

Changes to data collection from 2014

The European Directive 2010/63/EU⁶ sets out a common format for Member States of the EU, which includes the UK – and therefore Great Britain – to submit information on the use of animals for scientific purposes. Following the transposition of the directive into UK law in January 2013, through amendment regulations to the Animals (Scientific Procedures) Act 1986, some changes were made that affect data from 2014 onwards. The key changes are:

- in order to allow for the collection of data on actual severity of procedures (see below), these data are for procedures completed, as opposed to procedures *started*, as reported prior to the 2014 publication; any procedures started and counted in 2013 or earlier, but which were completed on or after 1 January 2014, should have been counted again
- details of the actual severity⁷ are recorded for all procedures, which is an assessment of the severity that animals experienced as a result of the entire procedure applied and reflects the peak severity of that procedure
- the species information collected has been revised (these changes were also in place for 2013):
 - data are now collected on all cephalopods⁸ as opposed to only one species (*Octopus vulgaris*), as is information on species newly listed in 2013 in Schedule 2 of the 1986 Act⁹
 - data on greyhounds are no longer collected separately; however, from 2015, species information is collected to distinguish beagles from other dogs and common quail from other birds
- information on free-feeding larval forms (e.g. tadpoles) is now collected, but unborn or un-hatched embryos are not counted
- precise information on the number of individual animals re-used is not collected; however, it is still possible to ascertain the number of procedures which involved the re-use of animals
- data are collected on place of birth rather than on source:
 - greater detail is collected on the place of birth of non-human primates, including on whether non-human primates were wild caught or captive bred
 - in addition, from 2015, information is now collected to allow for the differentiation between captive bred non-human primates born in the UK and the wider EU
 - for captive bred non-human primates, information is also collected on the number of generations that they have been bred in captivity

⁶ See: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063>.

⁷ The classification of severity followed the guidelines given in Annex 8 of European Directive 2010/63/EU, which the Home Office further interpreted in 'Advisory notes on recording and reporting the actual severity of regulated procedures'. See: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/276014/NotesActualSeverityReporting.pdf.

⁸ Marine invertebrate animals such as an octopus or squid.

⁹ The species listed in Schedule 2 are: mice; rats; guinea-pigs; hamsters; gerbils; rabbits; cats; dogs; ferrets; non-human primates; common quail (*Coturnix coturnix*); any frog of the species *Xenopus laevis*, *Xenopus tropicalis*, *Rana temporaria* or *Rana pipiens*; zebrafish; genetically modified pigs and genetically modified sheep.

- for genetically altered animals, separate breakdowns on genetically modified animals and animals with a harmful genetic mutation are not collected; instead, separate breakdowns are collected on animals that show a harmful phenotype (i.e. a harmful physical or biochemical defect) and animals which do not show a harmful phenotype
- data are no longer collected on use of anaesthesia, except where neuromuscular blocking agents (NMBA) are involved
- information on target body system is no longer collected for all procedures but similar data are collected for procedures undertaken for basic and translational research purposes
- specific information is collected on regulatory use; some of this information was previously reported as applied studies
 - fundamental toxicological research, method development, and those safety-related procedures, for which there is no regulatory requirement, are reported under translational/applied research

Data quality in relation to 2014 data

As outlined above, the 2014 collection underwent substantial changes. As a result, some inconsistencies were expected in the reporting of the 2014 information as project license holders (i.e. data suppliers) became familiar with the new reporting requirements and data collection format.

Due to the change from counting 'procedures started' to 'procedures completed', all procedures started before 2014 but completed in 2014 should have been reported in both the pre-2014 and 2014 figures. Any impact of the change from counting procedures started to counting procedures completed was temporary and would likely have had a small impact, if any, on the 2015 and 2016 data.

In order to gain a better understanding of the impact of the changes, Home Office statisticians produced a feedback questionnaire for data suppliers regarding the 2014 data collection, which received 118 responses. It is not clear how representative the results are of all data suppliers, and therefore the results should be treated with caution.

The questionnaire sought information on the ease of completing the data collection template, the accessibility of the accompanying instructions and data quality issues. The results of the questionnaire enabled the Home Office to improve the data collection materials.

Analysis of the results identified the following data quality issues¹⁰:

- some project licence holders had not reported details of procedures started before 2014 but completed in 2014, which they had reported on in earlier years
 - approximately 60% of respondents (39 responses) indicated that there were at least some instances where procedures started prior to 2014, but completed in 2014, had not been reported for 2014
 - this confirms that some under-reporting had occurred in relation to the 2014 figures

¹⁰ Respondents who indicated 'possibly', 'don't know / can't remember' and 'not applicable' are excluded.

- some project licence holders provided information in 2014 on the number of animals (used in procedures) instead of on the number of procedures, as should have been the case
 - approximately 55% of respondents (34 responses) indicated that there were at least some instances where information on animals used, not procedures, was provided
 - usually, one animal corresponds with one procedure so there will have been no under-reporting in those instances; however, where the use of one animal is associated with more than one procedure, this confirms a degree of under-reporting, in terms of the number of procedures, in some instances
- some project licence holders provided some information under creation of a new genetic line when it should have been reported under maintenance of genetically altered animals, not used in other procedures
 - approximately 31% of respondents (17 responses) indicated that there were at least some instances where the information was not recorded accurately
 - this confirms that there was a degree of incorrect categorisation in relation to genetically altered animals created/bred thereby over-estimating the number of procedures relating to the creation of new lines and under-estimating the number of procedures relating to the maintenance of genetically altered animal colonies
 - the size of this misclassification is not known

In light of feedback from the online questionnaire referred to above, Home Office statisticians made the following improvements to the data collection template:

- the field in the template for purpose was split into two columns – purpose and sub-purpose; this made it easier for data suppliers to identify the appropriate purpose for their study and to ensure that the correct purpose was provided
- the ease of populating the template was also improved in other ways, such as by ensuring column widths could be adjusted and non-applicable columns could be hidden
- a link to the accompanying guidance documents was provided in the template for ease of accessibility
- clearer labelling was applied to the data fields e.g. for the number of procedures column, it was more clear that information on the number of procedures, not animals, was required
- for the place of birth column, the term ‘registered breeder’ was changed to ‘licensed establishment’ when referring to animals born in the UK, to make it clearer to data suppliers in the UK
- warning messages were displayed, for Schedule 2 species, when animals **not** born at a licensed establishment/registered breeder was entered, as this can only happen in limited circumstances. For the 2014 data, a number of data suppliers incorrectly entered **not** born at a registered breeder for Schedule 2 species; this change ensured that, overall, correct place of birth data was provided at the point of entry

In addition, the guidance notes were improved in terms of clarity and further examples were provided to aid data suppliers. As a result of these improvements, Home Office statisticians expect the 2015 and 2016 data to be more robust than the 2014 data.

While quality assuring the 2015 data, Home Office statisticians identified that a small number of the 2014 returns contained duplicate information for procedures, resulting in an over-reporting of around 9,000 procedures, which represents 0.2% of the 2014 procedures. The species involved predominantly were mice, rats, chickens, and fish other than zebrafish.

Home Office statisticians have reviewed their processes and quality assurance checks in light of this issue.

For the first time in 2014, details on the severity of procedures were recorded and, as a result, it is likely that there were initially some misclassifications in the reporting of severity data for that year. However, statisticians believe these misclassifications have reduced as data suppliers become more familiar with the new reporting requirements. The Home Office provided additional support to all stakeholders on severity assessment and scoring throughout the 2015 and 2016 data collection periods. Given that severity information has only been available from 2014, clear trends for this data will take a few years to emerge.

Following changes to the reporting format from 2014 onwards, procedures are now counted when they are completed as opposed to when they started, as in 2013 and previous years. As discussed in the 2014 report, it is believed that this transition led to an under-reporting of procedures that had already been counted in 2013 but which were completed in 2014; this is supported by the feedback from the questionnaire. This one-off undercount was largely responsible for the 6% reduction in procedures counted in 2014 compared to 2013. This transitional effect is unlikely to have any notable impact on data collected from 2015 onwards, as only a very small number of procedures are likely to extend over more than one year.

Therefore, generally throughout the 2015 release, 2015 data were compared with 2013 data, as neither year of data were subject to the same data quality issues as the 2014 data. However, comparisons between 2015 and 2013 still needed to be exercised with a degree of caution due to the methodological changes in 2014.

For the 2016 release, the 2016 data have been compared with 2015 data, as neither year's data were subject to the same data quality issues as the 2014 data. In addition, both years of data were underpinned by the same methodology.

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 for Official Statistics¹¹.

One of the returns in 2015 initially reported the severity level of 1,230 procedures involving mice, for the maintenance of established genetically altered animals, not used in other procedures, as severe. After publication in July 2016, following further investigation by the Home Office, the number of procedures was revised to 1,200, with severity assessments being amended to mild for 920 procedures, moderate for 90 procedures, and severe for 190 procedures. The 2015 publication was not amended following this revision as it was deemed disproportionate and an unnecessary use of limited resources.

¹¹ See: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/341674/ho-compliance-state-aug14.pdf (specifically, revisions and corrections section).

Acknowledgements

Statisticians in the Chief Statistician's Unit, which is part of the Home Office Analysis & Insight Directorate, prepared this statistical release. They are grateful for the contribution of project licence holders who provided the returns on which this report is based. They also thank colleagues in the Animals in Science Regulation Unit for their assistance with collecting the data, colleagues in the Policing Data Collection Section for their assistance with processing the data, the Inspectorate in the Animals in Science Regulation Unit for their assistance with quality assuring the data and the statistical report, and finally colleagues in the Science Information and Publication Team for their assistance with proofreading and preparing the report for publication.

Further information available

This statistical release is available online at:

<https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2016>. The website also includes:

- a web version of the statistical report (and a print version of the statistical report, which was laid before parliament)
- data tables which include the (unrounded) 2016 figures
- time-series tables
- a statistical news release
- a pre-release access list

Forthcoming publications are pre-announced on the statistics release calendar on the GOV.UK website: <https://www.gov.uk/government/statistics/announcements>.

Feedback and enquiries

We welcome feedback on '[Annual Statistics of Scientific Procedures on Living Animals, Great Britain, 2016](#)'. If you have any feedback or enquiries about this publication, please email the Chief Statistician's Unit, the Home Office Unit which produced the statistics, at: CSU.Statistics@homeoffice.gsi.gov.uk or write to: Chief Statistician's Unit, 14th Floor, Lunar House, 40 Wellesley Road, Croydon, CR9 2BY.

Presentation, legislation, and definitions

Introduction and counting rules

The statistics are compiled from returns submitted by project licence holders at the end of each year, or on the termination of the licence when this occurs during the year. The instructions for completion of annual returns of procedures in the UK can be found at the back of this user guide. The instructions include code lists for describing procedures. Each procedure (which may consist of several stages) for a given purpose on an animal is counted as one returnable procedure for the year in which it was completed (prior to 2014, it was the year in which it commenced). A study involving procedures on a number of animals is counted once for each animal. Where an animal that has recovered fully from a completed procedure is used again for a further procedure it is counted as a separate procedure, but the animal itself is not recounted. The circumstances in which the re-use of an animal is permitted are limited. Procedures on adult or free-living animals (including neonatal and juvenile mammals, and newly hatched birds) are counted. Details of procedures on immature forms (e.g. larvae, embryos, fish fry) are not counted unless they have reached the free-feeding stage (e.g. zebrafish fry from five days post-fertilisation and tadpoles). Animals in the wild involved in rodenticide trials are also not counted. However, information is collected on the number of project licences which undertake rodenticide trials.

Presentation of the data

The figures provided in the statistical report refer to the numbers of procedures (completed) rather than the numbers of animals used (for the first time), unless indicated otherwise. However, in most cases the number of procedures corresponds to the number of animals used. In instances where the number of procedures is higher than the number of animals used, this is due to a re-use of animals.

In some instances, there may appear to be small discrepancies between totals and the sums of related breakdowns in some instances for figures in the report. These discrepancies are attributable to rounding.

Rounding was employed to simplify the presentation of figures. However, all numeric changes across years, percentages and percentage changes across years are based on unrounded data, which are available in the [data tables](#). The rounding conventions, which also ensure that a sufficient level of detail is still presented, are as follows:

- all figures in millions are presented as millions and rounded to two decimal places, e.g. 2,121,582 would be presented as 2.12 million
- all figures less than a million but greater than 10,000 are presented as whole numbers and rounded to the nearest thousand, e.g. 343,465 would be presented as 343,000
- all figures less than 10,000 but greater than 1,000 are presented as whole numbers to the nearest 100, e.g. 8,465 would be presented as 8,500
- all figures less than a thousand but greater than 10 are presented as whole numbers and rounded to the nearest 10, e.g. 49 would be presented as 50
- all figures less than 10 are presented as unrounded whole numbers
- all percentages greater than 1% are presented to the nearest percent, e.g. 1.43% would be presented as 1%

- all percentages less than 1% are rounded to the nearest significant figure e.g. 0.43% would be presented as 0.4%, and 0.043% would be presented as 0.04%

The data in the data tables are unrounded. All percentages in the data tables are rounded to the nearest 0.1%.

Legal purpose of the statistics

The annual statistics publication relates to scientific procedures performed using living animals subject to the provisions of the Animals (Scientific Procedures) Act 1986. The purpose of this publication is to meet the requirements of the 1986 Act to collect and publish statistical information on the use of protected animals in regulated procedures during the previous calendar year and to lay that information before Parliament. Specifically, section 21(7) of the 1986 Act states:

- (7) The Secretary of State shall in each year publish and lay before Parliament such information as he considers appropriate with respect to the use of protected animals in the previous year for experimental or other scientific purposes.

Further to the above, the European Directive 2010/63/EU¹² sets out a common format for Member States, which includes the UK, to submit information on the use of animals for scientific purposes. Following the transposition of the directive into UK law in January 2013, through amendment regulations to the Animals (Scientific Procedures) Act 1986, sections 21A(1) and 21A(2) state:

- (1) In each year, beginning with the year 2015, the Secretary of State must by 10 November:
- (a) collect and publish statistical information on the use of protected animals in regulated procedures during the previous year;
 - (b) lay that information before Parliament; and
 - (c) send that information to the European Commission.
- (2) The statistical information must include information—
- (a) on the actual severity of the regulated procedures; and
 - (b) on the origin and the species of any primates used in regulated procedures.

This release covers Great Britain while the Northern Ireland Department of Health separately collects and publishes information on regulated procedures under devolved arrangements.

Key definitions

Protected animals are defined in the 1986 Act¹³ as any living vertebrate other than man and any living cephalopod. Regulated procedures are defined in the 1986 Act as any procedure applied to a protected animal for an experimental or other scientific purpose, or for an educational purpose¹⁴, 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. As the 1986 Act indicates, the breeding of an

¹² See: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063>.

¹³ Section 1(1). The remainder of section 1 provides greater detail on what protected animals cover.

¹⁴ Sections 2(1) and 2(1A). The remainder of section 2 provides greater detail on what regulated procedures cover.

animal¹⁵ is a regulated procedure if the animal is bred from, or is the descendant of, an animal whose genes have mutated or been modified.

Non-experimental agricultural practices, non-experimental clinical veterinary practices, practices undertaken for the purposes of recognised animal husbandry, and the administration of any substance or article to an animal for research purposes in accordance with an animal test certificate granted under the Veterinary Medicines Regulations 2013¹⁶ are excluded from the controls of the 1986 Act.

The general system of control under the 1986 Act is explained in detail in Appendix B of the main statistical report for 2016¹⁷.

¹⁵ Section 2(3B).

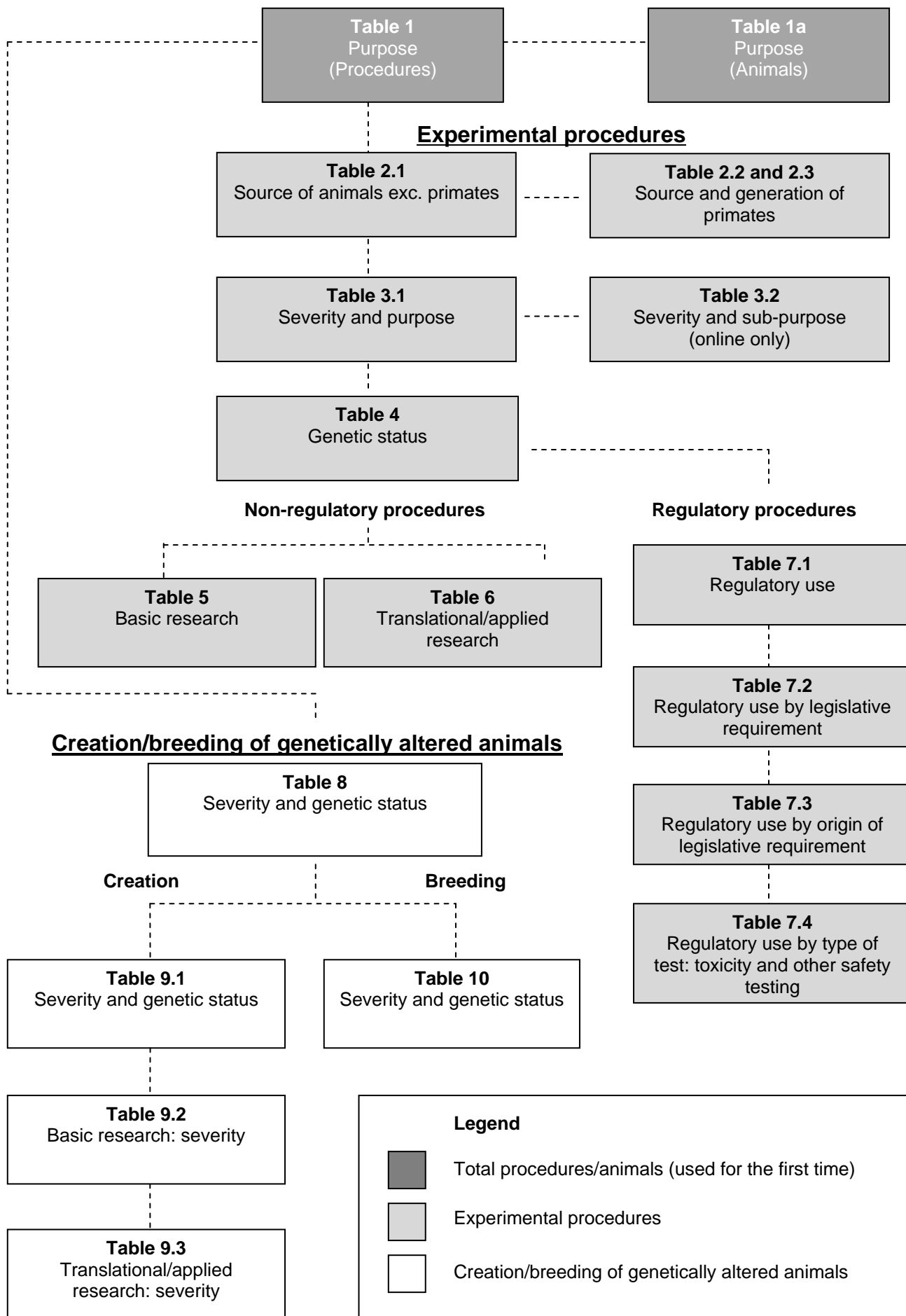
¹⁶ Statutory Instrument 2013/2033; see Part 1, Sect 3(2)(b)
<http://www.legislation.gov.uk/uksi/2013/2033/contents>.

¹⁷ See: <https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2016>.

Explanatory notes for 2016 data tables

Organisation chart

All procedures



Species of animal

All of the 2016 data tables, except Table 11, are classified by species of animal.

Full species breakdowns are provided in Tables 1, 1a, 2.1, 2.2, 2.3, 3.2 (online only), 4, 5, 6, 7.1 and 7.3, while Tables 3.1, 7.2, 7.4, 8, 9.1, 9.2, 9.3 and 10 use aggregated species groupings. For example, Table 1 contains breakdowns on marmosets and tamarins, cynomolgus monkeys, and rhesus monkeys, while Table 3.1 aggregates these to form 'primates'.

All tables are based on the number of procedures except 1a, 2.1, 2.2 and 2.3 which are based on the number of animals used for the first time in procedures.

In several of the tables (Tables 3.1, 3.2, 8, 9.1, 9.2, 9.3 and 10 in 2016) species are not listed in instances where the number of procedures completed in 2016 was 0.

Purpose

Total procedures (Tables 1, 1a and 11)

Total procedures is the sum of experimental procedures and procedures involving the creation/breeding of genetically altered animals (see below for more details).

Experimental procedures (Tables 2, 2.2, 2.3, 3.1, 3.2 (online only), 4, 5, 6, 7.1, 7.2, 7.3 and 7.4)

Experimental procedures includes all animals used in basic research, regulatory use, translational/applied research, protection of the natural environment, higher education and training, preservation of species and forensic enquiries. It excludes the use of animals for the creation of new lines of genetically altered animals and the breeding of established lines of genetically altered animals that were not used in further regulated procedures. The purpose categories for experimental procedures are listed below.

- **basic research:** includes studies of a fundamental nature, including physiology
 - these studies are designed to add knowledge about the normal and abnormal structure, functioning and behaviour of living organisms and the environment; these include fundamental studies in toxicology
- **translational and applied research:** studies that are designed to address human or animal disease including development of drugs and treatments but excluding studies carried out for regulatory purposes
- **protection of the natural environment:** studies in the interests of the health or welfare of human beings or animals
 - this includes studies aimed at investigating and understanding phenomena such as environmental pollution, loss of biodiversity and epidemiology studies in wild animals; this excludes the regulatory use of animals for ecotoxicology purposes
- **preservation of species:** includes research where the primary purpose is the preservation of a species
- **higher education or training:** studies for the acquisition, maintenance or improvement of vocational skills

- **forensic enquiries:** includes tests as part of forensic investigations and the production of materials, for example, antisera, for use in forensic investigations where this is not being carried out to meet a regulatory requirement
- **regulatory:** includes all procedures carried out to satisfy legal requirements including the production of substances to legal specification, such as material for diagnostic tests (e.g. blood products), studies to evaluate the safety or effectiveness of pharmaceuticals and studies to evaluate the safety of other chemicals

Procedures by purpose are shown in Tables 1, 1a, 3.1 and 3.2 (which is only available online and shows all sub-purposes). Table 5 is based on basic research alone, Table 6 is based on translational/applied research alone, and Tables 7.1, 7.2, 7.3, and 7.4 are based on regulatory use alone (with 7.4 being based on toxicity and other safety testing, a subset of regulatory use).

Creation and breeding of genetically altered animals not used in experimental procedures (Tables 8, 9.1, 9.2, 9.3 and 10)

This includes the use of animals for the creation of new lines of genetically altered animals, and the breeding of established lines (for the maintenance of colonies) of genetically altered animals that were not used in further regulated procedures. This category also includes some animals that were bred with the intention of producing genetically altered animals, but resulted in non-genetically altered animals being born. In addition, some animals used for the creation of a new genetic line would also have been genetically normal animals e.g. those used for superovulation.

While Tables 9.1, 9.2 and 9.3 are based on the creation of genetically altered animals not used in experimental procedures, they also detail the primary scientific purpose for which the new genetic line was created. Table 9.1 shows purpose breakdowns for basic research and translational/applied research, Table 9.2 is based on basic research alone and Table 9.3 is based on translational/applied research alone.

Place of birth of animals

Species listed in Schedule 2 of the Animals (Scientific Procedures) Act 1986 must be purpose bred (i.e. born at a licensed establishment in the UK or at a registered breeder elsewhere in the EU), unless the Secretary of State has specifically authorised sourcing from elsewhere (e.g. wild caught birds and small rodents). This is generally only authorised when there is a scientific justification for doing so. There is no requirement for species not listed in Schedule 2 to be purpose bred.

The species listed in Schedule 2 are: mice; rats; guinea-pigs; hamsters; gerbils; rabbits; cats; dogs; ferrets; non-human primates; common quail (*Coturnix coturnix*); any frog of the species *Xenopus laevis*, *Xenopus tropicalis*, *Rana temporaria* or *Rana pipiens*; zebrafish; genetically modified pigs and genetically modified sheep.

All species except non-human primates (Table 2.1)

The place of birth of all species except non-human primates is categorised according to whether they were born in the UK at a licensed establishment, born in the UK but not at a licensed establishment, born elsewhere in the EU at a registered breeder, born elsewhere in the EU but not at a registered breeder, born in the rest of Europe or born in the rest of the world.

Non-human primates (Tables 2.2 and 2.3)

The place of birth of non-human primates is classified according to whether they were born in the UK at a licensed establishment, born elsewhere within the EU at a registered breeder, born in the rest of Europe, born in Asia, born in America, born in Africa, or born elsewhere.

The generation of primates is classified according to whether they were wild caught (F0), were first generation born in captivity (F1), grandparent or earlier generation were wild caught (F2 or greater) or were from a self-sustaining colony.

Severity (Tables 3.1, 3.2 (online only), 8, 9.1, 9.2, 9.3, 10)

The severity of procedural harms (i.e. excluding harms caused to animals as a result of non-procedural events such as transport and housing) is assessed as one of five categories:

- **sub-threshold**: when a procedure was authorised under a project licence but did not actually cause suffering above the threshold of regulation (ASPA Section 2(1)), 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**: the key characteristic of mild procedures is that any pain or suffering experienced by an animal is, 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 characteristic of moderate procedures is that they do cause a significant and easily detectable disturbance to an animal's normal state, but this is 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 characteristics of severe procedures are that they cause a major departure from the animal's usual state of health and well-being. It would usually include long-term disease processes where assistance with normal activities such as feeding and drinking are 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

Full details of severity assessment and classification can be found in Annex 8 of the European Directive and in the Home Office guidance notes¹⁸.

The severity of genetically altered animals created/bred is assessed from:

- the 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 for genotyping¹⁹, the biopsy procedures would generally be assessed as mild

¹⁸ See:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/276014/NotesActualSeverityReporting.pdf.

¹⁹ 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.

- the animals assessed as severe in this category are expected to be 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 genetically altered animals would have been subjected to surgical or minor procedures such as the injection of drugs

Genetic status of animal (Tables 4, 8, 9.1 and 10)

Genetically altered animals are reported separately according to whether they have a harmful phenotype (i.e. a harmful physical or biochemical defect) or not. Many lines of genetically altered animals do not exhibit any harmful phenotype and are visually and behaviourally indistinguishable from wild type animals. Some show a harmful phenotype from birth, e.g. immune deficient mice; others are overtly normal at birth but exhibit a harmful phenotype, such as developing tumours, as they age. Animals are reported as being without a harmful phenotype if used/killed at an age prior to the development of the harmful effect.

Prior to 2014, data were collected separately on genetically modified animals and animals with a harmful genetic mutation. From 2014, data on these are now collected together as genetically altered animals with or without a harmful phenotype. The definitions for genetically altered animals are fully comparable between data prior to and subsequent to the change in 2014.

Basic research (Table 5)

Basic research covers studies that are designed to add knowledge about the normal and abnormal structure, functioning and behaviour of living organisms and the environment. These include fundamental studies in toxicology.

Table 5 shows experimental procedures undertaken for basic research purposes by sub-purpose. Some specific points on sub-categories are:

- **oncology:** includes any research studying oncology regardless of target system
- **nervous system:** includes neuroscience, peripheral or central nervous system, psychology
- **sensory organs:** covers skin, eyes, ears (studies involving the nose should have been recorded under respiratory system and studies involving the tongue should have been recorded under gastrointestinal system including liver)
- **multisystemic:** research where more than one system was the primary interest, for example, some infectious diseases, but excluding oncology
- **ethology/animal behaviour/animal biology:** covers both animals in the wild and in captivity with the primary goal of learning more about that specific species

Translational/applied research (Table 6)

Translational or applied research covers studies that are designed to address human or animal disease including the development of drugs and treatments but excluding studies carried out for regulatory purposes.

Table 6 shows experimental procedures undertaken for translational/applied research purposes by sub-purpose. Some specific points on sub-categories are:

- **human cancer:** includes any applied research studying human cancer, regardless of the target
- **human infectious disorders:** includes any applied research studying human infectious disorders, regardless of the target
- studies on the nose should have been recorded under **human respiratory disorders** and studies on the tongue should have been recorded under **human gastrointestinal disorders** including liver
- **diagnosis of diseases:** includes animals used in direct diagnosis of diseases such as rabies, botulism, but excluding those covered under regulatory use
- **non-regulatory toxicology:** covers discovery toxicology, method development and investigations prior to formal regulatory studies; this category does not include studies required for regulatory submissions
- **animal welfare:** includes studies as per Article 5(b)(iii) of Directive 2010/63/EU

Regulatory use

This category includes all experimental procedures carried out to satisfy legal requirements including the production of substances to legal specification, such as material for diagnostic tests (e.g. blood products), studies to evaluate the safety or effectiveness of pharmaceuticals and studies to evaluate the safety of other chemicals.

As of 2014, specific information is collected on regulatory use. Some of this information was previously reported as applied studies. Fundamental toxicological research, method development, and those safety-related procedures, for which there is no regulatory requirement, are now reported under translational/applied research.

Regulatory use by the type of regulatory use (Table 7.1)

The types of regulatory use are:

- **routine production:** applies to manufacturing processes requiring regulatory approval
- **quality control (including batch safety and potency testing):** includes animals used in the testing of purity, stability, efficacy, potency and other quality control parameters of the final product and its constituents, and any controls carried out during the manufacturing process for registration purposes, to satisfy any other national or international regulatory requirements or to satisfy the in-house policy of the manufacturer; this includes pyrogenicity testing
- **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
- **toxicity and other safety testing including pharmacology:** includes safety evaluation of products and devices for human medicine and dentistry and veterinary medicine. Covers studies carried out on any product or substance to determine its potential to cause any dangerous or undesirable effects in humans or animals as a result of its intended or abnormal use, manufacture or as a potential or actual contaminant in the environment

Regulatory use by legislative requirement (Table 7.2)

The legislative requirement should be as per the intended primary use. For example, if the regulatory use concerned tap water for drinking it should have been reported as food legislation.

Regulatory use by the origin of the legislative requirement (Table 7.3)

The categories for providing information on the origin of the legislative requirement are:

- **legislation satisfying EU requirements:** this includes national legislation derived from EU legislation and also includes any international requirement that at the same time satisfied EU requirements
- **legislation satisfying UK requirements only:** when the test was carried out to satisfy the requirements of one or more EU Member States, not necessarily the one in which the work was carried out; however, there was no equivalent requirement in the EU
- **legislation satisfying non-EU requirements:** when there was no equivalent requirement to carry out the test to satisfy EU requirements

Regulatory use by type of test – toxicity and other safety testing including pharmacology (Table 7.4)

Table 7.4 is a subset of Table 7.1 and shows toxicity and other safety testing including pharmacology by the type of test.

Total procedures and the project licences by type of licensed establishment (Table 11)

Total procedures is the sum of experimental procedures and procedures involving the creation/breeding of genetically altered animals.

The types of licensed establishment are: public health laboratories, universities, medical schools, National Health Service (NHS) hospitals, government departments, other public bodies, non-profit-making organisations, and commercial organisations.

The table shows figures on the number of project licences where countable procedures (see below) were completed, the number of project licences where only non-countable procedures (see below) were completed, the number of project licences where no procedures were completed, and the total number of project licences.

Procedures on adult or free-living animals (including neonatal and juvenile mammals, and newly hatched birds) are counted. Procedures on immature forms (e.g. larvae, embryos, fish fry) are not counted unless they have reached the free-feeding stage (e.g. zebrafish fry from five days post-fertilisation and tadpoles). Animals in the wild involved in rodenticide trials are also not counted. However, information is collected on the number of project licences which undertake rodenticide trials.

Using the statistics

The following list of uses of official statistics was produced (October 2010) by the UK Statistics Authority. A range of the expected uses of the statistics is given below and the examples are marked with a tick ✓

I. Informing the general public's choices:

- a. about investment decisions
- b. about service providers
- c. about lifestyle choices
- d. about the state of the economy, society and the environment ✓ e.g. via Parliament and the media
- e. about the performance of government and public bodies ✓ e.g. via Parliament and the media

II. Government decision making about policies, and associated decisions about related programmes and projects:

- a. policy making ✓
- b. policy monitoring ✓

III. Resource allocation – typically by central and local government ✓

IV. Informing private sector commercial choices: ✓

- a. targeting local markets
- b. targeting households and individuals
- c. designing market research surveys

V. Informing public marketing campaigns

VI. Supporting third-sector activity:

- a. lobbying ✓
- b. funding applications ✓

VII. Facilitating academic research ✓

Coverage for the 2015 statistics

Animal Aid

<https://www.animalaid.org.uk/new-government-vivisection-figures-scandal-continues/>

BBC

<http://www.bbc.co.uk/news/science-environment-36843587>

Breaking news

<http://www.breakingnews.ie/world/youll-be-shocked-to-know-how-many-lab-tests-were-carried-out-on-animals-in-the-uk-last-year-745756.html>

Cruelty Free International

<https://www.crueltyfreeinternational.org/what-we-do/breaking-news/unacceptable-levels-animal-suffering-uk-laboratories-2015>

Daily Express

<http://www.express.co.uk/news/nature/691576/Theresa-May-told-use-Brexit-end-cruel-animal-experiments>

Daily Mirror

<http://www.mirror.co.uk/news/uk-news/revealed-full-horror-brutal-animal-8452471>

Guardian

<https://www.theguardian.com/science/2016/jul/20/rise-in-number-of-animals-used-in-uk-research-home-office-report-shows>

Huffington Post

http://www.huffingtonpost.co.uk/entry/2015-animal-experiment-statistics-home-office-rise-in-animal-testing_uk_578f4136e4b0b545e5cbf920

Independent

<http://www.independent.co.uk/news/uk/home-news/brexit-animal-testing-stats-figures-increase-monkey-lab-tests-a7146351.html>

NC3Rs

<http://www.nc3rs.org.uk/news/home-office-statistics-announced-2015>

PETA

<http://www.peta.org.uk/blog/4-14-million-experiments-animals-uk-2015/>

RSPCA

<https://www.rspca.org.uk/adviceandwelfare/laboratory>

RT

<https://www.rt.com/uk/352292-brexit-animal-testing-regulation/>

Speaking of Research

<https://speakingofresearch.com/2016/07/20/animal-experiments-in-the-uk-statistics-show-4142631-procedures-in-2015/>

Yorkshire Post

<http://www.yorkshirepost.co.uk/news/more-than-100-000-animals-suffered-severe-pain-in-experiments-1-8025016>

Users

As well as Parliament, the media, the general public and individual licensees, there is a wide range of organisations with an interest in these statistics; some examples are listed below (the list is illustrative and not meant to be exhaustive).

Animals in Science Committee:

<https://www.gov.uk/government/organisations/animals-in-science-committee>

Animals in Science Regulation Unit, Home Office:

<https://www.gov.uk/guidance/research-and-testing-using-animals>

Cruelty Free International:

<https://www.crueltyfreeinternational.org/>

European Commission:

http://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm

Federation of European Laboratory Animal Science Associations:

<http://www.felasa.eu/>

Fund for the Replacement of Animals in Medical Experiments:

<http://www.frame.org.uk/>

Institute of Animal Technology:

<http://www.iat.org.uk/>

Laboratory Animal Science Association:

<http://www.lasa.co.uk/>

Laboratory Animals Veterinary Association:

<http://www.lava.uk.net/>

National Anti-Vivisection Society:

<http://www.navs.org.uk/>

National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs):

<http://www.nc3rs.org.uk/>

Research funders e.g. Wellcome Trust (<https://wellcome.ac.uk/>) and Medical Research Council (<http://www.mrc.ac.uk/>)

RSPCA:

<http://www.rspca.org.uk/>

Understanding Animal Research:

<http://www.understandinganimalresearch.org.uk/>

Collection procedures, coverage, confidentiality and quality assurance

Collection and coverage

The statistics are compiled from returns submitted by project licence holders at the end of each year, or on the termination of the licence when this occurs during the year. The instructions for the completion of annual returns of procedures in the UK can be found at the back of this user guide. The instructions include code lists for describing procedures.

Each procedure (which may consist of several stages) for a given purpose on an animal is counted as one returnable procedure for the year in which it was completed. A study involving procedures on a number of animals is counted once for each animal. Where an animal that has recovered fully from a completed procedure is used again for a further procedure it is counted as a separate procedure, but the animal itself is not re-counted. The circumstances in which the re-use of an animal is permitted are limited.

Licence holders are required, as a condition of their licence, to submit a return even if no work has been undertaken (nil returns). A record is kept of all licensees from whom returns have been received. Those who fail to do so are reminded of their obligation under the Animals (Scientific Procedures) Act 1986.

To ensure that the published data are as complete as possible the Home Office will not publish the statistics unless the number of missing returns represents less than 0.5% of all the returns expected. In 2016, returns were provided under 3,189 project licences, all of those in force for all or part of the year.

Confidentiality

Detailed information on the work of individual project licence holders is not readily identifiable in this publication.

Quality assurance

Home Office statisticians undertake a wide range of quality assurance checks with the expert assistance of colleagues in the Animals in Science Regulation Unit, and with follow-up contact with licensees as needed. The checks include:

- checking that incomplete data have not been provided in returns
- checking that invalid data or invalid combinations of data have not been provided in the returns
- checking that duplicate returns have not been provided
- checking that all licensees expected to provide returns have done so
- investigating returns which contain unusual data or unusual combinations of data
- variance checks i.e. investigating substantial changes in figures compared with the previous year

Details of previous annual publications

The most recent editions of this statistical release can be found at:

<https://www.gov.uk/government/collections/statistics-of-scientific-procedures-on-living-animals>

Older editions of this statistical release can be found at:

<http://webarchive.nationalarchives.gov.uk/20100613204643/http://rds.homeoffice.gov.uk/rds/scientific1.html>

Annual publications giving detailed figures for scientific procedures under the Animals (Scientific Procedures) Act 1986 were published as 'Statistics of Scientific Procedures on Living Animals' as follows:

Year	House of Commons/ Command Paper	Year	Command Paper
2016	HC 231	2001	Cm 5581
2015	HC 555	2000	Cm 5244
2014	HC 511	1999	Cm 4841
2013	HC 372	1998	Cm 4418
2012	HC 549	1997	Cm 4025
2011	HC 345	1996	Cm 3722
2010	HC 1263	1995	Cm 3516
2009	HC 317	1994	Cm 3012
2008	HC 800	1993	Cm 2746
2007	HC 933	1992	Cm 2356
2006	Cm 7153	1991	Cm 2023
2005	Cm 6877	1990	Cm 1574
2004	Cm 6713	1989	Cm 1152
2003	Cm 6291	1988	Cm 743
2002	Cm 5886	1987	Cm 515

Detailed figures for experiments on living animals under the Cruelty to Animals Act 1876 were published as 'Statistics of experiments on living animals' as follows:

Year	Command Paper	Year	Command Paper
1986	Cm 187	1981	Cmnd 8657
1985	Cmnd 9839	1980	Cmnd 8301
1984	Cmnd 9574	1979	Cmnd 8069
1983	Cmnd 9311	1978	Cmnd 7628
1982	Cmnd 8986	1977	Cmnd 7333

Less detailed information about experiments on living animals for the years prior to 1977 was published in the form of a 'Return to an Address of the Honourable the House of Commons'.

Further information

Information about the work of the Animals in Science Regulation Unit can be found in the latest Annual Report of the Home Office Animals in Science Regulation Unit at:

<https://www.gov.uk/government/collections/animals-in-science-regulation-unit-annual-reports>

A consolidated version of the Animals (Scientific Procedures) Act 1986 can be found at:

<https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986>

Guidance on the operation of the Animals (Scientific Procedures) Act 1986 can be found at:

<https://www.gov.uk/government/publications/operation-of-aspa>

Information about the Animals in Science Committee can be found at:

<https://www.gov.uk/government/organisations/animals-in-science-committee>

Information about the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) can be found at:

<http://www.nc3rs.org.uk/>.

Information relating to Northern Ireland is published by the Northern Ireland Department of Health and can be found at:

<https://www.health-ni.gov.uk/articles/animal-scientific-procedures#toc-1>

Information relating to the EU is available on the European Commission's website:

http://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm

Instructions for completion of annual Returns of Procedures in the UK

These instructions have been adapted from the EU Commission Implementing Decision of 14 November 2012:

http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm

They apply to Returns of Procedures completed in 2017.

The Excel form should be completed (one form for each project licence held during the year), saved using the project licence number as the filename in the format:

7001234 (i.e. replacing the '/' in 70/1234 with a zero)

- and sent to the Home Office at:
ROPReturns@homeoffice.gsi.gov.uk

Note: In contrast to years prior to 2014, procedures will be counted when they end, not when they begin. **Procedures begun in a previous year, and which have already been reported, but which end in 2017, should be counted again when they end with details of actual severity.**

Complete the preliminary questions on the establishment details tab.

Project details:

- Complete name of individual completing the return, name of project licence holder, establishment address and email address as per project licence. Provide a telephone number where you can be contacted if we need to seek further information on this Return.
- Complete the Establishment Licence number. This is shown on your project licence and can be obtained from the Home Office Liaison Contact or the Establishment Licence Holder. This should be in the format 4001001 (i.e replacing the '/' in 40/1001 with a zero) if you do not have an ASPeL licence. If you do have an ASPeL licence the licence number should be 9 characters long and start with an 'X'.
- Complete project licence number in the format 7001234 (i.e. replacing the '/' in 70/1234 with a zero) if you do not have an ASPeL licence. If you have an ASPeL project licence the licence number should be 9 characters long and start with a 'P'.

Guidance Notes 2017

Last updated 26 January 2017

- The report year will already be completed. This return should contain details of all procedures **completed** during that year, regardless of when they started.

The following questions must be answered:

1. Were any procedures carried out and completed in the reported year?

- **If 'No' then there is no need to complete the rest of this form so please return the form to the Home Office as described above.**
- **If 'Yes' then continue.**

2. Were only 'protected' embryonic forms (i.e. of sufficient age to be regulated) used exclusively.

This refers to mammalian embryos between two-thirds of gestation and term (prior to birth), avian and reptile eggs from two-thirds of incubation prior to hatching. Larvae prior to the free feeding stage are not regulated and as such should not be counted.

- **If 'Yes' only 'protected' embryonic forms were used (you did not use any postnatal forms), there is no need to complete the rest of this form.**
- **If 'No' and later stages were used then continue to provide further details of those animals but do not provide further details of embryonic forms.**
- **Note that embryonic forms of amphibian and larval forms of fish fry from the point when they become "protected animals", i.e. from when they are capable of free feeding, should be reported. For zebra fish kept under conventional conditions this means from 5 days post fertilisation.**

3. Endangered species. Were any animals used of species listed in [Annex A of Council Regulation \(EC\) No 338/97](#) of 9th December 1996. Annex A is based on Appendix 1 of CITES but may contain additional species.

However, captive bred animals of species listed in Annex A should not be returned as endangered species in the return of procedures.

- **If 'Yes' please provide details in the additional comments box.**

Note this does not refer to species listed in CITES appendix 2 (or Annex B).

Guidance Notes 2017

Last updated 26 January 2017

4. Were neuromuscular blocking agents used in any procedures during the previous year?
 - **If 'Yes' please answer the next question. If general anaesthesia was not used throughout the entire period of neuromuscular blockade then please provide details in the additional comments box.**
5. Rodenticide trials. Indicate if rodenticide trials were carried out under this project licence in the year relating to this return. There is no need to provide further details of those trials.

If you answered 'Yes' to question 1 above and 'No' to question 2 above please provide further details of procedures in the 'Procedure details' tab (this tab will only appear when both these criteria have been satisfied).

General

1. Data should be provided on each procedure, i.e. each use of an animal. If an animal has been used in more than one study or experiment, i.e. re-used, provide details on each use in a separate row.
2. Using the drop-down lists, choose one option for each column for each row. If necessary choose the 'best fit' from the drop down list options. If you select 'Other' please provide additional details in the appropriate column.
3. Do not count animals unless used on **regulated procedures** (these are procedures authorised on a project licence). Animals killed by Schedule 1 (or other PEL-permitted) methods of killing, for example, for tissue collection, are not counted unless they were genetically altered and bred under project licence authorities.
4. Surplus animals that are killed are not included, unless they have been produced under project licence authority, for example, genetically altered animals.
5. Mammals, birds and reptiles are only counted if they are born alive (including by caesarean section) or hatch.
6. Larval and embryonic forms are counted from when they become capable of free feeding. Zebra fish fry kept under conventional conditions should be counted from five days post-fertilisation.
7. Cephalopods should be counted from the stage at which the animal becomes capable of independent feeding. This will be immediately post-hatching for octopus and squid, and from around seven days post-hatching for cuttlefish.
8. In the case of very small animals, such as fish fry, an estimate of the total numbers used is acceptable.
9. In exceptional cases where a single study involving a large group of animals extends over two calendar years, and data collection is not complete until the end of the entire study (as opposed to at the time of death of each individual subject) it is acceptable to count all procedures in

Guidance Notes 2017

Last updated 26 January 2017

the year in which the last procedure ends, i.e. at the end of the study. This must be agreed with your Home Office Inspector in advance.

Data categories

Do not leave any relevant cells blank.

NB. Depending on previous entries, some cells will remain blank and will not allow information to be entered.

Use the drop down lists. Only enter free text in the 'Other ...' columns if this is relevant.

A single row can be completed for any number of procedures if all the details are identical, for example:

- a single animal, one procedure;
- a single experiment, a number of procedures; or
- a group of studies, many procedures.

However, if the number is large (see 'Column G - Number of procedures' section below) for a single cell you may need to explain the reason in the 'Comments 1' field (Column W).

Column E - Animal species

- Select the species from the drop down list.
- All cephalopods, regardless of species, should be reported under the one heading 'Cephalopod'.

Column F - Other species

- If you selected 'Other' in Column E then you must provide details of the actual species here, otherwise leave blank.

Column G - Number of procedures

- This of the number of uses, i.e. the number of times animals were used in a particular experiment or study.
- If an animal has been used multiple times then the number of procedures is the number of times it was used.

Example: PROCEDURE

10 rats were used in a study involving administration of a drug then 7 separate blood samples and a final surgical intervention, before being killed by a Schedule 1 method.

Guidance Notes 2017

Last updated 26 January 2017

Number of procedures = 10

Re-use = No

Note: If an animal is used on a long study, extending over more than one calendar year, it should not be counted until that procedure ends.

Example: PROCEDURE OVER TWO CALENDER YEARS

In November 2016 10 rats were used in a study that ended when all of the rats were killed in March 2017.

Number of procedures reported in the 2016 return = 0

All will be returned in the 2017 return.

Large numbers of procedures

- If more than 99 non-human primates or 999 of any other species are entered in a single cell then you should add a note in the 'Comments 1' field (Column W).
 - If the large number applies to a single study then briefly explain why so many animals were used in the 'Comments 1' field (Column W).
 - If multiple studies have been combined into one entry, and this is the reason for the large number, simply state e.g. 'Combination of studies' in the 'Comments 1' field (Column W).
 - If a large number of animals used on the same breeding protocol has been entered on one line, simply state "Breeding" in the 'Comments 1' field (Column W).

Column H - Re-use

- Each animal should be reported at the end of each procedure for which it was used. Most animals are used only once, and 'No' should be entered in this column. If an animal has been used before (at any time, not just in the reported year) enter 'Yes' in this column.
- Re-use must have been authorised in the project licence.

Example: RE-USE

10 rats were cannulated and used in a study involving administration of a drug then 7 separate blood samples.

At the end of that study those same rats had a wash out period then were used again to test a separate drug. There was no need to use the same rats for the second study, therefore the second study constitutes "Re-use"

Guidance Notes 2017

Last updated 26 January 2017

First Row:

Number of procedures = 10 and Re-use = No,
THEN IN A SECOND ROW

Number of procedures = 10 and Re-use = Yes (the place of birth for these re-use procedures is not completed).

Example: RE-USE

100 sheep were used to supply normal blood by being bled repeatedly at approximately monthly intervals.

90 had been used in previous years. 10 were bought in during this reporting year.

Each bleed constitutes a separate procedure, therefore all except the first bleed constitutes "re-use".

Each sheep was bled 10 times, therefore the total number of procedures was 1000 and should be reported in 3 (or possibly 2) separate rows of data, as follows:

Row 1.

The previously used sheep.

Number of procedures = 900, Re-use = Yes and the place of birth column is not completed.

Row 2.

The new sheep, first bleed.

Number of procedures = 10, Re-use = No and the place of birth column is completed.

Row 3 (or added to Row 1)

The second and subsequent bleeds of the new sheep.

Number of procedures = 90, Re-use = Yes and the place of birth column is not completed.

Note: For the purpose of statistical reporting a **single procedure, or use of an animal, extends from the time when the first technique was applied to the animal until the completion of data collection, observations or achievement of the particular purpose.** In most cases this means a single protocol.

'**Continued use**', when a single experiment or study extends over more than one licence or protocol, and constitutes a single use; it *is not re-use*. In this case the end user should report the entire procedure, even if it began on another project licence, and the initiator of the study does not report such procedures.

Guidance Notes 2017

Last updated 26 January 2017

Example: CONTINUED USE

10 rats were surgically prepared under Project Licence 7001234. This had actual severity of Moderate because it involved surgery.

These rats were then moved onto a different Project Licence 7005678 for use in a PK (pharmacokinetics) study. This part of the study has an actual severity of Mild.

PPL 7001234 does not report any of these rats.

PPL7005678 reports all 10 rats when the PK study is completed, and the Actual Severity is reported as Moderate to take account of the severity of the entire procedure which started on a different licence (or protocol).

Note that any subsequent PK studies using the same rats, reported as “Re-use” should have Actual Severity of Mild (if this is what happened on the re-use)

Continued use includes when genetically altered animals are bred under one licence then transferred to a second licence (possibly at a different establishment) for the remainder of the study; the breeder would not report these animals, they would be returned under the end user’s project licence return.

If in any doubt as to which classification is correct consult your Home Office Inspector.

Column I - Place of birth: all species except non-human primates

- Provide details of the place of birth of all species other than non-human primates (this column is disabled if non-human primates are entered).
- However, only provide details for the first use of an animal. If animals have been re-used, this column is disabled.
- For Schedule 2 species¹ NOT born at a licensed establishment or at a registered breeder, please provide an explanatory comment in the Comments 1 field (Column W). Schedule 2 species must be purpose bred, unless the Secretary of State has specifically authorised sourcing from elsewhere (e.g. wild caught animals).

Note: The *place of birth*, not the source of the animal, is required. A registered breeder can be any breeder within the EU who is registered under Article 20 of Directive 2010/63 EU. In the UK licensed establishments are registered breeders.

¹ Schedule 2 species are mice, rats, guinea pigs, hamsters, gerbils, rabbits, cats, dogs, ferrets, non-human primates, pigs (if genetically modified), sheep (if genetically modified), common quail (*Coturnix coturnix*), amphibians (of the species *Xenopus laevis*, *Xenopus tropicalis*, *Rana temporaria* and *Rana pipiens*), and zebrafish.

Guidance Notes 2017

Last updated 26 January 2017

Animals born in your own establishment should be entered as “Animals born in the UK at a licensed establishment”.

- In the case of eggs of birds, reptiles, amphibia and fish the “place of birth” should be the place where the eggs hatched, if this is different from where the eggs were produced.
- In the case of mammals where source of embryos is different from where the embryos are implanted or animals are born, the place of birth is the place where they were born, not the source of the embryos.
- The ‘Rest of Europe’ means Council of Europe² countries and Israel.

Example: PLACE OF BIRTH

1. Transgenic mice bred in house and used in a study.

Place of Birth “Animals born in the UK at a licensed establishment”

2. Transgenic mice bred at one university in the UK, licensed under Animals Scientific Procedures Act 1986 (ASPA), then moved to a different project licence at a second university for use in an experiment.

The PPL holder at the first university who supplied the mice does not report them at all.

The PPL holder who received and used the mice at the second university reports them all.

If 50 mice were supplied but actually only 40 were used, with the remaining 10 culled as surplus, the return would be as follows:

40 Mice, “Animals born in the UK at a licensed establishment” purpose as appropriate eg “Basic research; Immune system”

AND

10 mice “Animals born in the UK at a licensed establishment” purpose “Maintenance of established lines of GA animals”, because the only procedure the surplus 10 were subjected to was being born with a genetic alteration (even if this PPL does not authorise B&M).

3. Mice were bought from supplier, licensed under the EU Directive, in Germany.

Place of birth “Animals born in the EU (non UK) at a registered breeder”

4. Mice were bought from supplier in the USA.

Place of birth “Animals born in the rest of the world”

5. Cattle were sourced from a commercial dairy farm.

² Council of Europe countries are Albania, Andorra, Armenia, Azerbaijan, Bosnia & Herzegovina, Georgia, Iceland, Liechtenstein, Macedonia, Moldova, Monaco, Montenegro, Norway, Russian Federation, San Marino, Serbia, Switzerland, Turkey and Ukraine.

Guidance Notes 2017

Last updated 26 January 2017

Place of birth “Animals born in the UK but not at a licensed establishment”

6. Wild caught animals.

Place of birth “Animals born in the UK but not at a licensed establishment”

Column J - Place of birth: Non-human primates only

- Additional detail is required for non-human primates (NHPs). This column is disabled for all other species.
- Only provide details of the place of birth for the first use of an NHP. If NHPs have been re-used, this column is disabled.
- The *place of birth, not the source* of the animal, is required.
 - Asia includes China.
 - America includes North, Central and South America.
 - Africa includes Mauritius.
 - ‘Elsewhere’ includes Australasia. Provide details of place of birth in the Comments¹ column if this category is used.
- For non-human primates NOT born at a licensed establishment or at a registered breeder, please provide an explanatory comment in the Comments 1 field (Column W).

Column K - Non-human primate generation

- This column is required for non-human primates (NHPs). This column is disabled for all other species.
- Only provide details of the generation for the first use of an NHP. If NHPs have been re-used, this column is disabled.
- If sourced from a colony that is not self-sustaining then ‘F0’, ‘F1’ or ‘F2 or greater’ should be used.
- If the colony has become self-sustaining then you should enter every animal from this colony as ‘Self-sustaining colony’ regardless of generation of the individual animal, and not as ‘F0’, ‘F1’ or ‘F2 or greater’.

Column L - Genetic status

1: ‘Not genetically altered’: includes all wild-type animals, including inbred strains.

- This includes genetically normal parents of genetically altered offspring and genetically normal offspring.
- Triploid fish will generally be regarded as “Not genetically altered” unless induction of triploidy is specifically for a scientific purpose. If part

Guidance Notes 2017

Last updated 26 January 2017

of normal husbandry for the species (e.g. Salmonids) this should be reported as “Not genetically altered”.

- If “Not genetically altered” is reported in combination with the purpose “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures” (Column N), please provide an explanatory comment in the Comments 1 field (Column W).

‘Genetically altered animals (GAAs)’: includes all genetically modified animals (transgenic, knock-out and other forms of genetic alteration) and mutations, whether naturally occurring or induced.

2: ‘GAAs without a harmful phenotype’: includes all GAAs that do not show an overtly harmful phenotype, or individuals of strains on which a formal welfare assessment has been carried out which showed the strain to have either no phenotype or a phenotype of sub-threshold severity.

This category can apply to any purpose given in Column N. It includes animals used for the creation of new strains, animals used in further procedures and animals used for maintenance of established colonies.

Examples of GAA WITHOUT A HARMFUL PHENOTYPE

- Green fluorescent protein (GFP) expressing lines of mice or fish.
- Cre expressing lines of mice.
- Conditional genetic alterations without induction of conditional gene expression (assuming it is induction of expression that leads to harm, there may be examples where the reverse is the case).
- Transgenic and knockout mice which appear overtly normal

Also

- Strains of mice prone to disease, e.g. tumour development but used or killed prior to the onset of tumour development.

3: Genetically altered animals with a harmful phenotype.

- ‘GAAs with a harmful phenotype’ includes all GAAs that actually exhibit an overtly harmful phenotype at some time during the procedure. This category can apply to any purpose given in Column N. It includes animals used for the creation of new strains, animals used in further procedures and animals used for maintenance of established colonies, but only if a harmful phenotype manifests.
- If the strain is known to have a harmful phenotype but some individuals do not exhibit that phenotype, then do not use this category for those individuals, use ‘Genetically altered animals without a harmful phenotype’.

Example of GAA WITH A HARMFUL PHENOTYPE

Immunocompromised mice, e.g. Nudes, SCID, Rag KO. Although all of this type of strain have potentially harmful phenotypes and must be reported as such, the actual severity is likely to be “Sub-threshold” (if not used in further experiments)

EXAMPLE: Nude mice bred but not used in further studies and culled as surplus.

All will be reported under “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures” in Column N.

Heterozygous offspring

“Genetically altered without a harmful phenotype”, Actual severity “Sub-threshold”.

Homozygous Nude offspring:

Genetically altered with a harmful phenotype”, Actual severity “Sub-threshold”.

Wild type offspring. Not reported (unless genotyped by a regulated method, e.g. tail biopsy).

Column M - Creation of a new genetically altered animal line

- This category includes all animals involved in the creation of a novel line up to the point where a new line is considered ‘established’.
- This category includes the offspring from crossing of established lines of genetically altered animals; this is considered to lead to the creation of a new line. Crossing of a genetically altered animal with a wild type will not normally be considered to create a new line unless it is expected that the change of background will adversely affect the phenotype.
- Wild-type offspring that are not subjected to regulated procedures (for example, regulated genotyping methods) should not be reported.
- If “Yes” is used in this column, the purpose given in Column N **should not** be “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures”. The purpose given in Column N should be the primary scientific purpose for which the new strain was being created.
- It **excludes** animals of established strains on which a formal welfare assessment has been carried out and excludes long-standing strains of GAAs even if no formal welfare assessment has been carried out. These are reported as “No” in Column M and as “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures” in Column N.

Guidance Notes 2017

Last updated 26 January 2017

- Rederivation and archiving of lines is reported in Column N as “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures”.

Columns N and O - Purpose

- Classification of purpose is divided into two columns.
- **Column N** for the high level purpose, e.g. “Basic research”, “Translational/Applied research”, “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures”.
- **Column O** Sub purpose is for the sub-category of “Basic research”, “Translational/applied research” or “Regulatory use” only. The choices available in this column will be restricted to those relevant to the high level purpose given in Column N. For example, if “Regulatory Use” is entered in Column N then only the associated sub-categories will be available in Column O.
- If “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures”, “Higher education or training for the acquisition, maintenance or improvement of vocational skills”, “Forensic enquiries”, “Protection of the natural environment in the interests of the health or welfare of human beings or animals” or “Preservation of species” is entered in Column N then the drop-lists in Column O will be disabled and this column should be left blank.
- Choose the best fit for the purpose of the study. This will generally be the purpose given in the project licence. Please check that no other drop-down option is suitable before selecting “Other” as the sub-purpose.

1. Basic research includes studies of a fundamental nature, including physiology.

Studies that are designed to add knowledge about the normal and abnormal structure, functioning and behaviour of living organisms and the environment. These include fundamental studies in toxicology.

Investigation and analysis focused on a better or fuller understanding of a subject, phenomenon, or a basic law of nature instead of on a specific practical application of the results.

Any animals used for the creation of a new genetically altered animal (GAA) line (including the crossing of two established lines) intended to be used for the purposes of basic research should be recorded according to the purpose they are being created for and should be reported as ‘Yes’ in Column M ‘Creation of a new genetic line’.

Guidance Notes 2017

Last updated 26 January 2017

Basic research categories

- i. 'Oncology'. Any research studying oncology regardless of target system.
- ii. 'Nervous system'. Includes neuroscience, peripheral or central nervous system, psychology.
- iii. 'Sensory organs' (skin, eyes, ears).
You should report studies on the nose under 'Respiratory system' and those on the tongue under 'Gastrointestinal system including liver'.
- iv. 'Multisystemic'. Should only include research where the aim is to study multiple systems for example, some infectious diseases. However, if there is a primary target system, please report the primary target system as the sub-purpose. This category excludes oncology.
- v. 'Ethology/animal behaviour/animal biology' category covers both animals in the wild and in captivity with the primary goal of learning more about that specific species.
- vi. Dentistry should be reported under 'dentistry' not 'musculoskeletal system'.
- vii. 'Other'. Research not related to an organ/system listed above or is not organ/system specific.

Animals used for the production and maintenance of infectious agents, vectors and neoplasms or other biological material, and animals used for the production of antibodies, but excluding production of monoclonal antibodies by ascites method (which is covered under purpose "Regulatory use" and sub-purpose "Routine production ..."), should be reported under "Basic research" or "Translational/applied research". Where the purpose could be reported under the two categories you should only report the main purpose.

2. Translational/applied research includes discovery toxicology, investigations prior to formal regulatory studies and method development. It includes efficacy testing during the development of new medicinal products. It **does not** include studies required for regulatory submissions.

Any animals used for the creation of a new genetically altered animal line (including the crossing of two established lines) intended to be used for the purposes of translational and applied research should be recorded according to the purpose they are being created for and should be reported as 'Yes' in Column L 'Creation of a new genetic line'.

Translational and applied research categories

- i. "Human cancer". You should include any applied research studying human cancer, regardless of the target.
- ii. "Human infectious disorders". You should include any applied research studying human infectious disorders, regardless of the target.
- iii. Any regulatory use of animals is to be excluded, such as regulatory carcinogenicity studies.

Guidance Notes 2017

Last updated 26 January 2017

- iv. You should report studies on disorders of the nose under “Human respiratory disorders” and those of the tongue under “Human gastrointestinal disorders including liver”.
- v. Human dentistry should be reported under ‘human dentistry’ not ‘musculoskeletal system’.
- vi. Renal disease should be reported under “Human urogenital/reproductive disorders”.
- vii. “Diagnosis of diseases” includes animals used in direct diagnosis of diseases such as rabies, botulism, but excludes those covered under regulatory use.
- viii. Non-regulatory toxicology’ covers discovery toxicology and investigations prior to formalising the regulatory studies and method development. This category does not include studies required for regulatory submissions (preliminary studies, maximum tolerated dose).
- ix. Animal welfare should include studies as per Article 5(b)(iii) of Directive 2010/63 EU i.e. “the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes”

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

This includes studies aimed at investigating and understanding phenomena such as environmental pollution, loss of biodiversity and epidemiology studies in wild animals.

This excludes the regulatory use of animals used for ecotoxicology purposes.

4. Preservation of species. This includes research where the primary purpose is the preservation of a species.

5. Higher education or training for the acquisition, maintenance or improvement of vocational skills in the tertiary educational setting.

This includes training to acquire and maintain practical competence in techniques as required under Article 23(2) of Directive 2010/63 EU.

6. Forensic enquiries. This includes tests as part of forensic investigations and the production of materials, for example, antisera, for use in forensic investigations where this is not being carried out to meet a regulatory requirement.

7. Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures.

This includes the animals required for the maintenance of colonies of genetically altered animals (GAAs); the intended purpose for which the line is being bred is not recorded (in contrast to “creation of new genetic lines”).

Guidance Notes 2017

Last updated 26 January 2017

It includes genetically altered breeding stock and surplus animals unless killed for use of tissues post mortem, i.e. all of the GAA that are bred but not used for a further scientific purpose, whether regulated or not.

This category should be used for established or long-standing strains of GAAs, i.e. those that have had a welfare assessment carried out, or those that are generating animals being used in experimental procedures. The latter can be considered effectively “established”. You should report the creation of new strains under the purpose for which they are being created.

Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures excludes:

- Genetically altered animals bred under project authorisation but killed using Schedule 1 listed methods whose tissues are then used for research: these should be reported under the purpose for which their tissues were used.
- Live animals that go on to be used in further regulated procedures.

Examples: HOW TO RETURN BREEDING AND MAINTENANCE OF COLONIES OF ESTABLISHED LINES OF GAA (B&M)

If the phenotype of offspring of a newly created line is not yet known, return under “Creation of new genetic line” (Column M) = Yes, then under appropriate purpose for which the new line was created, e.g. Basic Research (Column N) Oncology (Column O). **Do not record under Column N as B&M.**

If the line has been bred for more than 2 generations and its phenotype is known, further breeding should be reported under purpose as B&M. “Creation of new genetic line” = NO.

The line has no phenotype when heterozygous but homozygotes show paralysis from 6 months of age.

A heterozygous transgenic mouse is mated with a wild type mouse, and produces offspring:

- The transgenic parent is reported when it dies under: purpose B&M, genetic status “Genetically altered without a harmful phenotype” and actual severity “Sub-threshold”.
- The wild type parent is not reported
- All heterozygous offspring’s (F1) genetic status are reported as “Genetically altered without a harmful phenotype” and their actual severity are reported as “Sub-threshold”.
- Wild type offspring are not reported
- Occasional offspring have to have a second biopsy to confirm genotype.

This cannot be considered identification and so must be included in the severity assessment. These will be reported as actual severity = “Mild”, reflecting the biopsy procedure, whether transgenic or wild type.

The next generation is bred by crossing 2 heterozygous offspring:

- Parents (F1) are returned under genetic status as “Genetically altered without a harmful phenotype”, under purpose as B&M and under actual severity as “Sub-threshold”, when they are eventually culled.

Guidance Notes 2017

Last updated 26 January 2017

- Homozygous offspring (F2) culled at 3 months of age, before appearance of phenotype: are recorded under genetic status as “Genetically altered without a harmful phenotype” and under actual severity as “Sub-threshold”
- Some of these were used for tissues following Schedule 1 killing, these should be reported under the purpose for which the tissues were used, not under B&M.
- Some offspring were kept and culled because they developed paralysis. If these mice were discarded and tissues not used return under: purpose B&M, genetic status “Genetically altered with a harmful phenotype” and actual severity “Severe”.

8. Regulatory use and routine production - Use of animals in procedures carried out with a view to satisfying legal requirements for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed. For all Regulatory use, please provide the legislation name(s) and number(s) in the Comments 1 field (Column W).

Regulatory use includes tests carried out on products/substances for which no regulatory submission is made i.e. tests performed on those products/substances (for which a regulatory submission was foreseen) that are ultimately deemed unsuitable for the market by the developer, and thus fail to reach the end of the development process.

This category also includes animals used in the manufacturing process of products *if that manufacturing process requires regulatory approval* (for example, animals used in the manufacturing of serum-based medicinal products should be included within this category). This includes quality assurance and potency testing of biologicals.

The efficacy testing during the development of new medicinal products is excluded and you should report this under “Translational/applied research”.

Categories of regulated use and routine production:

- **Routine production.** Applies to manufacturing processes requiring regulatory approval.
 - PR51 Routine production/blood-based products: Blood products including serum and polyclonal antisera by established methods.
 - PR52 Routine production/monoclonal antibodies: Covers the production of monoclonal antibodies by ascites. This excludes immunisation of animals for hybridoma production, which should be captured under ‘Basic research’ or ‘Translational and applied research’ under the appropriate category.
 - PR53 Other forms of production of biological material to meet regulatory standards or requirements that use live animals.

Guidance Notes 2017

Last updated 26 January 2017

Note that production of antibodies, antigens etc. using routine or standard methods but not to meet a regulatory requirement should be reported under “Basic research”, “Translational/applied research” etc.

- **Quality control (including batch safety and potency testing)**
Quality control includes animals used in the testing of purity, stability, efficacy, potency and other quality control parameters of the final product and its constituents. It also includes any controls carried out during the manufacturing process for registration purposes, to satisfy any other national or international regulatory requirements or to satisfy the in-house policy of the manufacturer. This includes pyrogenicity testing.
 - PR61 (Quality control) Batch safety testing. Batch safety testing excludes pyrogenicity testing.
 - PR62 (Quality control) Pyrogenicity testing.
 - PR63 (Quality control) Batch potency testing.
 - PR64 (Quality control) Other quality controls.

- **PR71 (Regulatory use) 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.

Combined tolerance/efficacy studies, dose range finding studies and maximum tolerated dose studies when being carried out to support regulatory submissions should be reported under this category.

- **Toxicity and other safety testing including pharmacology by test type** - Includes safety evaluation of products and devices for human medicine and dentistry and veterinary medicine. This covers studies carried out on any product or substance to determine its potential to cause any dangerous or undesirable effects in humans or animals as a result of its intended or abnormal use, as a result of its manufacture or as a potential or actual contaminant in the environment.
 - Choose the most appropriate test description.
 - Immunotoxicology studies should be reported under “Repeated dose toxicity”.
 - Kinetics (pharmacokinetics, toxicokinetics, residue depletion): If toxicokinetics is performed as part of the regulatory repeat dose toxicity study, you should report it under ‘Repeated dose toxicity’.
 - Safety testing in the food and feed area includes testing of drinking water (including target animal safety testing).

Guidance Notes 2017

Last updated 26 January 2017

- Target animal safety: This is testing to ensure that a product for a specific animal can be used safely on that species (excluding batch safety testing, which is covered under “Quality control”).

Column P – Other purpose

- If you have chosen any of the “Other” categories in Column O you should provide details in this column. Otherwise this column should be left blank.

Column Q - Testing by legislation

- Information should only be entered in this field if '[PR] Regulatory use' was listed as the purpose in Column N; otherwise this field should be left blank.
- The legislative requirement should be entered as per the *intended primary* use. For example, in relation to water quality, if it is concerning tap water for drinking you should report it under “Food legislation”.

Column R – Other testing by legislation

- If you have entered “Other” in Column P provide details in this column. Otherwise this field should be left blank.

Column S - Legislative requirements (origin of the legislation)

- Information should only be entered in this field if '[PR] Regulatory use' was listed as the purpose in Column N; otherwise this field should be left blank.
- This category allows identification of the level of harmonisation between different legislative requirements. The determining factor is not *who* requests the test to be carried out but which legislation is satisfied, giving priority to the widest level of harmonisation.
- Where national legislation is derived from EU legislation, only “Legislation satisfying EU requirements” should be chosen. “Legislation satisfying EU requirements” also includes any international requirement that at the same time satisfies EU requirements (such as testing to the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), the Organisation for Economic Cooperation and Development (OECD), and European Pharmacopoeia monographs).
- “Legislation satisfying UK requirements only” is to be chosen only when the test is carried out to satisfy UK requirements and there is no equivalent requirement in the EU.

Guidance Notes 2017

Last updated 26 January 2017

- “Legislation satisfying non-EU requirements only” is to be chosen when there is no equivalent requirement to carry out the test to satisfy EU requirements.

Column T - Severity

You should give the actual severity that animals used on the procedure experienced, **not** the severity classification or limit of the protocol.

Refer to the Home Office document “Advisory notes on recording and reporting the actual severity of regulated procedures” for detailed guidance on this:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/276014/NotesActualSeverityReporting.pdf

and on severity assessment for breeding and maintenance of genetically altered animals:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/276015/AdviceSeverityAssessmentGA.pdf

Assign the severity to one of the categories:

- sub-threshold;
- mild;
- moderate;
- severe; or
- non-recovery.

If different animals on a study suffered different levels of severity you should enter a separate line for each class of severity.

Sub-threshold severity is chosen when a procedure was regulated, and therefore it was considered that the procedure might have caused mild, moderate or severe suffering, but which in retrospect did not.

If “sub-threshold” is reported in combination with an experimental study please provide an explanatory comment in the Comments 1 field (Column W). An experimental study is one where “No” was entered for “Creation of a new genetic line” (Column M) and a purpose (Column N) was entered other than “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures”.

Whenever the severe classification is exceeded*, whether pre-authorised or not, you should report these animals and their use normally like any other use, and under the “severe” category. You should add further details in the Comments 1 column (Column W) explaining:

- whether prior exemption was authorised;
- the details of the use; and
- the reasons why the severe classification was exceeded.

Guidance Notes 2017

Last updated 26 January 2017

*This would be if an animal was suffering severe prolonged pain that was not alleviated.

If “severe” is reported for over 999 procedures in combination with the purpose “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures” (Column N), please provide an explanatory comment in the Comments 1 field (Column W).

If “non-recovery” is reported in combination with either “Creation of a new genetic line” (Column M) or “Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures” (Column N), please provide an explanatory comment in the Comments 1 field (Column W).

Reporting of wild animals used in procedures under ASPA.

- Procedures should be reported and severity assessed at the end of a procedure; this poses challenges for work in the wild.
- The procedures should be reported in the best way practicable, following guidance given in separate documents on “Work in the Wild” and on Severity, available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/535574/working-with-wild-animals-160706.pdf

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/276014/NotesActualSeverityReporting.pdf

- Where possible animals should be reported when the procedure ends or the animal is known to have died. If this is not practicable then:
 1. At the end of the study when attempts to recapture are no longer made
 2. At the end of the relevant project licence when the work will not continue on another licence
- There will often be uncertainty as to the fate of animals in the wild. Refer to the above guidance and discuss this with your local inspector.

Column V - Techniques of special interest

- Household product testing. Choose this option only if the work involved safety testing of substances used in the household.
- Use of ascites models for monoclonal antibody production. Choose this option only if monoclonal antibodies were harvested from ascites fluid. Do not use this option for immunisation of animals to provide tissues to generate monoclonal antibodies *in vitro*.

Guidance Notes 2017

Last updated 26 January 2017

- Tobacco. Choose this option only for the safety testing of products containing tobacco, not for use of nicotine or other compounds found in tobacco and not for use of tobacco in disease models.
- Alcohol. Choose this option only for the safety testing of products containing alcohol, not for the use of alcohol as a research tool or in disease models.

Column W - Comments 1: for the attention of the Home Office

Use this column to add comments for the attention of the Home Office.

If more than 99 non-human primates or 999 of any other species are entered in a single cell then you should add a note in the 'Comments 1' field (Column W).

- If the large number applies to a single study then briefly explain why so many animals were used in the 'Comments 1' field (Column W).
- If multiple studies have been combined into one entry, and this is the reason for the large number, simply state e.g. 'Combination of studies' in the 'Comments 1' field (Column W).
- If a large number of animals used on the same breeding protocol has been entered on one line, simply state "Breeding" in the 'Comments 1' field (Column W).

For procedures reported as "Regulatory use" (Column N), please use this column to report the legislation name(s) and number(s).

In addition, please provide an explanatory comment when reporting any of the following:

- Schedule 2 species³ (Column E) NOT born at a licensed establishment or at a registered breeder (Column I/J).
- "Not genetically altered" animals (Column L) reported in combination with the purpose "Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures" (Column N).
- "Sub-threshold" (Column T) is reported in combination with an experimental study. An experimental study is one where "No" was entered for "Creation of a new genetic line" (Column M) and a purpose (Column N) was entered other than "Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures".
- "Severe" (Column T) reported for over 999 procedures in combination with the purpose "Breeding/maintenance of colonies of established genetically altered animals, not used in other procedures" (Column N).
- "Non-recovery" (Column T) reported in combination with either "Creation of a new genetic line" (Column M) or "Breeding/maintenance

³ Schedule 2 species are mice, rats, guinea pigs, hamsters, gerbils, rabbits, cats, dogs, ferrets, non-human primates, pigs (if genetically modified), sheep (if genetically modified), common quail (*Coturnix coturnix*), amphibians (of the species *Xenopus laevis*, *Xenopus tropicalis*, *Rana temporaria* and *Rana pipiens*), and zebrafish.

Guidance Notes 2017

Last updated 26 January 2017

of colonies of established genetically altered animals, not used in other procedures” (Column N).

Column X - Comments 2: for personal use e.g. study numbers

Use this column to add comments that are not relevant to the Home Office but are for your own reference/information only e.g. study reference numbers.

Guidance Notes 2017

Last updated 26 January 2017

Annex - Code lists

PLEASE NOTE: These lists are for information only. To ensure that the data you provide is correct, please select the options available to you in the drop-down lists in the data collection template. What appears in the drop-down lists, in some instances, will depend on what was selected in the preceding columns.

Animal Species (Column E)

[A1] Mice (<i>Mus musculus</i>)	[A20] Cynomolgus monkey (<i>Macaca fascicularis</i>)
[A2] Rats (<i>Rattus norvegicus</i>)	[A21] Rhesus monkey (<i>Macaca mulatta</i>)
[A3] Guinea-Pigs (<i>Cavia porcellus</i>)	[A22] Vervets <i>Chlorocebus</i> spp. (usually either <i>pygerythrus</i> or <i>sabaeus</i>)
[A4] Hamsters (Syrian) (<i>Mesocricetus auratus</i>)	[A23] Baboons (<i>Papio</i> spp.)
[A5] Hamsters (chinese) (<i>Cricetulus griseus</i>)	[A24] Squirrel monkey (eg. <i>Saimiri sciureus</i>)
[A6] Mongolian gerbil (<i>Meriones unguiculatus</i>)	[A25-1] Other species of Old World Monkeys (<i>Cercopithecoidea</i>)
[A7] Other Rodents (other <i>Rodentia</i>)	[A25-2] Other species of New World Monkeys (<i>Ceboidea</i>)
[A8] Rabbits (<i>Oryctolagus cuniculus</i>)	[A26] Apes (<i>Hominoidea</i>)
[A9] Cats (<i>Felis catus</i>)	[A27] Other Mammals (other <i>Mammalia</i>)
[A10_1] Beagles (<i>Canis lupus familiaris</i>)	[A28] Domestic fowl (<i>Gallus gallus domesticus</i>)
[A10_2] Other dogs (Other <i>Canis</i>)	[A29_1] Quail (<i>Coturnix coturnix</i>)
[A11] Ferrets (<i>Mustela putorius furo</i>)	[A29_2] Other birds (other <i>Aves</i>)
[A12] Other carnivores (other <i>Carnivora</i>)	[A30] Reptiles (<i>Reptilia</i>)
[A13] Horses, donkeys & cross-breeds (<i>Equidae</i>)	[A31] Rana (<i>Rana temporaria</i> and <i>Rana pipiens</i>)
[A14] Pigs (<i>Sus scrofa domesticus</i>)	[A32] Xenopus (<i>Xenopus laevis</i> and <i>Xenopus tropicalis</i>)
[A15] Goats (<i>Capra aegagrus hircus</i>)	[A33] Other Amphibians (other <i>Amphibia</i>)
[A16] Sheep (<i>Ovis aries</i>)	[A34] Zebra fish (<i>Danio rerio</i>)
[A17] Cattle (<i>Bos primigenius</i>)	
[A18] Prosimians (<i>Prosimia</i>)	
[A19] Marmoset and tamarins (eg. <i>Callithrix jacchus</i>)	

Guidance Notes 2017

Last updated 26 January 2017

[A35] Other Fish (other Pisces)

[A36] Cephalopods (Cephalopoda)

Place of birth (Column I)

[O1_1] Animals born in the UK at a licensed establishment

[O1_2] Animals born in the EU (non UK) at a registered breeder

[O2_1] Animals born in the UK but **NOT** at a licensed establishment

[O2_2] Animals born in the EU (non UK) but **NOT** at a registered breeder

[O3] Animals born in rest of Europe

[O4] Animals born in rest of world

Non-human Primate Source (Column J)

[NHPO1_1A] Animals born in the UK at a licensed establishment

[NHPO1_2A] Animals born in the EU (non UK) at a registered breeder

[NHPO1_1B] Animals born in the UK but **NOT** at a licensed establishment

[NHPO1_2B] Animals born in the EU (non UK) but **NOT** at a registered breeder

[NHPO2] Animals born in rest of Europe

[NHPO3] Animals born in Asia

[NHPO4] Animals born in America

[NHPO5] Animals born in Africa

[NHPO6] Animals born elsewhere

NHP Generation (Column K)

[NHPG1] F0

[NHPG2] F1

[NHPG3] F2 or greater

[NHPG4] Self-sustaining colony

Genetic status (Column L)

[GS1] Not genetically altered

[GS2] Genetically altered without a harmful phenotype

[GS3] Genetically altered with a harmful phenotype

Purpose (Columns N and O)

[PB1] (Basic Research) Oncology

[PB2] (Basic Research)

Cardiovascular Blood and Lymphatic System

[PB3] (Basic Research) Nervous System

[PB4] (Basic Research) Respiratory System

[PB5] (Basic Research)

Gastrointestinal System including Liver

[PB6_1] (Basic Research)

Musculoskeletal System

[PB6_2] (Basic Research) Dentistry

[PB7] (Basic Research) Immune System

[PB8] (Basic Research)

Urogenital/Reproductive System

[PB9] (Basic Research) Sensory Organs (skin, eyes and ears)

[PB10] (Basic Research) Endocrine System/Metabolism

Guidance Notes 2017

Last updated 26 January 2017

[PB11] (Basic Research) Multisystemic

[PB12] (Basic Research) Ethology /

Animal Behaviour /Animal Biology

[PB13] (Basic Research) Other

[PT21] (Trans/Appl Research) Human
Cancer

[PT22] (Trans/Appl Research) Human
Infectious Disorders

[PT23] (Trans/Appl Research) Human
Cardiovascular Disorders

[PT24] (Trans/Appl Research) Human
Nervous and Mental Disorders

[PT25] (Trans/Appl Research) Human
Respiratory Disorders

[PT26] (Trans/Appl Research) Human
Gastrointestinal Disorders including
Liver

[PT27_1] (Trans/Appl Research)
Human Musculoskeletal Disorders

[PT27_2] (Trans/Appl Research)
Human Dentistry

[PT28] (Trans/Appl Research) Human
Immune Disorders

[PT29] (Trans/Appl Research) Human
Urogenital/Reproductive Disorders

[PT30] (Trans/Appl Research) Human
Sensory Organ Disorders (skin, eyes
and ears)

[PT31] (Trans/Appl Research) Human
Endocrine/Metabolism Disorders

[PT32] (Trans/Appl Research) Other
Human Disorders

[PT33] (Trans/Appl Research) Animal
Diseases and Disorders

[PT34] (Trans/Appl Research) Animal
Welfare

[PT35] (Trans/Appl Research)
Diagnosis of diseases

[PT36] (Trans/Appl Research) Plant
diseases

[PT37] (Trans/Appl Research) Non-
regulatory toxicology and
ecotoxicology

[PE40] Protection of the natural
environment in the interests of the
health or welfare of human beings or
animals

[PS41] Preservation of species

[PE42] Higher education or training for
the acquisition, maintenance or
improvement of vocational skills

[PF43] Forensic enquiries

[PG43] Breeding/maintenance of
colonies of established genetically
altered animals, not used in other
procedures

[PR51] (Regulatory use/ Routine
production) Blood based products

[PR52] (Regulatory use/ Routine
production) Monoclonal antibodies

[PR53] (Regulatory use/ Routine
production) Other

[PR61] (Regulatory use/ Quality
control) Batch safety testing

Guidance Notes 2017

Last updated 26 January 2017

[PR62] (Regulatory use/ Quality control) Pyrogenicity testing

[PR63] (Regulatory use/ Quality control) Batch potency testing

[PR64] (Regulatory use/ Quality control) Other quality controls

[PR71] (Regulatory use) Other efficacy and tolerance testing

[PR81] (Regulatory use/Toxicity and../Acute and sub-acute) LD50, LC50

[PR82] (Regulatory use/Toxicity and../Acute and sub-acute) Other lethal methods

[PR83] (Regulatory use/Toxicity and../Acute and sub-acute) Non lethal methods

[PR84] (Regulatory use/Toxicity and..) Skin irritation/corrosion

[PR85] (Regulatory use/Toxicity and..) Skin sensitisation

[PR86] (Regulatory use/Toxicity and..) Eye irritation/corrosion

[PR87] (Regulatory use/Toxicity and../Repeated dose toxicity) up to 28 days

[PR88] (Regulatory use/Toxicity and../Repeated dose toxicity) 29 - 90 days

[PR89] (Regulatory use/Toxicity and../Repeated dose toxicity) > 90 days

[PR90] (Regulatory use/Toxicity and..) Carcinogenicity

[PR91] (Regulatory use/Toxicity and..) Genotoxicity

[PR92] (Regulatory use/Toxicity and..) Reproductive toxicity

[PR93] (Regulatory use/Toxicity and..) Developmental toxicity

[PR94] (Regulatory use/Toxicity and..) Neurotoxicity

[PR95] (Regulatory use/Toxicity and..) Kinetics

[PR96] (Regulatory use/Toxicity and..) Pharmacodynamics (incl safety pharmacology)

[PR97] (Regulatory use/Toxicity and..) Phototoxicity

[PR98] (Regulatory use/Toxicity and../Ecotoxicity) Acute toxicity

[PR99] (Regulatory use/Toxicity and../Ecotoxicity) Chronic toxicity

[PR100] (Regulatory use/Toxicity and../Ecotoxicity) Reproductive toxicity

[PR101] (Regulatory use/Toxicity and../Ecotoxicity) Endocrine activity

[PR102] (Regulatory use/Toxicity and../Ecotoxicity) Bioaccumulation

[PR103] (Regulatory use/Toxicity and../Ecotoxicity) Other

[PR104] (Regulatory use/Toxicity and..) Safety testing in food and feed area

Guidance Notes 2017

Last updated 26 January 2017

[PR105] (Regulatory use/Toxicity and..) Target animal safety

[PR106] (Regulatory use/Toxicity and..) Other

Testing by legislation (Column Q)

[LT1] Legislation on medicinal

products for human use

[LT2] Legislation on medicinal

products for veterinary use and their residues

[LT3] Medical devices legislation

[LT4] Industrial chemicals legislation

[LT5] Plant protection product legislation

[LT6] Biocides legislation

[LT7] Food legislation including food contact material

[LT8] Feed legislation including legislation for the safety of target animals, workers and environment

[LT9] Cosmetics legislation

[LT10] Other

Legislative requirements (Column S)

[LO1] Legislation satisfying EU requirements

[LO2] Legislation satisfying national requirements only [within EU]

[LO3] Legislation satisfying Non-EU requirements only

Actual severity (Column T)

Sub-threshold

[SV1] Non-recovery

[SV2] Mild

[SV3] Moderate

[SV4] Severe

Techniques of Special Interest (Column V)

None

Household product testing

Use of ascites models for monoclonal antibody production

Tobacco

Alcohol