

# Statistics of Scientific Procedures on Living Animals Northern Ireland 2018



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Prepared pursuant to section 21(7) of the Animals (Scientific Procedures) Act 1986 as adapted by section 29 of that Act



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### Introductory notes

### Animals (Scientific Procedures) Act 1986 and key definitions

In the UK the use of animals in scientific procedures is regulated by the Animals (Scientific Procedures) Act 1986, an animal protection measure that requires licensing and oversight of all places, projects and personnel involved in such work. The general system of control under the 1986 Act is explained in detail in the Appendix.

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 the Northern Ireland Assembly.

Protected animals are defined in the 1986 Act 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 purpose, that may have the effect of causing an animal pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice. As the 1986 Act indicates, the breeding of an animal is a regulated procedure if the animal is bred from, or is the descendant of, an animal whose genes have mutated or been modified. For simplicity, these procedures will be referred to from this point on as the creation/breeding of genetically altered animals.

The number of regulated procedures, which will be simply referred to as procedures from this point on, usually corresponds with the number of animals used. However, animals are sometimes 're-used' when they have fully recovered from a previous procedure and in these instances they are counted as separate, additional, procedures. Overall, the number of procedures is always slightly higher than the number of animals used. The figures in this release focus on the number of procedures, not the number of animals, unless otherwise stated.

### Changes to data collection from 2014 onwards

The European Directive 2010/63/EU7 sets out a common format for member states of the European Union, which includes the UK – and therefore Northern Ireland – 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 listed below.

- 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.
- Details of the actual severity are recorded for all procedures. This is an assessment of the severity that animals experienced as a result of the entire procedure and reflects the peak severity of that procedure.
- The species information was revised in 2013.
- Information on all cephalopods as opposed to only one species (Octupus vulgaris) is now collected, as is information on species newly listed in 2013 in Schedule 2 of the Animal (Scientific Procedures) Act 1986.
- Since 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.
- Statistics are collected on place of birth rather than on source.
- 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.
- Statistics 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 (as opposed to non-regulatory) use; some of this information was previously reported as applied studies.

#### Further information available

This statistical release is available online at the DoH website https://www.health-ni.gov.uk/

The Animals (Scientific Procedures) Act 1986 can be accessed at https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986

European Directive 2010/63/EU can be found at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063

https://publications.europa.eu/en/publication-detail/-/publication/36ef2c9c-33b4-11e2-84do-o1aa75ed71a1/language-en

### Description of Statistical Tables

1. Project holders were asked to answer detailed questions about the procedures completed in 2018. A description of the information gathered is set out below.

### Species of animal

- 2. The majority of the tables refer to experimental procedures with the exception of tables 1a and 2, which refer to animals used for the first time, and tables 8 and 9, which refer to genetically altered animals created/bred in 2018 but not used in further experimental procedures.
- 3. The list of species of categories of animals is selective to avoid undue complications; where collective terms are used it is because previous experience suggests that the category will contain a relatively small number or because further breakdown is of little interest. In several tables, rows which are completely zero have been omitted and if an animal is not mentioned then it is because the rows pertaining to that species are completely blank.

#### Genetic status of animal

- 4. For genetically altered animals, separate breakdowns on genetically modified animals and animals with a harmful genetic mutation are no longer collected. Instead, separate breakdowns are now collected on animals which show a harmful phenotype (i.e. a harmful physical or biochemical defect) and animals which do not show a harmful phenotype.
- 5. Since 2014, genetic status is shown separately for experimental procedures (Table 4) and those involving the creation/breeding of genetically altered animals that were not used in further experimental procedures (Tables 8 and 9).

### Primary purpose

- 6. Use of animals for regulated procedures is limited by Section 5 (3) of the Act to one of the following primary purposes:
  - a. **basic research:**
  - b. **translational or applied research** with one of the following aims—
    - (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;
    - (ii) the assessment, detection, regulation or modification of physiological conditions in man, animals or plants; or
    - (iii) the improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes.
  - c. the **development, manufacture or testing** of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs or any other substances or products, with one of the aims mentioned in paragraph (b);
  - d. **protection of the natural environment:** research in the interests of the health or welfare of man or animals:
  - e. **preservation of species:** research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;

- f. **higher education or training** for the acquisition, maintenance or improvement of vocational skills:
- g. **forensic inquiries:** including tests as part of forensic investigations and the production of materials, for example, antisera, for use in forensic investigations;

### Place of Birth (Table 2)

- 7. From 2013, Schedule 2c and 25(e) of the Act require, unless a specific exemption is granted, that certain animals, listed in Schedule 2 to the Act, have to be specifically bred for the use in regulated procedures. The species so listed are: mouse, rat, guinea-pig, hamster, rabbit, dog, cat, primate, quail, ferret, gerbil, frog, zebra fish and pigs and sheep if genetically modified.
- 8. Information is collected on place of birth. Statistics relate to animals used for the first time rather than on the number of procedures. The place of birth of these animals is tabulated according to whether it is within the UK, within the remainder of the EU, or elsewhere.

### **Stage of Development**

9. Details of procedures on immature forms were collected but not enumerated because it is impracticable in some cases to count such procedures, e.g. a foetus resorbed during gestation, or fish fry which are very small and fast-moving.

### **Severity** (Tables 3 & Tables 8-9)

- 10. Details of actual severity are recorded for all procedures.
- 11. 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 as follows.
  - Sub-threshold: When a procedure was authorised under a project licence but did not actually cause suffering above the threshold of regulation (ASPA 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.

- 12. The severity of genetically altered animals 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 genotyping, the biopsy procedures will generally be assessed as mild;
  - 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 will
    have been subjected to surgical or minor procedures such as the injection of drugs or
    viral vectors (i.e. viruses containing the genes of interest).
- 13. Full details of severity assessment and classification can be found in Annex 8 of the European Directive 2010/63/EU.

### Type of procedure

- 14. Table 5 provides a breakdown of all experimental procedures undertaken for the primary purpose of basic research, by area of study. These are:
  - Oncology
  - Cardiovascular blood and lymphatic system
  - Nervous system
  - Respiratory system
  - Gastrointestinal system including liver
  - Musculoskeletal system
  - Immune system
  - Urogenital/reproductive system
  - Sensory organs (skin, eyes and ears)
  - Endocrine system/metabolism
  - Multi-systemic
  - Ethology/animal behaviour/animal biology
  - Other
- 15. Table 6 provides a breakdown of experimental procedures undertaken for the primary purpose of translation/applied research by area of study. These are:
  - Human cancer
  - Human infectious disorders
  - Human cardiovascular disorders
  - Human nervous and mental disorders
  - Human respiratory disorders
  - Human gastrointestinal disorders including liver
  - Human musculoskeletal disorders
  - Human immune disorders
  - Human urogenital/reproductive disorders
  - Human sensory disorders (skin, eyes and ears)
  - Human endocrine system/metabolism disorders
  - Other human disorders
  - Animal diseases and disorders
  - Animal welfare

- Diagnosis of diseases
- Plant diseases
- Non regulatory toxicology and ecotoxicology
- 16. Table 7.1 provides a breakdown of experimental procedures undertaken for regulatory purposes. These fall into 4 categories:
  - Routine production of blood based products, monoclonal antibodies (ascites) or other products;
  - Quality control;
  - Other efficacy and tolerance testing;
  - Toxicity and other safety testing including pharmacology.
- 17. Table 7.4 provides a further breakdown on toxicity and other safety testing, by the various testing methods used.

### **Legislative requirements** (Table 7.2 and 7.3)

- 18. Tables 7.2 provides a breakdown of all regulatory procedures by type of legislative requirement. Table 7.3 documents the origin of the requirement. The following are examples of legislative requirements which may be included:
  - Medicines Act 1968;
  - Legislation on medicinal products for veterinary use and their severity;
  - Workplace safety e.g. Health and Safety at Work (Northern Ireland) Order 1978,
     COSHH Regulations;
  - Substances used in agriculture e.g. Control of Pesticides Regulations (Northern Ireland) 1987; EU Pesticides Directives;
  - Substances used in foodstuffs e.g. The Food Safety (Northern Ireland) Order 1991.

### Creation/breeding of genetically altered animals (Tables 1, 8-9)

19. The creation/breeding of genetically altered animals includes 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. This category also includes some animals which were bred with the intention of producing genetically altered animals, but resulted in non-genetically altered animals being born.

### **Projects, project licence holders and licensed establishments** (Table 10)

20. Project licence holders have been classified according to the type of designated place which was their main place of employment at the end of the year, although they could be licensed to carry out procedures at more than one place. Procedures have been classified according to the type of designated place of the project licence holder reporting them.

### Commentary

The main features of the statistics for 2018 were:

- a. The number of procedures completed was 28,790. Of these 4,907 (17%) related to the creation/breeding of genetically altered animals that were not used in further procedures and the remaining 23,883 (83%) were experimental procedures (Table 1).
- b. The number of animals used for the first time was 28,012. This is in comparison to 24,166 in 2017 (Table 1a).
- c. Of the 23,883 experimental procedures completed in 2018, the majority involved mice (70% or 16,822 procedures). Cattle were used in 10% of procedures (2,405 procedures) and fish (other than Zebrafish) in 7% of procedures (1749 procedures). Sheep, rats and pigs each accounted for 3% of the total experimental procedures and the remaining procedures were carried out on other mammals and amphibians. (Table 1).
- d. In 2018, 97% of animals used for the first time in experimental procedures were born at establishments within the UK (22,834 animals). Most of the remaining 3% (241 animals) were born in the EU, whereas a small number were born elsewhere in the world (Table 2).
- e. The majority of experimental procedures completed in 2018 used animals that had not been genetically modified (73.4% or 17,521 procedures). 24.4% (5,819 procedures) involved genetically modified animals without a harmful phenotype, i.e. a harmful physical or chemical defect and 2.3% (543 procedures) involved genetically modified animals with a harmful phenotype (Table 4).
- f. Of the severity assessments undertaken for the 23,883 experimental procedures completed in 2018: 1.1% were assessed as sub-threshold; 43.8% were assessed as mild; 50.1% were assessed as moderate; 3.9% were assessed as severe and 1.2% were non-recovery (Table 3).
- g. Of the 28,790 total procedures carried out in 2018: 47.6% (13,690) were undertaken for basic research; 29.4% (8,477) were undertaken for translational/applied research; 3.2% (914) were undertaken for regulatory purposes; 2.5% (726) related to protection of the natural environment; and 0.3% (76) were undertaken for forensic enquiries (Table 1).
- h. In 2018, 13,690 procedures were undertaken for basic research purposes. Of these, the majority, 96.7% (13,237 procedures) were undertaken for the study of oncology and specified or multi-organ systems. The remaining 3.3% (453 procedures) were undertaken for the study of animal biology (including ethology/animal behaviour) or other purposes (Table 5).
- i. In 2018, 8,477 procedures were undertaken for translational/applied research purposes. Of those 70% (5,976 procedures) were undertaken for research relating to human cancer and other disorders. Procedures relating to research into animal diseases and welfare amounted to 25% (2,110 procedures). The remaining 5% (391 procedures) were undertaken for the diagnosis of diseases and for non-regulatory toxicology and ecotoxicology (Table 6).
- j. In 2018, 914 experimental procedures were undertaken for regulatory purposes. The majority of these, 97.4% (890 procedures) were for toxicity and other safety testing, including pharmacology. The remainder were for the routine production of blood based products (Table 7.1).

- k. Of the 914 procedures undertaken for regulatory use, most were carried out to satisfy legislation on medicinal products for veterinary use (and their residues), 89.5% or 818 procedures. The remaining 10.5% (96 procedures) were for food legislation, including legislation on food contact material. (Table 7.2). Almost all legislation was to satisfy EU/UK requirements, though a small percentage (6.1%) was to satisfy requirements outside the EU (Table 7.3).
- l. All of the 4907 genetically altered animals created/bred in 2018 (and not used in further experimental procedures) were for the maintenance of established lines of genetically modified animals. None were created/bred to create new lines of genetically modified animals (Table 8).
- m. The majority of procedures undertaken in 2018 (22,472 or 78.1%) were carried out in universities/medical schools. Non-profit making organisations accounted for 3,621 of the total procedures (12.6%); and Government departments 1,419 procedures (4.9%). The rest were carried out by commercial organisations 1,278 procedures (4.4%) (Table 10).
- n. Returns were completed in respect of 106 project licences in 2018 (10 less than 2017). A total of 63 licences where countable procedures were completed were carried out in 2018 (Table 10).
- o. During 2018, the number of personal licences which were operational and authorised to carry out regulated procedures under the act was 598 (Table 12).

Table 1 Number of procedures by species of animal and purpose of the procedure

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braffish ( <i>Danio rerio</i> )  o  o  o  o  o  o  o  dapod ( <i>Cephalopoda</i> )	ο (	0 0	0 0	0 0	0 0	0.0
braffsh (Danio rerio)       0	D		У.	<b>D</b>	<b>o</b>	0.0
ner fish (other <i>Pisces</i> ) 0 1,305 444 0 0 alopod ( <i>Cephalopoda</i> ) 0 0 0 0	C		(	(	•	•
alopod (Cephalopoda) 0 0 0 0	) a	) 0	1.749	0	1.740	2.0
alopod (Cephalopoda) 0 0 0 0 0 0			· ·	'	ì	}
	0	0	0	0	0	0.0
	0	76 914	23,883	4,907	28,790	100.0

Table 1a Number of animals used for the first time in procedures by species of animal and purpose of the procedure

Northern Ireland 2018

2.6 2.6 0.0 0.0 0.0 0.0 100.0 used for the first time in 0.0 0.1 0.0 7.0 0.0 0.0 0.0 6.2 0.0 procedures % of total animals 18 652 0 803 00000 9000 0 0 235 000 1,749 28,012 100.0 used for the first time in 307 **Fotal animals** procedures 0 0 0 4,907 0 Creation & breeding of GA animals not used in experimental procedures 16,645 736 0 0 0 0 0 0 0 235 Total animals used for the first time in experimental 18 652 0 0 0 0 0 0 23,105 82.5 307 procedures 50 40000000 0000 0 0 0 0 816 2.9 18 179 0 278 286 0 0 0 0 Regulatory Experimental purpose of procedure (excluding creation & breeding) 76 0.3 Forensic enquiries 0.0 Higher education or 00000 00000 0 0 0 0 0 0 0 0 00000 0 0 0 0 0 0 training 0.0 Preservation of species Protection of the natural 0000000 00000 00000 0 0 0 0 0 0 0 0 0 444 726 2.6 environment 5,777 25 0 0 0 1,305 8,409 30.0 Translational/ Applied research 57 10,864 482 0 0 0 0 0 0 0000 0 0 0 0 0 0 0 0 13,078 46.7 Basic Research Cynomolgus monkey (Macaca fascicularis) Mongolian Gerbil (Meriones unguiculatus) Hamster (Syrian) (Mesocricetus auratus) Hamster (Chinese) (Cricetulus griseus) Rhesus monkey (Macaca mulatta) Domestic fowl (Gallus domesticus) Xenopus (laevis and tropicalis) Other amphibian (other Amphibia) Other carnivore (other Carnivora) Horse and other equid (Equidae) Other mammal (other Mammalia) Rabbit (Oryctolagus cuniculus) Beagle (Canis lupus familiaris) Rana (temporaria and pipiens) Other rodent (other Rodentia) Ferret (Mustela putorius furo) Pig (Sus scrofa domesticus) Goat (Capra aegagrus hircus) Guinea-pig (Cavia porcellus) Other dog (other Canis) Marmoset and tamarin Quail (Coturnix coturnix) Other fish (other Pisces) Cattle (Bos primigenius) **Cephalopod** (Cephalopoda) Mouse (Mus musculus) Rat (Rattus norvegicus) Other bird (other Aves) Zebrafish (Danio rerio) Primate New World monkey Old World monkey Sheep (Ovis aries) Cat (Felis catus) Species of animal Reptile (Reptilia) Prosimians **Amphibian** Total % of total

Table 2 Place of birth of animals used for the first time in experimental procedures by species of animal (excludes non-human primates)

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			Place of hirth	f hirth				
Species of animal	Animals born in the UK at a licensed establishment	Animals born in the UK but not at a licensed establishment	Animals born elsewhere in the EU at a registered breeder	Animals born elsewhere in the EU but <b>not</b> at a registered breeder	Animals born in rest of Europe	Animals born in rest of world	Total	% of total
Mammal Mouse (Mus musculus)*	16,374	0	241	0	0	30	16.645	72.0
Rat (Rattus norvegicus)*	736	0	0	0	0	0	736	3.5
Guinea-pig (Cavia porcellus)*	0	0	0	0	0	0	•	0.0
Hamster (Syrian) (Mesocricetus auratus)*	0	0	0	0	0	0	0	0.0
Hamster (chinese) (Cricetulus griseus)*		0	0	0	0	0	0	0.0
Mongolian Gerbil (Meriones unguiculatus)*		0	0	0	0	0	•	0.0
Other rodent (other <i>Rodentia)</i>	0 (	0 (	0 (	0 (	0 (	0 (	0	0.0
Kabbit (Uryctolagus cuniculus)	0	0	0	0	0	0	•	0.0
Cat (Felis catus)	10	0	0	0	0	0	10	0.0
Beagle (Canis lupus familiaris)	0	0	0	0	0	0	0	0.0
Other dog (other Canis)	0	0	0	0	0	0	0	0.0
Ferret (Mustela putorius furo)	0	0	0	0	0	0	0	0.0
Other carnivore (other <i>Carnivora</i> )	0	1	0	0	0	0	н	0.0
Horse and other equid ( <i>Equidae</i> )	0	18	0	0	0	0	18	0.1
Pig (Sus scrofa domesticus)	473	179	0	0	0	0	652	2.8
Goat (Capra aegagrus hircus)	0	0	0	0	0	0	•	0.0
Sheep (Ovis aries)	104	669	0	0	0	0	803	3.5
Cattle (Bos primigenius)	180	1,769	0	0	0	0	1,949	8.4
Other mammal (other Mammalia)	0	307	0	0	0	0	307	1.3
Bird  Domontic found (Colling Assessment Street			Ć	·	Ć	(	1	
Onesiic 10wi ( <i>Gaiids donnesiicus)</i>		235				0 0	235	1.0
Other bird (other Aves)	0	0	0	0	0	0	0 0	0.0
Reptile (Reptilia)	0	0	0	0	0	0	0	0.0
Amphibian Rana (femoraria and ninians)*	C	c	c	c	c	C	C	Ġ
Xenonis (Jaevis and tropicalis)*	· c	) C	o c		o c	0 0	<b>o c</b>	2.0
Other amphibian (other Amphibia)	0	0	0	0	0	0 0	0	0.0
Fish								
Zebrafish ( <i>Danio rerio</i> )*	0	0	0	0	0	0	0	0.0
Other fish (other <i>Pisces</i> )	0	1,749	0	0	0	0	1,749	9.2
Cephalopod (Cephalopoda)	0	0	0	0	0	0	0	0.0
Total	17,877	4,957	241	0	0	30	23,105	100.0
% of total	77.4	21.5	1.0	0.0	0.0	0.1	100.0	

\* Denotes species listed in Schedule 2; pigs and sheep are only listed in Schedule 2 if they are genetically altered.

Table 3 Experimental procedures by species of animal, severity and purpose of the procedure

Page 1 of 2

Northern Iret				Experimenta	al purpose of p	rocedure				
Species of animal	Actual Severity	Basic Research	Translational/ Applied research	Protection of the natural environment	Preservation of species	Higher education or training	Forensic enquiries	Regulatory	Total	% of species total
Mouse (Mus musculus)	Sub threshold Non-recovery Mild Moderate Severe Total	234 172 3,389 6,994 252 <b>11,041</b>	0 7 720 4,435 615 <b>5,777</b>	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0 4 <b>4</b>	234 179 4,109 11,429 871 <b>16,822</b>	1.4 1.1 24.4 67.9 5.2 <b>100.0</b>
Rat (Rattus norvegicus)	Sub threshold Non-recovery Mild Moderate Severe <b>Total</b>	3 39 304 137 0 <b>483</b>	0 0 157 97 0 <b>254</b>	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	3 39 461 234 0 <b>737</b>	0.4 5.3 62.6 31.8 0.0
Guinea-pig ( <i>Cavia</i> porcellus)	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0.0 0.0 0.0 0.0 0.0
Other rodent <sup>1</sup>	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0.0 0.0 0.0 0.0 0.0
Rabbit (Oryctolagus cuniculus)	Sub threshold Non-recovery Mild Moderate Severe <b>Total</b>	0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0.0 0.0 0.0 0.0 0.0
Cat (Felis catus)	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 0 0	0 0 47 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 24 0 0	0 0 71 0 0	0.0 0.0 100.0 0.0 0.0
Dog²	Sub threshold Non-recovery Mild Moderate Severe <b>Total</b>	0 0 0 0	20 0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 44 0 0	20 0 44 0 0 <b>64</b>	31.3 0.0 68.8 0.0 0.0
Ferret (Mustela putorius furo)	Sub threshold Non-recovery Mild Moderate Severe <b>Total</b>	0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0.0 0.0 0.0 0.0 0.0
Horse and other equid (Equidae)	Sub threshold Non-recovery Mild Moderate Severe <b>Total</b>	0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 18 0 0	0 0 18 0 0	0.0 0.0 100.0 0.0 0.0
Pig (Sus scrofa domesticus)	Sub threshold Non-recovery Mild Moderate Severe <b>Total</b>	0 0 164 0 30	0 0 0 257 22 <b>279</b>	0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 180 0 0	0 0 344 257 52 <b>653</b>	0.0 0.0 52.7 39.4 8.0
Other ungulate <sup>3</sup>	Sub threshold Non-recovery Mild Moderate Severe <b>Total</b>	0 0 1,898 16 0	0 595 38 0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 76 0 0 <b>76</b>	0 0 594 0 0 <b>594</b>	0 0 3,163 54 0 <b>3,217</b>	0.0 0.0 98.3 1.7 0.0
Other mammal (other <i>Mammalia</i> )	Sub threshold Non-recovery Mild Moderate Severe <b>Total</b>	0 0 1 0 0	0 0 25 0 0	0 0 282 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 308 0 0 <b>308</b>	0.0 0.0 100.0 0.0 0.0

### Table 3 Experimental procedures by species of animal, severity and purpose of the procedure

Page 2 of 2

				Experimenta	al purpose of p	rocedure				
Species of animal	Actual Severity	Basic Research	Translational/ Applied research	Protection of the natural environment	Preservation of species	Higher education or training	Forensic enquiries	Regulatory	Total	% of species total
	Sub threshold	0	0	0	0	0	0	0	0	0.0
	Non-recovery Mild	0	0	0	0	0	0	0	0	0.0
Primate	Moderate	0	0	0	0	0	0	0	0	0.0
	Severe	ő	ő	o	ő	Ö	o	Ö	ő	0.0
	Total	0	0	0	o	0	0	0	0	0.0
	Sub threshold	О	О	0	О	0	0	0	0	0.0
	Non-recovery	57	0	0	0	0	0	0	57	24.3
Bird	Mild Moderate	0	128	0	0	0	0	50	178	75.7
	Severe	0	0	0	0	0	0	0	0	0.0
	Total	57	128	0	0	0	0	50	235	100.0
	Sub threshold	0	0	0	0	0	0	0	0	0.0
	Non-recovery	0	0	0	0	0	0	0	0	0.0
	Mild	0	0	0	0	0	0	0	0	0.0
Reptile	Moderate	0	0	0	0	0	0	0	0	0.0
	Severe	0	0	0	0	0	0	0	0	0.0
	Total	О	o	0	o	0	0	0	0	0.0
	Sub threshold	О	0	0	0	0	0	0	0	0.0
	Non-recovery	0	0	0	0	0	0	0	0	0.0
Amphibian	Mild	0	9	0	0	0	0	0	9	100.0
	Moderate Severe	0	0	0	0	0	0	0	0	0.0
	Total	o	9	0	0	0	0	0	9	100.0
	Sub threshold	0	0	0	0	0	0	0	0	0.0
	Non-recovery	ő	Ö	ō	ō	Ö	ō	Ö	ō	0.0
Fish	Mild	0	1,305	444	0	0	0	0	1,749	100.0
11311	Moderate Severe	0	0	0	0	0	0	0	0	0.0
	Total	0	1,305	444	0	<b>0</b>	0 <b>0</b>	0 <b>0</b>	1,749	0.0 <b>100.0</b>
	Sub threshold	0	0	0	0	0	0	0	0	0.0
	Non-recovery	0	0	0	0	0	0	0	0	0.0
Cephalopods	Mild	0	0	0	0	0	0	0	0	0.0
cephalopous	Moderate	0	0	0	0	0	0	0	0	0.0
	Severe <b>Total</b>	0 <b>0</b>	0 <b>0</b>	0	0 <b>0</b>	0	0	0 <b>0</b>	0 <b>0</b>	0.0
	Total					0	0			0.0
	Sub threshold	237	20	0	0	0	0	0	257	1.1
	Non-recovery Mild	268 5,756	7 2,986	0 726	0	0	o 76	0 910	275 10 <b>,</b> 454	1.2 43.8
All species	Moderate	7,147	4,827	720	0	0	0	910	11,974	50.1
	Severe	282	637	0	0	0	0	4	923	3.9
	Total	13,690	8,477	726	0	0	76	914	23,883	100.0

 <sup>&</sup>quot;Other rodent" includes Syrian hamster (*Mesocricetus auratus*), Chinese hamster (*Cricetulus griseus*), Mongolian gerbil (*Meriones unguiculatus*), and other rodents (other *Rodentia*).
 "Dog" includes beagles (*Canis lupus familiaris*) and other dogs (other *Canis*)
 "Other ungulate" includes goat (*Capra aegagrus hircus*), sheep (*Ovis aries*), and cattle (*Bos primigenius*).

### Table 4 Experimental procedures by species of animal and genetic status

#### Northern Ireland 2018

		Genetic status			
Species of animal	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	% of total
Mammal					
Mouse (Mus musculus)	10,708	5,571	543	16,822	70.4
Rat (Rattus norvegicus)	489	248	О	737	3.1
Guinea-pig (Cavia porcellus)	0	0	О	o	0.0
Hamster (Syrian) (Mesocricetus auratus)	0	0	О	О	0.0
Hamster (Chinese) (Cricetulus griseus)	0	0	О	О	0.0
Mongolian Gerbil (Meriones unguiculatus)	0	0	О	o	0.0
Other rodent (other Rodentia)	0	0	О	o	0.0
Rabbit (Oryctolagus cuniculus)	0	0	0	0	0.0
Cat (Felis catus)	71	0	О	71	0.3
Beagle (Canis lupus familiaris)	64	0	О	64	0.
Other dog (other Canis)	0	0	0	О	0.0
Ferret (Mustela putorius furo)	0	0	0	О	0.
Other carnivore (other Carnivora)	1	0	0	1	0.0
Horse and other equid (Equidae)	18	0	О	18	0.
Pig (Sus scrofa domesticus)	653	0	0	653	2.
Goat (Capra aegagrus hircus)	0	0	0	o	0.0
Sheep (Ovis aries)	812	0	0	812	3.
Cattle (Bos primigenius)	2,405	0	0	2,405	10.
Primate New World monkey					
Marmoset and tamarin	0	0	0	o	0.0
Old World monkey		· ·	Ĭ	١	0.
Prosimians	0	0	0	o	0.
Cynomolgus monkey (Macaca fascicularis)	0	0	0	o	0.
Rhesus monkey (Macaca mulatta)	0	0	О	0	0.
Other mammal (other Mammalia)	307	0	0	307	1.
Bird					
Domestic fowl (Gallus domesticus)	235	0	О	235	1.
Quail (Coturnix coturnix)	О	0	0	o	0.
Other bird (other Aves)	0	0	0	o	0.
Reptile (Reptilia)	0	0	0	О	0.
Amphibian					
Rana (temporaria and pipiens)	0	0	0	o	0.0
Xenopus (laevis and tropicalis)	0	0	0	o	0.0
Other amphibian (other Amphibia)	9	0	0	9	0.0
Fish					
Zebrafish (Danio rerio)	0	0	0	0	0.0
Other fish (other Pisces)	1,749	0	0	1,749	7.
Cephalopod (Cephalopoda)	О	0	0	О	0.0
Total	17,521		543	23,883	100.0
% of total	73.4	24.4	2.3	100.0	

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Table 5 Experimental procedures (non-regulatory) by species of animal: basic research

Species of animal  Mammal Mouse (Mus musculus) Rat (Rattus norvegicus) Guinea-big (Gavia porcellus)							Basic Research	Ę.							
Mammal Mouse (Mus musculus) Rat (Rattus norvegicus) Guinea-pig (Cavia porcellus)	Oncology	Cardio- vascular Blood and Lymphatic System	Nervous System	Respiratory System	Gastro- intestinal System including Liver	Musculo- skeletal System	Immune System	Urogenital/ Reproductive System	Sensory Organs (skin, eyes and ears)	Endocrine System/ Metabolism	Multisystemic	Ethology/ Animal Behaviour/ Animal Biology	Other	Total	% of total
Rat (Rattus norvegicus) Guinea-pig (Cavia porcellus)	נ זבנ	163	1 225	217	38	75	1164	88	1 656	760	c	c	91	17011	80.7
Guinea-pig (Cavia porcellus)	116		0	9	2 0	0	1,104	8 0	271	787	0	0	9 0	11,041	9.7
	0		0	0	0	0	0	0	0	0	0	0	0	}	
Hamster (Syrian) (Mesocricetus auratus)	0		0	0	0	0	0	0	0	0	0	0	0	•	0.0
Hamster (Chinese) (Cricetulus griseus)	0		0	0	0	0	0	0	0	0	0	0	0	•	0.0
Mongolian Gerbil (Meriones unguiculatus)			0	0	0	0	0	0	0	0	0	0	0	0	0.0
Other rodent (other Rodentia)			0	0	0	0	0	0	0	0	0	0	0	•	0.0
Rabbit (Oryctolagus cuniculus)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Cat (Felis catus)	0		0	0	0	0	0	0	0	0	0	0	0	•	0.0
Beagle (Canis lupus familiaris)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Other dog (other Canis)	0		0	0	0	0	0	0	0	0	0	0	0	•	0.0
Ferret (Mustela putorius furo)	0		0	0	0	0	0	0	0	0	0	0	0	•	0.0
Other carnivore (other Carnivora)	0		0	0	0	0	0	0	0	0	0	1	0	-	0.0
Horse and other equid (Equidae)	0		0	0	0	0	0	0	0	0	0	0	0	c	Ö
Pig (Sus scrofa domesticus)	_	0	0	0	0	0	0	0	0	0	0	194	0	10,0	77
Goat (Capra aegagrus hircus)	0		0	0	0	0	0	0	0	0	0	0	0	ţ. 0	1 0
Sheep (Ovis aries)	0	0	0	0	0	0	0	0	0	0	0	163	0	163	1.2
Cattle (Bos primigenius)	0		0	0	0	0	1,208	0	0	0	521	22	0	1,751	12.8
<b>Primate</b> New World monkey															
Marmoset and tamarin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	•	0.0
Cynomolgus monkey (Macaca fascicularis)			0	0	0	0	0	0	0	0	0	0	0	•	0.0
Rhesus monkey (Macaca mulatta)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Other mammal (other Mammalia)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Bird															
Domestic fowl (Gallus domesticus)	0		0	0	0	0	0	0	0	0	0	0	57	57	0.4
Quail (Coturnix coturnix)		0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 (	0.0
Doutile (Doutilia)				o c	o c	o c		0 0	o c	o c	o c	o c	) (	•	<i>-</i>
vepure (vepuna)			)	0	o	)	)	Þ	)	o	o	o	-	•	3
Amphibian Rana (temporaria and pipiens)	0		0	0	0	0	0	0	0	0	0	0	0	0	0.0
Xenopus (laevis and tropicalis)	0	0	0	0	0	0	0	0	0	0	0	0	0	•	0.0
Other amphibian (other Amphibia)	0		0	0	0	0	0	0	0	0	0	0	0	•	0.0
Fish			C	Ċ	C	C	C	C	C	C	C	Ċ	C		
Other fish (other <i>Pisces</i> )		0	0	0	0	0 0	0	0	0	0	0	0	0 0	•	9 %
Cephalopod (Cephalopoda)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	5.471		1.335	223	82	75	2,384	88	1,927	1,012	521	380	73	13,690	100.0
% of total	40.0	1.2	9.8	1.6	0.3	0.5	17.4	9.0	14.1	7.4	3.8	2.8	0.5	100.0	

Table 6 Experimental procedures (non-regulatory) by species of animal: translational/applied research, page 1 of 2

Northern Ireland 2018									
Species of animal	Human Cancer	Human Infectious Disorders	Human Cardiovascular Disorders	Transle Human Nervous and Mental Disorders	Translational/applied research  ous Human Gas al Respiratory I Disorders incl	human Gastrointestinal Disorders including Liver	Human Musculoskeletal Disorders	Human Immune Disorders	Human Urogenital/ Reproductive Disorders
Manmal Mouse (Mus musculus) Rat (Rattus norvegicus) Guinea-pig (Cavia porcellus) Hamster (Syrian) (Mesocricetus auratus) Hamster (Chinese) (Cricetulus griseus) Mongolian Gerbil (Meriones unguiculatus) Other rodent (other Rodentia) Rabbit (Oryctolagus cuniculus)		349	0000000	4000000	666 0000000000000000000000000000000000		186 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	157	0000000
Cat (Felis catus) Beagle (Canis lupus familiaris) Other dog (other Canis) Ferret (Mustela putorius furo) Other carnivore (other Canivora)	00000	0000	00000	00000	00000	0000	00000	00000	00000
Horse and other equid (Equidae) Pig (Sus scrofa domesticus) Goat (Capra aegagrus hircus) Sheep (Ovis aries) Cattle (Bos primigenius)	0000	00000	00000	00000	00000	00000	00000	00000	00000
Primate New World monkey Marmoset and tamarin Old World monkey Prosimians Cynomolgus monkey (Macaca fascicularis) Rhesus monkey (Macaca mulatta)	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
Other mammal (other Mammalia)	0	0	0	0	0	0	0	0	0
Bird Domestic fowl (Gallus domesticus) Quail (Cotumix coturnix) Other bird (other Aves)	000	000	000	000	000	000	000	000	000
Reptile (Reptilia)	0	0	0	0	0	0	0	0	0
Amphibian Rana (temporaria and pipiens) Xenopus (aevis and tropicalis) Other amphibian (other Amphibia)	000	000	000	000	000	000	000	000	000
<b>Fish</b> Zebrafish ( <i>Danio rerio</i> ) Other fish (other <i>Pisces</i> )	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
Cephalopod (Cephalopoda)	0	0	0	0	0	0	0	0	0
Total % of total	3,800	349	0.0	12 0.1	993	0.0	186	157	0.0

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Table 6 Experimental procedures (non-regulatory) by species of animal: translational/applied research, page 2 of 2

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Urogenital/ Reproductive Disorders Human

> Human Immune Disorders

Musculoskeletal Disorders Human

47 20 0 0 0 0 0 0 279 0 286

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0 0 0

311 Disorders including Liver Gastrointestinal Human Translational/applied research 000000000000 00000 0 0 0 0000000 0 0 0 000 0 0 0 128 128 1.5 Respiratory Disorders Human 279 0 0 0 347 0 0 0 000000 0 0 0 0 1,982 23.4 Human Nervous and Mental 0 000 1,305 Disorders 9.5 000000000000 Cardiovascular Disorders Human Human Infectious 000000000000 00000 0 0 0 0000000 0 0 0 0 0 0 0 0 0 0 Disorders 357 97 0 0 0 0 0 0 0 0 0 0 00000 000 0000000 0 0 0 0 0 0 0 0 0 470 5.5 Human Cancer Cynomolgus monkey (Macaca fascicularis) Hamster (Chinese) (*Cricetulus griseus*) Mongolian Gerbil (*Meriones unguiculatus*) Guinea-pig (Cavia porcellus) Hamster (Syrian) (Mesocricetus auratus) Rhesus monkey (*Macaca mulatta*) Other mammal (other Mammalia) Domestic fowl (Gallus domesticus) **Amphibian**Rana (temporaria and pipiens)
Xenopus (laevis and tropicalis)
Other amphibian (other Amphibia) Beagle (Canis lupus familiaris) Other dog (other Canis) Ferret (Mustela putorius furo) Other carnivore (other Carnivora) Horse and other equid (Equidae) Other rodent (other Rodentia) Rabbit (Oryctolagus cuniculus) Pig (Sus scrofa domesticus) Goat (Capra aegagrus hircus) Squirrel Monkey Other New World Monkey Apes Other Old World Monkey **Primate** New World monkey Marmoset and tamarin Sheep (Ovis aries) Cattle (Bos primigenius) Zebrafish (Danio rerio) Other fish (other Pisces) Quail (Coturnix coturnix) Other bird (other Aves) C**ephalopod** (Cephalopoda) Rat (Rattus norvegicus) Mouse (Mus musculus) Northern Ireland 2018 Old World monkey Cat (Felis catus) Species of animal Reptile (Reptilia) Prosimians Baboons % of total Aammal

Table 7.1 Experimental procedures by species of animal: regulatory use

	<u>~</u>	Routine Production			Quality	Quality control			Toxicity and		
Species of animal	Blood based products	Monoclonal antibody production (ascites)	Other	Batch safety testing	Pyrogenicity testing	Batch potency testing	Other quality controls	Other efficacy and tolerance testing	other safety testing including pharmacology	Total	% of total
Mammal											
Mouse (Mus musculus)	0	0	0	0	0	0	0	0	4	4	0.4
Rat (Rattus norvegicus)	0	0	0	0	0	0	0	•	•	0	0.0
Guinea-pig ( <i>Cavia porcellus)</i>	0	0	0	0	0	0	0	•	0	0	0.0
Hamster (Syrian) (Mesocricetus auratus)	0	0	0	0	0	0	0	•	•	0	0.0
Hamster (Chinese) (Cricetulus griseus)	0	0	0	0	0	0	0	•	•	0	0.0
Mongolian Gerbil (Meriones unguiculatus)	0	0	0	0	0	0	0	•	•	0	0.0
Other rodent (other Rodentia)	0	0	0	0	0	0	0	•	•	0	0.0
Rabbit (Oryctolagus cuniculus)	0	0	0	0	0	0	0	• •	• •	0	0.0
Cat (Felis catus)	0	0	0	0	0	0	0	•	24	24	2.6
Beagle (Canis lupus familiaris)	0	0	0	0	0	0	0	•	\$	44	4.8
Other dog (other <i>Canis</i> )	0	0	0	0	0	0	0	•	0	0	0.0
Ferret (Mustela putorius furo)	0	0	0	0	0	0	0	•	0	0	0.0
Other carnivore (other <i>Carnivora</i> )	0	0	0	0	0	0	0	•	•	0	0.0
Horse and other equid (Equidae)	0	O	C	C	C	O	C	•	ď.	ά	0.0
Pig (Sus scrofa domesticus)	0	0	0	0	0	0	0	•	180	180	7.01
Goat (Capra aegagrus hircus)	0	0	0	0	0	0	0	0	3		0.6
Sheep ( <i>Ovis aries</i> )	24	0	0	0	0	0	0	•	263	287	317
Cattle (Bos primigenius)	0	0	0	0	0	0	0	0	307	307	33.6
Primate											
(identical surprise)											
Marmoset and tamarin	0	0	0	0	0	0	0	•	•	0	0.0
Prosimians	0	0	0	0	0	0	0	C	c	C	0.0
Cynomolgus monkey (Macaca fascicularis)	0	0	0	0	0	0	0	•	•	0	0.0
Rhesus monkey (Macaca mulatta)	0	0	0	0	0	0	0	•	•	0	0.0
Other mammal (other Mammalia)	C	C	C	C	C	C	Ċ	•	c	c	Ċ
	·		Ò	)	Ò		·	•	>	•	š
Sird Domortic foul (Gallue domorticue)		(	(	C	(	C	Č		1	•	i
Dullestic IOWI (Gallus dolllesticus) Ougil (Coturnix coturnix)				0 0			0	0 (	20	50	5.5
Other bird (other Aves)	0	0	0	0	0	0	0	0	0	0	0.0
Soutilis)		c	c	c	C	C	Ċ	•	•	•	d
repure (nepura)		)	)	)	)		·	•	•		š
Amphibian Rana (temporaria and pipiens)	Production   Pro	ć									
trients auratis) trients											
Other amphibian (other Amphibia)	0	0	0	0	0	0	0		0 0	0	0.0
di.											
Zebrafish ( <i>Danio rerio</i> )	0	0	0	0	0	0	0	0	0	0	0.0
Other fish (other <i>Pisces</i> )	0	0	0	0	0	0	0	•	0	0	0.0
Cephalopod (Cephalopoda)	0	0	0	0	0	0	0	0	0	0	0.0
Total	76	-				•	•	•	Soo	017	1001
Otal	7	>									

Table 7.2 Experimental procedures by species of animal: regulatory use by legislative requirement

Northern Ireland 2018												
					Testing by legislation	legislation						
Species of animal	Legislation on medicinal products for human use	Legislation on medicinal products for veterinary use and their residues	Medical devices legislation	Industrial chemicals legislation	Plant protection product legislation	Biocides legislation	Food legislation including food contact material	Feed legislation including legislation for the safety of target animals, workers and environment	Cosmetics legislation	Other	Total	% of total
Mammal												
Mouse (Mus musculus)	0	0	0	0	0	0	4	0	0	0	4	4.0
Rat (Rattus norvegicus)	0	0	0	0	0	0	0	0	0	0	•	0.0
All other rodent <sup>1</sup>	0	0	0	0	0	0	0	0	0	0	•	0.0
Rabbit (Oryctolagus cuniculus)	0	0	0	0	0	0	0	0	0	0	0	0.0
Cat (Felis catus)	0	24	0	0	0	0	0	0	0	0	24	2.6
Dog	0	44	0	0	0	0	0	0	0	0	4	4.8
Ferret (Mustela putorius furo)	0	0	0	0	0	0	0	0	0	0	•	0.0
Other carnivore (other Carnivora)	0	0	0	0	0	0	0	0	0	0	•	0.0
Horse and other equid (Equidae)	0	18	0	0	0	0	0	0	0	0	18	2.0
Pig (Sus scrofa domesticus)	0	180	0	0	0	0	0	0	0	0	180	19.7
Other ungulate²	0	502	0	0	0	0	92	0	0	0	594	65.0
Primate												
New World monkey	0	0	0	0	0	0	0	0	0	0	0	0.0
Old World monkey	0	0	0	0	0	0	0	0	0	0	•	0.0
Other mammal (other Mammalia)	0	0	0	0	0	0	0	0	0	0	0	0.0
Bird	0	50	0	0	0	0	0	0	0	0	20	5.5
Reptile, amphibian	0	0	0	0	0	0	0	0	0	0	0	0.0
Fish	0	0	0	0	0	0	0	0	0	0	0	0.0
Cephalopod	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	•	818	•	0	0	0	96	•	•	0	914	100.0
% of total	0.0	89.5	0.0	0.0	0.0	0.0	10.5	0.0	0.0	0.0	100.0	

"All other rodent" includes guinea pig (Cavia porcellus), Syrian hamster (Mesocricetus auratus), Chinese hamster (Cricetulus griseus), Mongolian gerbil (Meriones unguiculatus), and other rodents

<sup>(</sup>other *Rodentia*).
2. "Other ungulate" includes goat (Capra aegagrus hircus), sheep (Ovis aries), and cattle (Bos primigenius).

Table 7.3 Experimental procedures by species of animal: regulatory use by origin of legislative requirement

### Northern Ireland 2018

	L	egislative requiremen	nt		
Species of animal	Legislation satisfying EU requirements	Legislation satisfying only UK requirements	Legislation satisfying Non-EU requirements only	Total	% of total
Mammal					
Mouse (Mus musculus)	4	0	О	4	0.4
Rat (Rattus norvegicus)	0	0	О	o	0.0
Guinea-pig (Cavia porcellus)	0	0	О	o	0.0
Hamster (Syrian) (Mesocricetus auratus)	0	0	О	o	0.0
Hamster (Chinese) (Cricetulus griseus)	0	0	О	О	0.0
Mongolian Gerbil (Meriones unguiculatus)	0	0	О	О	0.0
Other rodent (other Rodentia)	0	0	О	o	0.0
Rabbit (Oryctolagus cuniculus)	0	0	О	o	0.0
Cat (Felis catus)	12	0	12	24	2.
Beagle <i>(Canis lupus familiaris)</i>	0	0	44	44	4.
Other dog (other <i>Canis</i> )	0	0	0	О	0.
Ferret (Mustela putorius furo)	0	0	0	o	0.0
Other carnivore (other <i>Carnivora</i> )	0	0	o	o	0.0
Horse and other equid (Equidae)	18	0	О	18	2.0
Pig (Sus scrofa domesticus)	180	0	0	180	19.
Goat (Capra aegagrus hircus)	0	0	0	o	0.
Sheep (Ovis aries)	287	0	0	287	31.
Cattle (Bos primigenius)	307	0	О	307	33.
Primate					
New World monkey					
Marmoset and tamarin	0	0	0	0	0.
Old World monkey					
Prosimians Cynomologys mankey (Massass fassicylaris)	0	0	0	0	0.
Cynomolgus monkey (Macaca fascicularis)	0	0	0	0	0.
Rhesus monkey ( <i>Macaca mulatta</i> )	0	0	0	0	0.
Other mammal (other <i>Mammalia</i> )	0	0	0	o	0.
Bird					
Domestic fowl (Gallus domesticus)	50	0	0	50	5.
Quail (Coturnix coturnix)	0	0	0	0	0.
Other bird (other Aves)	0	0	0	0	0.
Reptile (Reptilia)	0	0	О	o	0.
Amphibian					
Rana (temporaria and pipiens)	0	0	0	o	0.
Xenopus (laevis and tropicalis)	0	0	0	o	0.
Other amphibian (other Amphibia)	0	0	0	o	0.
Fish	_	_	_		
Zebrafish (Danio rerio)	0	0	0	0	0.
Other fish (other <i>Pisces</i> )	0	0	0	0	0.
Cephalopod (Cephalopoda)	0	0	0	0	0.0
Total	858	-	56	914	100.0
% of total	93.9	0.0	6.1	100.0	

.....

Table 7.4 Experimental procedures by species of animal: regulatory use by type of test - toxicity and other safety testing including pharmacology, page 1 of 2

	Acute and tes	Acute and sub-acute toxic testing methods	toxicity s				Other type	Other type of regulatory test or procedure	ry test or p	rocedure			
Species of animal	LD5o and LC5o	Other lethal methods	Non-lethal methods	Skin irritation/ corrosion	Skin sensitisation	Eye irritation/ Repeated dose corrosion toxicity		Carcinogenicity	Genotoxicity	Reproductive toxicity	Developmental toxicity	Safety testing in food and feed area	Target animal safety
Mammal													
Mouse (Mus musculus)	0	0	0	0	0	0	0	0	0	0	0	4	0
Rat (Rattus norvegicus)	0	0	0	0	0	0	0	0	0	0	0	0	0
All other rodent	0	0	0	0	0	0	0	0	0	0	0	0	0
Rabbit (Onyctolagus cuniculus)	0	0	0	0	0	0	0	0	0	0	0	0	0
Cat (Felis catus)	0	0	0	0	0	0	0	0	0	0	0	0	0
Dog	0	0	0	0	0	0	0	0	0	0	0	0	0
Ferret (Mustela putorius furo)	0	0	0	0	0	0	0	0	0	0	0	0	0
Other carnivore (other <i>Camivora</i> )	0	0	0	0	0	0	0	0	0	0	0	0	0
Horse and other equid (Equidae)	0	0	0	0	0	0	0	0	0	0	0	0	0
Pig (Sus scrofa domesticus)	0	0	0	0	0	0	0	0	0	0	0	0	0
Other ungulate <sup>2</sup>	0	0	0	0	0	0	0	0	0	0	0	105	0
Primate													
New World monkey	0	0	0	0	0	0	0	0	0	0	0	0	0
Old World monkey	0	0	0	0	0	0	0	0	0	0	0	0	0
Other mammal (other Mammalia)	0	0	0	0	0	0	0	0	0	0	0	0	0
Bird	0	0	0	0	0	0	0	0	0	0	0	50	0
Reptile, amphibian	0	0	0	0	0	0	0	0	0	0	0	0	0
Fish	0	0	0	0	0	0	0	0	0	0	0	0	0
Cephalopod	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	•	•	0	0	0	•	0	0	0	0	0	159	•
% of total	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	17.9	0.0

<sup>&</sup>quot;All other rodent" includes guinea pig (Cavia porcellus), Syrian hamster (Mesocricetus auratus), Chinese hamster (Cricetulus griseus), Mongolian gerbil (Meriones unguiculatus), and other rodents (other Rodentia). ;

<sup>2. &</sup>quot;Other ungulate" includes goat (Capra aegagrus hircus), sheep (Ovis aries), and cattle (Bos primigenius).

Table 7.4 Experimental procedures by species of animal: regulatory use by type of test - toxicity and other safety testing including pharmacology,

page 2 of 2

	Other type	Other type of regulatory test or procedure	ry test or p	rocedure				Ecotoxicity				
Species of animal	Neurotoxicity	Kinetics	Pharmo- dynamics	Phototoxicity	Acute toxicity Chronic toxicity	ity Reproductive toxicity	Endocrine activity	Bioaccumulation	Other	Other type of toxicity or safety test	Total	% of total
Mammal												
:   Mouse ( <i>Mus musculus</i> )	0	0	0	0	0	0 0	0	0	0	0	4	0.4
Rat (Rattus norvegicus)	0	0	0	0	0	0 0	0	0	0	0	•	0.0
All other rodent	0	0	0	0	0	0 0	0	0	0	0	•	0.0
Rabbit (Onyctolagus cuniculus)	0	0	0	0		0 0	0	0	0	0	0	0.0
Cat (Felis catus)	0	24	0	0	0		0	0	0	0	24	2.7
Dog	0	44	0	0			0	0	0	0	44	4.9
Ferret (Mustela putorius furo)	0	0	0	0			0	0	0	0	•	0.0
Other carnivore (other <i>Carnivora</i> )	0	0	0	0		0 0	0	0	0	0	0	0.0
Horse and other equid (Equidae)	0	18	0	0			0		0	0	18	2.0
Pig (Sus scrofa domesticus)	0	136	44	0	0	0 0	0	0	0	0	180	20.2
Other ungulate²	0	239	226	0	0	0 0	0	0	0	0	570	64.0
Primate												
New World monkey	0	0	0	0	0	0 0	0	0	0	0	•	0.0
Old World monkey	0	0	0	0		0 0	0	0	0	0	0	0.0
Other mammal (other <i>Mammalia</i> )	0	0	0	0	0	0 0	0	0	0	0	•	0.0
Bird	0	0	0	0	0	0 0	0	0	0	0	50	5.6
Reptile, amphibian	0	0	0	0	0	0 0	0	0	0	0	•	0.0
Fish	0	0	0	0	0	0 0	0	0	0	0	•	0.0
Cephalopod	0	0	0	0	0	0 0	0	0	0	0	0	0.0
Total	•	461	270	0	0	0 0	•	0	0	0	890	100.0
% of total	0.0	51.8	30.3	0.0	0.0 0.0	0.0	0.0	0.0	0.0	0.0	100.0	

<sup>&</sup>quot;All other rodent" includes guinea pig (Cavia porcellus), Syrian hamster (Mesocricetus auratus), Chinese hamster (Cricetulus griseus), Mongolian gerbil (Meriones unguiculatus), and other rodents

<sup>(</sup>other Rodentia).
2. "Other ungulate" includes goat (Capra aegagrus hircus), sheep (Ovis aries), and cattle (Bos primigenius).

### Table 8 Creation of new lines and maintenance of established lines of genetically altered animals (not used in experimental procedures) by species of animal, severity and genetic status

			Genetic status			
Species of animal <sup>1</sup>	Actual severity	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	% of species total
	Sub threshold	11	2,647	40	2,698	55.0
	Non-recovery	0	0	О	0	0.0
Mouse	Mild	110	1,425	21	1,556	31.7
(Mus musculus)	Moderate	1	26	541	568	11.6
	Severe	6	69	10	85	1.7
	Total	128	4,167	612	4,907	100.0
	Sub threshold	11	2,647	40	2,698	55.0
	Non-recovery	0	0	О	0	0.0
	Mild	110	1,425	21	1,556	31.7
All species	Moderate	1	26	541	568	11.6
	Severe	6	69	10	85	1.7
	Total	128	4,167	612	4,907	100.0

<sup>1.</sup> Some species were not displayed on this tables as they were not used in any relevant procedures in 2018.

### Table 9 Maintenance of established lines of genetically altered animals (not used in experimental procedures) by species of animal, severity and genetic status

			Genetic status			
Species of animal <sup>1</sup>	Actual severity	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	% of species total
	Sub threshold	11	2,647	40	2,698	55.0
	Non-recovery	0	0	О	0	0.0
Mouse	Mild	110	1,425	21	1,556	31.7
(Mus musculus)	Moderate	1	26	541	568	11.6
	Severe	6	69	10	85	1.7
	Total	128	4,167	612	4,907	100.0
	Sub threshold	11	2,647	40	2,698	55.0
	Non-recovery	0	0	О	0	0.0
	Mild	110	1,425	21	1,556	31.7
All species	Moderate	1	26	541	568	11.6
	Severe	6	69	10	85	1.7
	Total	128	4,167	612	4,907	100.0

<sup>1.</sup> Some species were not displayed on this tables as they were not used in any relevant procedures in 2018.

Table 10 Procedures and project licences by type of licensed establishment

	Number o	f project lice	Number of project licences where countable procedur	ountable <sup>1</sup> pro	cedures we	es were completed in 2017 by number of procedures	in 2017 by	number of p	rocedures	Number			Number of procedures	procedures
				Number of proced	procedures					of project	Number			
Type of licensed establishment	1 to 50	51 to 100	51 to 100 101 to 200 201 to 400 401 to	201 to 400	_	600 601 to 800	801 to 1,000	More than 1,000	Total	only non- only non- countable <sup>1</sup> procedures were completed in 2018	or project licences where no procedures were completed in 2018	Total number of project licences	Total	% of total
Public health laboratories	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Universities, medical schools	13	ω	4	9	4	m	4	7	41	0	27	89	22,472	78.1
Government departments	0	0	0	Ħ	0	0	0		2	0	н		1,419	4.9
Other public bodies	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Non-profit- making organisations	7.	4	m	7.0	0	0	0	т	18	н	12	31	3,621	12.6
Commercial organisations	0	0	0	0	T	н	0	0	2	0	2	4	1,278	4.4
Total	18	7	7	12	5	4	4	9	63	1	42	106	28,790	100.0

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 5 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 undertook rodenticide trials (o returns in 2017).

### Table 11 Designated establishments: 2008-2018

Number of designated places at 31 December 2018

### Northern Ireland

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Scientific procedure establishments	5	5	5	5	5	4	4	4	4	4	4
Scientific procedure and breeding establishments	О	0	0	0	О	0	0	0	0	0	1
Scientific procedure breeding and supplying establishments	5	3	3	3	3	4	4	4	4	5	4
Scientific procedure and supplying establishments	О	0	0	0	0	0	0	0	0	О	0
Breeding and supplying establishments	1	1	1	1	1	1	1	1	1	1	1
Total designated places	11	9	9	9	9	9	9	9	9	10	10

### Table 12 Personal Licensees: 2008-2018

Number of personal licences at 31 December 2018

2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
561	565	585	582	590	480	480	548	630	669	598

### **Appendix**

### General system of control under the Animals (Scientific Procedures) Act 1986

#### Introduction

21. The Animals (Scientific Procedures) Act 1986 put in place a rigorous system of controls on scientific work on living animals, including the need for both the researcher and the project to be separately licensed; stringent safeguards on animal pain and suffering; and general requirements to ensure the care and welfare of animals.

### **Scope of the Act**

- 22. The Act controls any experimental or other scientific procedure applied to a 'protected animal' which may have the effect of causing that animal pain, suffering, distress or lasting harm. Such work is referred to in the Act as a 'regulated procedure'. 'Protected animals' are defined as all living vertebrate animals, except man, plus cephalopods. The definition extends to foetal, larval or embryonic forms that have reached specified stages in their development. Under the Act an animal is regarded as 'living' until "the permanent cessation of circulation or complete destruction of its brain". Procedures carried out on decerebrate animals are also subject to the controls of the Act.
- 23. The definition of a regulated procedure encompasses most breeding of animals with genetic defects; production of antisera and other blood products; the maintenance and passage of tumours and parasites; and the administration for a scientific purpose of an anaesthetic, analgesic, tranquilliser or other drug to dull perception. Killing an animal requires licence authority in certain circumstances.
- 24. The controls of the 1986 Act do not extend to procedures applied to animals in the course of recognised veterinary, agricultural or animal husbandry practice; procedures for identification of animals for scientific purposes, if this causes no more than momentary pain or distress and no lasting harm; or clinical tests on animals for evaluating a veterinary product under authority of an Animal Test Certificate (issued under the Medicines Act 1968).

### **Project and Personal Licences**

- 25. Two kinds of licence are required for all scientific work controlled by the Act. The procedures must be part of a programme of work authorised by a project licence and the person applying the regulated procedures must hold a personal licence. No work may be done unless the procedure, the animals used and the place where the work is to be done are specifically authorised in both project and personal licences.
- 26. A project licence is granted when the Department of Health (hereinafter referred to as the Department) considers that the use of living animals in a programme of work, for a purpose permitted by the Act, is justified and the methods proposed appropriate.
- 27. In deciding whether and on what terms to authorise the project, the likely adverse effects on the animals used must be weighed against the benefit (to humans, other animals or the environment) which is likely to accrue from the work. Adequate consideration must also have been given to the feasibility of using alternative methods not involving living animals. The holder of a project licence undertakes overall responsibility for the scientific direction and control of the work and is responsible for making the statistical returns on which this publication is based. New project licence applicants are required to complete an accredited training course.

28. A personal licence is the Department's endorsement that the holder is a suitable and competent person to carry out specified procedures on specified animals, under supervision where necessary. Applicants must be over 18 and are required to give details of their qualifications, training and experience. Those who have not previously held a licence need the endorsement of the named training and competency officer. Satisfactory completion of an accredited training course is also required before a personal licence is issued.

#### **Establishment Licences**

- 29. Except where otherwise authorised in a project licence (for example, for field work at a specified place and time), any place where work is carried out under the Act must be licensed. Establishments that breed certain types of animal listed in Schedule 2 of the Act for use in scientific procedures ('breeding establishments'), and establishments that obtain such animals from elsewhere and supply them to laboratories ('supplying establishments') must hold an appropriate licence to do so. Animals listed in Schedule 2 are: mice; rats; guinea pigs; hamsters; gerbils; rabbits; cats; dogs; primates; ferrets; 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.
- 30. Licensed establishments are required to appoint the following named persons:
  - Named Animal Care and Welfare Office (NACWO)
  - Named Veterinary Surgeon (NVS)
  - Named Training and Competence Officer (NTCO)
  - Named Information Officer (NIO)
  - Named Compliance Officer (NCO)

### The Inspectorate

- 31. The Act gives statutory recognition to the Animals (Scientific Procedures) Inspectorate and describes the Inspectors' duties. Inspectors hold either medical or veterinary qualifications. Inspectors assess all applications for new licences or amendments to existing licences in detail and advise the Department on how to ensure that only properly justified work is licensed. When assessing research proposals, the Inspectorate ensures that full consideration is given to alternatives, not only the **replacement** of procedures with others which do not use animals, but also the **reduction** of the number of animals used and the **refinement** of procedures to minimise pain and suffering. These are known as the **3Rs**. Inspectors carry out visits, mainly without notice, to establishments designated under the Act to inspect the premises and to ensure that the establishment's controls are adequate and that the terms and conditions of the licences issued under it are being observed.
- 32. Inspectors also advise the Department on policy matters connected with the operation of the Act and they are available to give advice and assistance to licensees and other personnel working under the Act.
- 33. During 2018 the Inspectorate made 115 visits to establishments.

### The Animals in Science Committee (ASC)

34. The Animals in Science Committee is an advisory non-departmental public body of the Home Office. The Animals in Science Committee was established by the Animals (Scientific Procedures) Act 1986 as amended to comply with Directive EU 2010/63/EU which came in to force on the 1st January 2013. Article 49 of this Directive requires each EU country to set up a National Committee for the Protection of Animals used for Scientific Purposes. In the UK the committee is known as the Animals in Science Committee and has superseded the Animal Procedures Committee.

The Animals in Science Committee is responsible for providing impartial, balanced and objective advice to the Home Office, the Department of Health to animal welfare bodies and within the European Union on issues relating to the Animals (Scientific Procedures) Act 1986 as amended.

### **Guidance, Codes of Practice and Statistics**

- 35. In addition to these annual statistics, the Act requires that there be published and laid before Parliament guidance on the operation of the controls of the Act and codes of practice as to the care and accommodation of animals and their use in regulated procedures. Current Home Office publications include:
  - Guidance on the operation of the Animals (Scientific Procedures) Act 1986 (2014)
  - Working to reduce the use of animals in research (February 2014)
  - Code of practice for the housing and care of animals bred, supplied or used in scientific procedures (December 2014)
  - Household Products testing ban advice note (October 2015)
  - Use, keeping alive and reuse advice note (October 2015)
  - Rehoming and setting free of animals (October 2015)
  - Identification and Management of patters of low level concerns at licenced establishments (December 2015)
  - The Harm-Benefit Analysis Process (December 2015)
  - Guidance on the use of Human Materials in Animals (January 2016)
  - Working with animals taken from the wild (July 2016)

### **Education and training**

- 36. The Animals (Scientific Procedures) Act 1986 imposes clear responsibilities on persons with specific roles in relation to the care and use of animals in scientific procedures. These are elaborated further in the Home Office guidance on the operation of the Act published in March 2014 https://www.gov.uk/government/publications/operation-of-aspa. As the roles differ, it follows that the education and training required before assuming these responsibilities will differ:
  - personal licence holders are responsible for the welfare of animals on which they carry out regulated procedures; applicants will be granted licences only if adequately trained to take on this responsibility and they will usually be required to work under supervision initially;
  - project licences will be issued only to persons with appropriate qualifications to direct
    a programme of work which is well-justified and takes account of all reasonable
    possibilities for reducing the number of animals used, refining the procedures to
    reduce suffering and replacing animal procedures with alternatives which do not involve
    protected animals;
  - holders of establishment licences have responsibility not only for ensuring that the fabric
    and staffing of designated places are maintained to appropriate standards but also for
    ensuring that reasonable steps are taken to prevent unauthorised procedures being
    carried out and that adequate training facilities are available for all animal users.

37. European Directive 2010/63/EU requires that staff are adequately trained to carry out procedures on animals; design procedures and projects; take care of or kill animals. All training programmes are accredited under a scheme recognised by the Department. Accreditation seeks to achieve common and high standards for licensee training.

### Performance against code of practice standards

38. The licensing team works to specific targets set out in the draft Code of Practice. The Code of Practice requires new personal licences, certificates and amendments to be issued within 20 working days. Project licences will be considered and issued/refused within 40 working days from receipt of application, unless the application involves a complex or multidisciplinary programme in which case the process may be extended by a further 15 working days (3 weeks). In 2018, all personal and project licences were processed within the targets prescribed within the Code of Practice.



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