety of products and devices for human medicine, dentistry, and veterinary medicine.

The species of primates that were used in experimental procedures in 2018 were cynomolgus monkeys (2,900 procedures), rhesus monkeys (160 procedures) and marmosets and tamarins (110 procedures). The only primates used in regulatory procedures were cynomolgus monkeys.

The number of procedures involving horses had remained relatively stable over the past decade until the increase in 2017. The figure for 2018 has remained at a similar level to 2017, with the majority (91%) of procedures using horses carried out for the routine production of blood-based products. Blood-based products are used for a variety of diagnostic purposes.

The number of experimental procedures that used cats has decreased by 20% in the last year and 42% compared to 10 years ago. There were 160 experimental procedures that used cats in 2018.

Use of endangered species

Information was collected on whether any endangered species, as listed in Annex A of Council Regulation (EC) No 338/97⁴, were used.

Of the 3,136 returns, two reported the use of endangered animals in 2018, within which eight species of wild birds were used in research for the conservation of the species.

Place of birth of primates

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.

Table 2.2 shows that of the 2,500 primates used for the time in experimental procedures, all marmosets and tamarins (90) and rhesus monkeys (110) were born in the UK at a licensed establishment, whereas 92% of cynomolgus monkeys were born in either Africa or Asia (2,100 of 2,300 monkeys).

The generation of non-human primates used for the first time in experimental procedures can be found in Table 2.3. of the data tables.

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⁴ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R1320

4.2 Genetic status

Of the 1.80 million experimental procedures completed in 2018, over half (60%) used animals that were not genetically altered.

Figure 6. Experimental procedures by genetic status, 2009 to 2018

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: 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, in line with the overall decrease in experimental procedures, the number of experimental procedures involving non-GA animals has decreased by 27% over the last decade, falling by 8% in the last year.

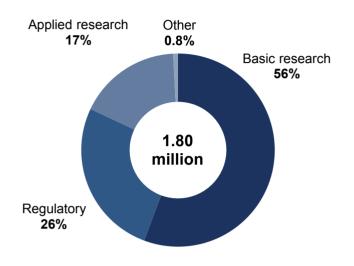
The use of GA animals in experimental procedures has increased over the last decade by 17%. However, their use has remained stable over the past three years, increasing by 1% since last year. The stability in the use of GA animals over the past three years does not correspond with the overall decrease seen in the number of procedures for the creation and breeding of GA animals (as can be seen in figure 2).

Further information regarding the genetic status of GA animals used in experimental procedure in 2018 can be found in Table 4 of the data tables.

4.3 Purpose

Experimental procedures accounted for half (51%) of the 3.52 million procedures in 2018. Figure 7 shows the purpose of these procedures.

Figure 7. Experimental procedures by purpose, 2018



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.

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data tables, Table 1.2

Notes: Experimental procedures carried out for higher education or training, the preservation of species and for the protection of the national environment accounted for less than 1% and therefore are not visible on the chart above.

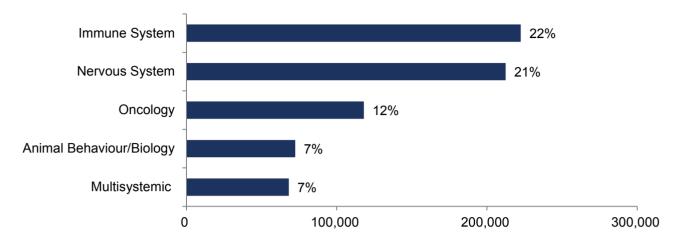
As shown in Figure 7, over half (56%) of the experimental procedures carried out in 2018 were for **basic research**. A further 26% were conducted for **regulatory testing** purposes, and the remainder were mostly for **applied research** (17%).

The proportions shown in Figure 7 have remained stable since 2014 when the data was first collected using these purpose classifications. The experimental purpose classifications prior to 2014 are not directly comparable.

Basic research

In 2018, 1.00 million experimental procedures were carried out for basic research purposes. The most common areas focused upon in this research, as shown in Figure 8, were: the immune system (22%), the nervous system (21%), and cancer (oncology; 12%).

Figure 8. Most common areas focused upon in experimental procedures for basic research, 2018



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: 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)) been reported within the top five most common areas for basic research in each year since 2014.

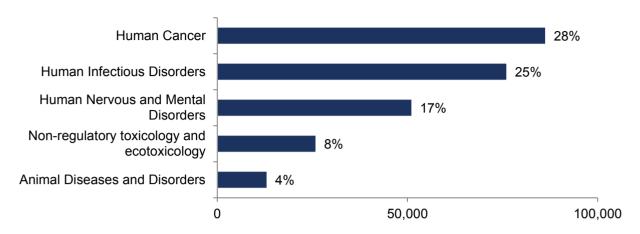
For data on all purposes for basic research by species, see Table 5 of the data tables.

Applied research

There were 310,000 experimental procedures for applied research (17% of all experimental procedures). Applied research attempts to address diseases through prevention and development of treatments and, as shown in Figure 9, the most common areas of research were human cancer (28%), human infectious disorders (25%), and human nervous and mental disorders (17%).

Almost all of the experimental procedures for applied research focusing on human cancer used mice (99%). Over half (53%) of experimental procedures for applied research focusing on human infectious disorders used fish, and almost all (99%) experimental procedures for applied research focusing on the human nervous and mental disorders used mice, rats or fish.

Figure 9. Most common areas focused upon in experimental procedures for applied research, 2018



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data tables, Table 6

Notes: Non-regulatory toxicology and ecotoxicology covers toxicology, method development and investigations prior to regulatory studies.

Similar to basic research, the distribution of purposes for applied research has also remained similar since 2014, with infectious disorders, cancer, and nervous and mental disorders consistently being 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 474,000 procedures carried out for regulatory purposes in 2018 (26% 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 focusses on safety and efficacy.

Of the 474,000 regulatory procedures in 2018, the most common legislative requirements were legislation on medicinal products for human (43%) or veterinary use (29%). No procedures were carried out for cosmetics testing.

The majority (95%) of regulatory procedures were undertaken to satisfy either or both UK and EU legislation.

Figure 10 shows that the proportion of each purpose of regulatory procedures carried out in 2018 were relatively similar for **routine production**, **toxicity and other safety testing** and **quality control** reasons.

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, and veterinary medicine.

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.

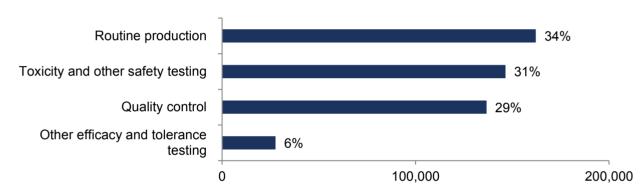


Figure 10. Experimental procedures for regulatory purposes by sub-purpose, 2018

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data tables, Table 7.1

In contrast to their predominant use in experimental procedures for basic research and applied research, mice were used in a third (33%) of all regulatory procedures, although were the most commonly used species. The second most common species used in regulatory procedures were domestic fowl which were used in 27% (128,000) of all regulatory procedures. More specifically, 99,000 regulatory procedures using domestic fowl in 2018 were for the routine production of 'other' products, such as antigens for vaccines.

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.⁵

In 2018, there were 397 experimental procedures (regulatory (toxicity) testing for industrial chemicals legislation) which involved the testing of household product ingredients. There was no re-use of animals for these procedures, therefore 397 animals were used. Of the 397 animals; 52 mice, 13 rabbits and 59 rats were used in procedures that were assessed

⁵ An additional area of interest is ascites methods of monoclonal antibody production. No ascites methods of monoclonal antibody production were used in 2018.

as mild, 219 rats were used in procedures that were moderate and 54 rats were used in procedures that were assessed as severe.

No finished tobacco or alcohol products were tested in 2018.

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 3,136 returns, four reported that rodenticide trials occurred in 2018. We ask data suppliers only to indicate whether field trials of rodenticide substances occurred, as these trials are conducted in semi-field situations where the number of animals is not accurately known as the colonies are not intensively managed.

4.4 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 without recovery.

Mild: Any pain or suffering experienced by an animal that 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 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.

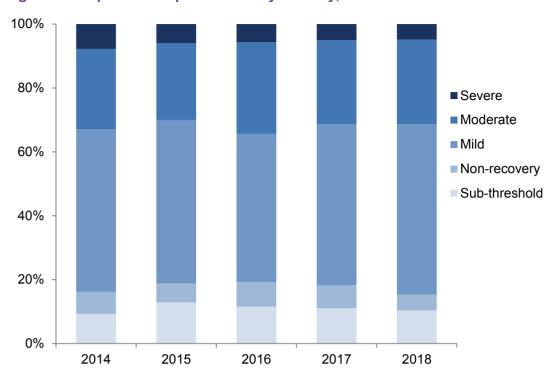


Figure 11. Experimental procedures by severity, 2014 to 2018

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data tables, Table 3.1

Over half (53%) of experimental procedures in 2018 were mild. The proportions of severity assessments for procedures reported in 2018 were similar to those seen in previous years, as shown in Figure 11. Since 2014, sub-threshold procedures have accounted for around 10% of experimental procedures, whilst severe and non-recovery procedures have each accounted for less than 10%.

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.

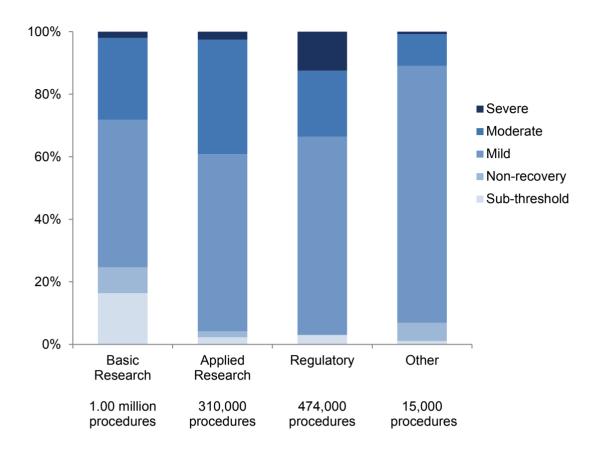


Figure 12. Experimental procedures by severity and purpose, 2018

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: 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.

The use of NMBA was recorded in 18 of the 3,136 returns. Of these, 14 returns reported that use of NMBA was whilst the animal was under general anaesthesia.

5 Creation and breeding of genetically altered animals

Key results

- Almost all (over 99%) of the 1.72 million procedures for the creation and breeding of GA animals involved mice, fish and rats.
- Most procedures counted under creation and breeding (88%) were for the maintenance of already established GA lines.
- The majority (72%) of procedures for creation and breeding in 2018 were assessed as sub-threshold in severity.

This section covers only procedures counted under the creation and breeding of GA animals. That is, the breeding of animals whose genes have mutated or have been modified.

5.2. Species

Almost all (over 99%) of the procedures for the creation and breeding of GA animals involved mice (87%), fish (13%), and rats (0.4%). Other species used for creation and breeding of GA animals include: amphibians, ungulates (including pigs), and birds – but together they accounted for less than 0.3% of these procedures.

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 1.66 million procedures for creation and breeding that used GA animals in 2018, the majority (85%) used GA animals with no harmful phenotype (i.e. the animals did not appear or behave any differently from non-GA animals).

100% 80% ■ Not genetically altered ■ Genetically 60% altered - harmful phenotype Genetically altered - no 40% harmful phenotype 20% 0% 2014 2015 2016 2017 2018

Figure 13. Creation and breeding of GA animals by type of genetic alteration, 2014 to 2018

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data tables, Table 8

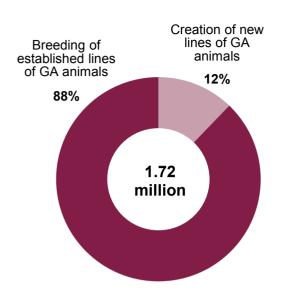
As shown in Figure 13, there has been an increase in proportion of animals used for creation and breeding that are genetically altered without a harmful phenotype (rising from 73% of all creation and breeding in 2014 to 82% in 2018).

There were some animals that were bred with the intention of producing GA animals, but resulted in non-GA animals being born (4% of animals in this category in 2018). 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).

5.3. Purpose

As shown in Figure 14, of the total 1.72 million procedures for the creation and breeding of GA animals, 88% were for the maintenance of already established GA lines, with the remainder of procedures for the creation of new lines.

Figure 14. Creation and breeding of GA animals by purpose, 2018



Creation: includes the natural breeding of different stains 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.

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data tables, Tables 8, 9.1 and 10

Of the 209,000 procedures that were for the creation of new GA lines, almost all (95%) were to create new GA lines to be used in basic research. More specifically, these animals were bred to be used in procedures focusing on multisystemic research (54,000 breeding procedures), oncology (cancer; 40,000 breeding procedures) and the immune system (30,000 breeding procedures).

5.4 Severity

Animals in this category 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 specifically for genotyping⁶, 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).

⁶ Genotyping is the process of taking a sample of tissue (a biopsy) and then testing it to determine the genetic make-up of an animal.

Nearly three quarters (72%) of procedures counted under creation and breeding in 2018 were assessed as sub-threshold.

100% 80% ■ Severe ■ Moderate Mild 60% ■ Non-recovery Sub-threshold 40% 20% 0% 2014 2015 2016 2017 2018

Figure 15. Creation and breeding of GA animals by severity, 2014 to 2018

Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data tables, Table 8.

Notes: For each year, non-recovery procedures have accounted for less than 1% and are therefore not visible on the chart.

As shown in Figure 15, overall, the proportion of sub-threshold creation and breeding procedures has increased and mild have decreased since 2014, whereas the proportion of severe and moderate procedures has remained relatively stable.

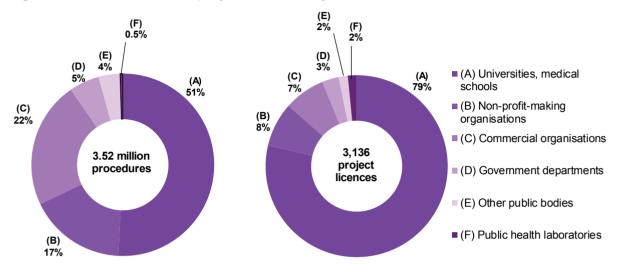
Home Office Inspectors believe that the change in sub-threshold and mild procedures from 2015 does not reflect a true change in severity and initially, many creation and breeding procedures reported as 'mild' should have been reported as 'sub-threshold'. Therefore, the change in severity assessment reflects data suppliers improved familiarity and understanding of severity classifications. As shown in Figure 15, the severity assessments for creation and breeding in 2018 have remained similar to 2017.

6 Establishment and project licences

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

During 2018, there were 157 establishment licences⁷ and 3,136 project licences in force.

Figure 16. Procedures and project licenses by establishment, 2018



Source: Home Office, Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2018: data tables, Table 11

As shown in Figure 16, the majority of project licenses are held by those conducting research at universities or medical schools (79%) although half of all procedures took place at these universities or medical school. In contrast, 7% of project licenses are held within commercial organisations although they conducted 22% of all procedures carried out in 2018. This is due to commercial organisations conducting large programmes of work involving repetitive procedures and tests under fewer project licences.

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⁷ Seven of which did not have any active project licenses in 2018.

7 Further information

Accompanying user guide

See the accompanying <u>user guide</u>⁸ 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 Official 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 2007 following a compliance check by the Office for Statistics Regulation⁹. The statistics last underwent a full assessment¹⁰ against the Code of Practice in 2012.

Since the latest review by the Office for Statistics Regulation, we have continued to comply with the Code of Practice for Statistics, and have made the following improvements:

- Easier, more intuitive data entry with pop-up messages alerting suppliers to incompatible combinations of data being entered;
- For the 2017 data onwards, data collected on 'other' species is subject to data quality checks which have allowed for further analyses of the animals returned under 'other' (non-Schedule 2) species categories;
- Each year, we consult with colleagues in the Animals in Science Regulation Unit to ensure the collection remains suitable for its purpose.

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

⁸ https://www.gov.uk/government/publications/user-guide-to-home-office-statistics-of-scientific-procedures-on-living-animals.

⁹ https://www.statisticsauthority.gov.uk/osr/.

¹⁰ https://www.statisticsauthority.gov.uk/wp-content/uploads/2015/12/images-assessmentreport203statisticsonscientificproceduresonlivinganimal tcm97-41802.pdf.

Office's statement of compliance¹¹ with the Code of Practice for Official Statistics.

During the production of the 2017 annual statistics, quality assurance checks revealed a small number of misclassifications within the 2014, 2015 and 2016 datasets. See Appendix A of the 2017 statistical report for details of all revisions to the 2014, 2015 and 2016 data made since the 2016 release.

In addition to the revisions listed in the 2017 statistical report, further revisions were made to the 2015 data. The generation of eight marmosets/tamarins, originally classified as 'F0 wild caught', were revised to 'self-sustaining colony' and 31 breeding procedures involving mice were removed.

Following the publication of the 2017 annual statistics, a revision was made to one of the return of procedures. The genetic status of four rhesus monkeys, originally classified as 'genetically altered without a harmful phenotype' were revised to 'not genetically altered'.

The time series data tables published in the 2018 statistical report include any revisions that have been made to previously published data for the years 2014 to 2017.

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 end 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 guide¹² 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 (e.g. sentinel animals for the monitoring of disease within the facilities). This data for 2017 was published by the Home Office in November 2018 on GOV.UK at the following webpage: https://www.gov.uk/government/statistics/additional-statistics-on-breeding-and-genotyping-of-animals-for-scientific-procedures-great-britain-2017.

¹¹ <u>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/341674/ho-compliance-state-aug14.pdf.</u>

¹² https://www.gov.uk/government/publications/user-guide-to-home-office-statistics-of-scientific-procedures-on-living-animals.

Feedback and enquiries

We welcome feedback on the annual statistics release. If you have any feedback or enquiries about this publication, please contact the Fire, Licensing and Public Order Analysis Unit, the Home Office Unit which produced the statistics, via FLPOAU@homeoffice.gov.uk.

Icon credit

The mouse icon used on the summary statistics page was made by <u>Freepik</u>¹³ from www.flaticon.com.

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 ¹³ https://www.freepik.com/?
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Year	Animal Group	Species of animal	Basic Research	Translational/ Applied research	Protection of the natural environment	Preservation of species	Higher education Fo	Forensic enquiries	Regulatory	Total experimental procedures	Creation & breeding of GA animals not used in experimental procedures	Total procedures	% of total procedures
2018	Total	*Total - all species	1,003,582	309,764	12,264	1,037	1,327	0	474,056	1,802,030	1,717,887	3,519,917	100.0
2018	Mammal	Mouse (Mus musculus)	733,514	185,487	645	0	541	0	158,551	1,078,738	1,489,459	2,568,197	73.0
2018	Mammal	Rat (Rattus norvegicus)	45,175	34,069	201	0	664	0	90,556	170,665	7,239	177,904	5.1
2018	Mammal	Guinea-pig (Cavia porcellus)	693	1,382	0	0	66	0	4,271	6,445	0	6,445	0.2
2018	Mammal	Hamster (Syrian) (Mesocricetus auratus)	22	993	0	0	0	0	731	1,416	0	1,416	0:0
2018	Mammal	Hamster (Chinese) (Cricetulus griseus)	0	0	0	0	0	0	0	0	0	0	0:0
2018	Mammal	Mongolian Gerbil (Meriones unguiculatus)	498	12	0	0	0	0	0	510	0	510	0:0
2018	Mammal	Other rodent (other Rodentia)	744	48	47	0	0	0	0	839	0	839	0:0
2018	Mammal	Rabbit (Oryctolagus cuniculus)	1,357	792	က	0	0	0	9,032	11,159	0	11,159	0.3
2018	Mammal	Cat (Felis catus)	155	4	0	0	0	0	0	159	0	159	0:0
2018	Mamma	Beagle (Canis Iupus familiaris)	430	969	2	0	0	0	3,184	4,314	0	4,314	0.1
2018	Mamma	Other dog (other Canis)	141	26	0	0	0	0	0	167	0	167	0:0
2018	Mammal	Ferret (Mustela putorius furo)	91	330	0	0	80	0	37	466	0	466	0:0
2018	Mammal	Other carnivore (other Camivora)	64	42	198	9	0	0	0	307	0	307	0:0
2018	Mammal	Horse and other equid (Equidae)	006	43	0	0	0	0	9,481	10,424	0	10,424	0.3
2018	Mammal	Pig (Sus scrofa domesticus)	402	1,332	0	0	7	0	2,009	3,750	254	4,004	0.1
2018	Mammal	Goat (Capra aegagrus hircus)	0	-	0	0	0	0	25	58	0	28	0.0
2018	Mammal	Sheep (Ovis aries)	3,296	1,322	0	0	0	0	48,881	53,499	173	53,672	1.5
2018	Mammal	Cattle (Bos primigenius)	935	292	903	0	0	0	1,318	3,723	0	3,723	0.1
2018	Primate	Marmoset and tamarin	55	58	0	0	0	0	0	113	0	113	0:0
2018	Primate	Cynomolgus monkey (Macaca fascicularis)	24	298	0	0	0	0	2,612	2,934	0	2,934	0.1
2018	Primate	Rhesus monkey (Macaca mulatta)	91	69	0	0	0	0	0	160	0	160	0.0
2018	Mammal	Other mammal (other <i>Mammalia</i>)	523	29	0	0	0	0	0	582	0	285	0.0
2018	Bird	Domestic fowl (Gallus domesticus)	7,651	3,905	0	0	0	0	128,326	139,882	1,187	141,069	4.0
2018	Bird	Quail (Cotumix cotumix)	37	0	0	0	0	0	0	37	0	37	0:0
2018	Bird	Other bird (other Aves)	5,735	311	177	461	0	0	257	6,941	0	6,941	0.2
2018	Reptile	Reptile (Reptilia)	104	0	0	0	0	0	0	104	0	401	0:0
2018	Amphibian	Rana (temporaria and pipiens)	675	0	0	0	0	0	0	675	0	675	0:0
2018	Amphibian	Xenopus (laevis and tropicalis)	5,217	167	0	0	0	0	0	5,384	3,046	8,430	0.2
2018	Amphibian	Other amphibian (other Amphibia)	768	0	0	0	0	0	0	768	0	292	0:0
2018	Fish	Zebrafish (Danio rerio)	133,792	67,726	3,169	0	80	0	488	205,183	216,025	421,208	12.0
2018	Fish	Other fish (other Pisces)	60,493	10,381	6,916	573	0	0	14,265	92,628	504	93,132	5.6
2018	Cephalopod	Cephalopod (<i>Cephalopoda</i>)	0	0	0	0	0	0	0	0	0	0	0.0

CORRECTION SLIP

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