

Statistics of Scientific Procedures On Living Animals Northern Ireland 2015



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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, 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 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 has been revised (these changes were also in place for 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.
- Data on greyhounds are no longer collected separately; however, 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.
- Data 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.
- 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 (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

Description of Statistical Tables

1. Project holders were asked to answer detailed questions about the procedures completed in 2015. 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 8-10, which refer to genetically altered animals created/bred in 2015 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. Unlike previous years, 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, 9.1, 9.2, 9.3 and 10).

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.

Source of animals (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, cat, dog, quail, ferret, gerbil, frog, zebra fish and pigs and sheep if genetically modified.
- 8. Data is collected on place of birth, which replaces source. Information is provided regarding 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 8-10)

- 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
 - 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
 - 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 and 7.3 provide a breakdown of all regulatory procedures by type and origin of the legislative 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, 8-10)

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.

Project and Personal licence holders and licensed establishments (Tables 11)

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

Introduction

Following the transposition of European Directive 2010/63/EU into UK law through amendment regulations to the Animals (Scientific Procedures) Act 1986, some changes were applied to the 2014 collection. The 2015 figures in this release are the second year for which these changes apply. In particular, information is now collected on procedures completed, not procedures started, as for previous publications. This now enables details on the actual severity of procedures to be collected.

Comparison between the 2015 and 2014 data should be exercised with caution due to some under-reporting and misclassification in 2014. As a result, 2015 data are compared with 2013 data, as neither year of data are subject to the same data quality issues as the 2014 data. Comparisons with 2014 data are made for severity as information on the actual severity of procedures was not collected prior to 2014, and are only made in percentage terms due to the data quality issues for that year.

- 1. The main features of the statistics for 2015 were:
 - a) The number of procedures completed was 22,508. Of these 5,332 (23.7%) related to the creation/breeding of genetically altered animals that were not used in further procedures and the remaining 17,176 (76.3%) were experimental procedures (Table 1).
 - b) The number of animals used for the first time was 21,642. This is in comparison to 18,889 in 2014 (Table 1a).
 - c) Of the 17,176 experimental procedures completed in 2015, the majority involved mice (68.9% or 11,842 procedures). Domestic fowl were used in 8.5% or 1,454 procedures, cattle in 8.5% or 1,468 procedures, sheep in 3.8% or 651 procedures, pigs in 3.1% or 530 procedures, and rats in 2.8% or 488 procedures (Table 1).
 - d) Some 16,226 or 99.5% of experimental procedures completed in 2015 used animals born in the UK. 84 or 0.5% of experimental procedures used animals born in the EU (outside the UK) or elsewhere (rest of the world) (Table 2).
 - e) The majority of experimental procedures completed in 2015 used animals that had not been genetically modified (65.1% or 11,187 procedures). 24.9% (4,285) of experimental procedures involved genetically modified animals without a harmful phenotype, i.e. a harmful physical or chemical defect. 9.9% (1,704) of experimental procedures involved genetically modified animals with a harmful phenotype (Table 4).
 - f) Of the severity assessments undertaken for the 17,176 experimental procedures completed in 2015: 0.1% were assessed as sub-threshold; 53% were assessed as mild; 41.2% were assessed as moderate; 4.4% were assessed as severe and 1.3% were assessed as non-recovery (Table 3).
 - g) Of the 17,176 procedures (76.3%) undertaken for experimental purposes: 10,885 (48.4%) were undertaken for basic research; 4,918 (21.9% were undertaken for translational/applied research; 793 (3.5%) were undertaken for regulatory use; 459 (2%) were undertaken for the purpose of protection of the natural environment; and 121 (0.5%) were undertaken for forensic enquiries (Table 1).
 - h) In 2015, 10,885 procedures were undertaken for basic research purposes. Of these, 84.3% (9,173) procedures were undertaken for the study of oncology and specified organ systems. 15.7% (1,712 procedures) were undertaken for the study of animal biology (including ethology/animal behaviour) or other purposes (Table 5).

- i) In 2015, 4,918 procedures were undertaken for translational/applied research purposes. Of those 91% (4,477procedures) were undertaken for research on humans, 7.2% (355 procedures) were undertaken for animal research and 1.8% (86 procedures) were undertaken for the diagnosis of diseases (Table 6).
- j) In 2015, 793 procedures were undertaken for regulatory use. Of these 89.2% (707) procedures) were for toxicity and other safety testing, including pharmacology, and 10.8% (86) procedures were for routine production of blood based products (Table 7.1).
- k) Of the 793 procedures undertaken for regulatory use, 56.7% (450) involved legislation on medicinal products for veterinary use (and their residues) and 43.3% (343) involved in food legislation (including food contact material) (Table 7.2). All regulatory procedures satisfied both UK and EU legislation (Table 7.3).
- l) Of the 3,737 genetically altered animals created/bred in 2015, 1,595 were for the maintenance of established lines of genetically modified animals. The remaining 2,142 were created/bred to create new lines of genetically modified animals (Table 9.1 and 10).
- m) The total number of procedures during 2015 that were carried out in universities/medical schools was 17,615 (78.3%), in government departments the total was 341 (1.5%), in non-profit-making organisations there were 3,409 (15.1%) and commercial organisations accounted for 1,143 (5.1%) (Table 11).
- n) Returns were completed in respect of 124 project licences in 2015 (1 less than 2014). Some project holders would have made 2 returns for 2015, one relating to the expiring licence and one relating to the successor licence. A total of 73 licences carried out procedures in 2015 (Table 11).
- o) During 2015, the number of personal licences which were operational and authorised to carry out regulated procedures under the act was 548. (Table 13).

Statistics of Scientific Procedures on Living Animals Northern Ireland 2

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

lorthern Ireland 2015		Expe	rimental purpo	se of procedui	e (excluding cr	eation & bree	ding)		Creation &		
Species of animal	Basic Research	Translational/ Applied research	Protection of the natural environment	Preservation of species	Higher education or training	Forensic enquiries	Regulatory	Total experimental procedures	breeding of GA animals not used in experimental procedures	Total procedures	% of total procedures
Mammal											
Mouse (Mus musculus)	7,564	4,259	0	0	0	0	19	11,842	5,289	17,131	76.:
Rat (Rattus norvegicus)	338	150	0	0	0	0	0	488	43	531	2.
Guinea-pig <i>(Cavia porcellus)</i>	О	0	0	0	0	0	0	0	0	o	0.0
Hamster (Syrian) (Mesocricetus auratus)	0	0	0	0	0	0	0	0	o	o	0.0
Hamster (Chinese) (Cricetulus griseus)	o	0	0	0	0	0	0	0	0	О	0.0
Mongolian Gerbil (Meriones unguiculatus)	О	0	0	0	0	0	0	О	О	О	0.0
Other rodent (other Rodentia)	О	0	0	0	0	0	0	О	О	О	0.0
Rabbit (Oryctolagus cuniculus)	16	0	0	0	0	0	53	69	О	69	0.3
Cat (Felis catus)	0	50	0	0	0	0	63	113	0	113	0.
Beagle (Canis lupus familiaris)	0	36	0	0	0	0	74	110	o	110	0.
Other dog (other Canis)	О	0	0	0	0	0	0	О	0	О	0.0
Ferret (Mustela putorius furo)	0	0	0	0	0	0	0	О	o	o	0.0
Other carnivore (other Carnivora)	О	0	0	0	0	0	0	0	О	0	0.0
Horse and other equids (Equidae)	0	0	0	0	0	0	0	0	О	О	0.0
Pig (Sus scrofa domesticus)	287	139	0	0	0	0	104	530	0	530	2.4
Goat (Capra aegagrus hircus)	o	0	0	0	0	0	0	0	o	0	0.0
Sheep (Ovis aries)	81	86	0	0	0	121	363	651	О	651	2.9
Cattle (Bos primigenius)	1,145	183	23	0	0	0	117	1,468	o	1,468	6.
Other mammal (other Mammalia)	О	0	341		0	0	0	341	О	341	1.5
Bird											
Domestic fowl (Gallus domesticus)	1,454	0	0	0	0	0	0	1,454	0	1,454	6.
Quail (Coturnix coturnix)	0	0	0	0	0	0	0	0	o	0	0.0
Other bird (other Aves)	0	0	0	0	0	0	0	0	0	0	0.0
Reptile (Reptilia)	0	0	0	0	0	0	0	0	0	o	0.0
Amphibian											
Rana (temporaria and pipiens)	0	0	0	0	0	0	0	0	0	o	0.0
Xenopus (laevis and tropicalis)	0	0	0	0	0	0	0	0	0	o	0.0
Other amphibian (other Amphibia)	0	15	0	0	0	0	0	15	0	15	0.
ish											
Zebrafish (Danio rerio)	0	0	0	0	0	0	0	0	0	0	0.0
Other fish (other Pisces)	0	0	95	0	0	0	0	95	0	95	0.4
Cephalopod (Cephalopoda)	0	0	0	0	0	0	0	0	0	О	0.0
Total % of total	10,885 48.4	4,918 21.9	459 2.0	0 0.0	0 0.0	121 0.5	793 3·5	17,176 76.3	5,332 23.7	22,508 100.0	100.0

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

		Expe	rimental purpo	se of procedu	re (excluding cr	reation & bree	ding)		Creation &		% of total
Species of animal	Basic Research	Translational/ Applied research	Protection of the natural environment	Preservation of species	Higher education or training	Forensic enquiries	Regulatory	Total animals used for the first time in experimental procedures	breeding of GA animals not used in experimental procedures	Total animals used for the first time in procedures	animals used for the first time in procedures
Mammal											
Mouse (Mus musculus)	7,564	4,259	0	0	0	0	19	11,842	5,289	17,131	79.2
Rat (Rattus norvegicus)	338	150	0	0	0	0	0	488	43	531	2.
Guinea-pig (Cavia porcellus)	0	0	0	0	0	0	0	0	0	o	о.
Hamster (Syrian) (Mesocricetus auratus)	0	0	0	0	0	0	0	0	0	O	о.
Hamster (Chinese) (Cricetulus griseus)	0	0	0	0	0	0	0	0	0	O	o.
Mongolian Gerbil (Meriones unguiculatus)	0	0	0	0	0	0	0	0	0	0	о.
Other rodent (other Rodentia)	0	0	0	0	0	0	0	0	0	0	О.
Rabbit (Oryctolagus cuniculus)	16	0	0	0	0	0	53	69	0	69	0.
Cat (Felis catus)	0	23	0	0	0	0	10	33	0	33	o.:
Beagle (Canis lupus familiaris)	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
Ferret (Mustela putorius furo)	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.
Horse and other equids (Equidae)	0	0	0	0	0	0	0	0	0	o	o.
Pig (Sus scrofa domesticus)	287	138	0	0	0	0	104	529	0	529	2.
Goat (Capra aegagrus hircus)	0	0	0	0	0	0	0	0	0	0	0.
Sheep (Ovis aries)	28	86	0	0	0	121	363	598	0	598	2.
Cattle (Bos primigenius)	653	119	23	0	0	0	60	855	0	855	4.
Other mammal (other Mammalia)	0	0	341	0	0	0	0	341	О	341	1.
Bird											
Domestic fowl (Gallus domesticus)	1,454	0	0	0	0	0	0	1,454	0	1,454	6.
Quail (Coturnix coturnix)	0	0	0	0	0	0	0	0	0	0	о.
Other bird (other Aves)	0	0	0	0	0	0	0	0	0	0	0.
Reptile (Reptilia)	0	0	0	0	0	0	0	0	0	o	o.
Amphibian											
Rana (temporaria and pipiens)	0	0	0	0	0	0	0	0	0	o	o.
Xenopus (laevis and tropicalis)	0	0	0	0	0	0	0	0	0	o	о.
Other amphibian (other Amphibia)	0	6	0	0	0	0	0	6	0	6	0.
ish											
Zebrafish (Danio rerio)	0	0	0	0	0	0	0	0	0	o	o.
Other fish (other Pisces)	0	0	95	0	0	0	0	95	0	95	o.
Cephalopod (Cephalopoda)	0	0	0	0	0	0	0	0	0	0	0.0
Total	10,340	4,781	459	0	0	121	609	16,310	5,332	21,642	100.
% of total	47.8	22.1	2.1	0.0	0.0	0.6	2.8	75.4	24.6	100.0	

Table 2 Place of birth of animals used (for the first time) in experimental procedures by species of animal Northern Ireland 2015

			Place o	of birth				
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 not at a registered breeder	Animals born in rest of Europe	Animals born in rest of world	Total	% of total
Mammal								
Mouse (Mus musculus)*	11,798	0	20	0	0	24	11,842	72.6
Rat (Rattus norvegicus)*	488	0	0	0	0	0	488	3.0
Guinea-pig (Cavia porcellus)*	0	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	0.0
Mongolian Gerbil (Meriones unguiculatus)*	0	0	0	0	0	0	0	0.0
Other rodent (other Rodentia)	0	0	0	0		0	0	0.0
Rabbit (Oryctolagus cuniculus)*	69	0	0	0	0	0	69	0.2
Cat (Felis catus)*	1	0	0	0	0	32	33	0.2
Beagle (Canis lupus familiaris)*	0	0	0	0		0	0	0.0
Other dog (other Canis)*	0	0	0	0		0	0	0.0
Ferret (Mustela putorius furo)*	0	0	0	0		0	0	0.0
Other carnivore (other Carnivora)	0	0	0	0	0	0	0	0.0
Horse and other equids (Equidae)	0	0	0	0	0	o	О	0.
Pig (Sus scrofa domesticus)*	145	384	0	0	0	0	529	3.
Goat (Capra aegagrus hircus)	0	0	0	0	0	0	0	0.
Sheep (Ovis aries)*	4	588	6	0	0	0	598	3.⁴
Cattle (Bos primigenius)	676	179	0	0	0	0	855	5.:
Other mammal (other Mammalia)	0	341	0	0	0	0	341	2.
Bird								
Domestic fowl (Gallus domesticus)	1,360	94	0	0	0	0	1,454	8.9
Quail (Coturnix coturnix)	0	0	0	0	0	0	0	0.0
Other bird (other Aves)	0	0	0	0	0	0	0	0.
Reptile (Reptilia)	0	0	0	0	0	0	0	0.0
Amphibian								
Rana (temporaria and pipiens)*	0	0	0	0	0	0	0	0.0
Xenopus (laevis and tropicalis)*	0	0	0	0		0	0	0.0
Other amphibian (other Amphibia)	0	4	0	0	0	2	6	0.
Fish								
Zebrafish (Danio rerio)*	0	0	0	0		0	0	0.
Other fish (other Pisces)	0	95	0	0	0	0	95	0.
Cephalopod (Cephalopoda)	0	0	0	0	0	0	О	0.0
Total	14,541	1,685	26	0	0	58	16,310	100.
% of total	89.2	10.3	0.2	0.0	0.0	0.4	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 procedure¹

Northern Irea				Purp	ose of proce	dure				
Species of animal	Actual Severity	Basic Research	Translational/ Applied studies	Protection of the natural environment	Preservation of species	Higher education or training	Forensic enquiries	Regulatory	Total	% of total
Mouse	Sub threshold Non-recovery Mild Moderate Severe Total	4 62 3,328 3,500 670 7,564	0 2 987 3,185 85 4,259	0 0 0 0	0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 17 0 2 19	4 64 4,332 6,685 757 11,842	0.0 0.5 36.6 56.5 6.4 100.0
Rat	Sub threshold Non-recovery Mild Moderate Severe Total	0 92 246 0 338	0 0 12 138 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0 0	0 0 104 384 0 488	0.0 0.0 21.3 78.7 0.0 100.0
Rabbit	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 16 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 53 0 0 53	0 69 0 0 69	0.0 0.0 100.0 0.0 0.0 100.0
Cat	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 0 0	0 50 0 0 50	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 63 0 0	0 0 113 0 0	0.0 0.0 100.0 0.0 0.0 100.0
Dog	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 0 0	0 0 36 0 0 36	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 74 0 0 74	0 0 110 0 0	0.0 0.0 100.0 0.0 0.0 100.0
Pig	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 283 4 0 287	0 63 76 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 104 0 0	0 63 463 4 0 530	0.0 11.9 87.4 0.8 0.0 100.0
All other ungulate	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 1,226 0 0 1,226	13 0 253 2 1 269	0 0 23 0 0	0 0 0 0	0 0 0 0	0 0 121 0 0	0 0 480 0 0 4 80	13 0 2,103 2 1 2,119	0.6 0.0 99.2 0.1 0.0 100.0
Other mammal	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 0 0	0 0 0 0	0 0 341 0 0 3 41	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0 0	0 0 341 0 0 341	0.0 0.0 100.0 0.0 0.0 100.0
Bird	Sub threshold Non-recovery Mild Moderate Severe Total	0 94 1,360 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 94 1,360 0 0	0.0 6.5 93.5 0.0 0.0
Amphibian	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 0 0	0 0 15 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 15 0 0	0.0 0.0 100.0 0.0 0.0 100.0
Fish	Sub threshold Non-recovery Mild Moderate Severe Total	0 0 0 0	0 0 0 0	0 95 0 0 95	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0 0	0 95 0 0 95	0.0 0.0 100.0 0.0 0.0 100.0
All species	Sub threshold Non-recovery Mild Moderate Severe Total	4 156 6,305 3,750 670 10,885	13 65 1,429 3,325 86 4,918	0 0 459 0 0 459	0 0 0 0	0 0 0 0 0	0 0 121 0 0	0 0 791 0 2 793	17 221 9,105 7,075 758 17,176	0.1 1.3 53.0 41.2 4.4 100.0

^{1.} Some species were not involved in experimental procedures in 2015. Therefore, these species are not listed individually in this table.

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Table 4 Experimental procedures by species of animal and genetic status

		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)	5,853	4,285	1,704	11,842	68.9
Rat (Rattus norvegicus)	488	0	0	488	2.8
Guinea-pig (Cavia porcellus)	0	0	0	0	0.0
Hamster (Syrian) (Mesocricetus auratus)	0	0	0	0	0.0
Hamster (Chinese) (Cricetulus griseus)	0	0	0	0	0.0
Mongolian Gerbil (Meriones unguiculatus)	0	0	0	0	0.0
Other rodent (other Rodentia)	0	0	0	0	0.0
Rabbit (Oryctolagus cuniculus)	69	0	0	69	0.4
Cat (Felis catus)	113	0	О	113	0.7
Beagle (Canis lupus familiaris)	110	0	0	110	0.6
Other dog (other Canis)	0	0	0	0	0.0
Ferret (Mustela putorius furo)	0	0	0	0	0.0
Other carnivore (other Carnivora)	0	0	0	0	0.0
Horse and other equids (Equidae)	0	0	О	o	0.0
Pig (Sus scrofa domesticus)	530	0	0	530	3.:
Goat (Capra aegagrus hircus)	0	0	0	0	0.0
Sheep (Ovis aries)	651	0	0	651	3.8
Cattle (Bos primigenius)	1,468	0	0	1,468	8.5
Other mammal (other Mammalia)	341	0	0	341	2.0
Bird					
Domestic fowl (Gallus domesticus)	1,454	0	0	1,454	8.5
Quail (Coturnix coturnix)	0	0	0	0	0.0
Other bird (other Aves)	0	0	0	0	0.0
Reptile (Reptilia)	0	0	0	О	0.0
Amphibian					
Rana (temporaria and pipiens)	0	0	0	0	0.0
Xenopus (laevis and tropicalis)	0	0	0	0	0.0
Other amphibian (other Amphibia)	15	0	0	15	0.1
Fish					
Zebrafish (Danio rerio)	0	0	0	0	0.0
Other fish (other Pisces)	95	0	0	95	0.6
Cephalopod (Cephalopoda)	0	0	0	0	0.0
Total	11,187	4,285	1,704	17,176	100
% of total	65.1	24.9	9.9	100	

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

						Ba	sic Resea	rch							
Species of animal	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 tota
Mammal															
Mouse (Mus musculus)	2,813	285	172	724	0	0	1,328	38	1,471	544	0	40	149	7,564	69.
Rat (Rattus norvegicus)	106	0	0	0	0	100	0	0	116	0	0	0	16	338	3.
Guinea-pig <i>(Cavia porcellus)</i>	О	0	0	0	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	0.0
Hamster (Chinese) (Cricetulus griseus)	О	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Mongolian Gerbil (Meriones unguiculatus)	О	0	0	0	0	0	0	0	0	0	0	0	О	0	0.0
Other rodent (other Rodentia)	О	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Rabbit (Oryctolagus cuniculus)	0	0	0	0	0	0	16	0	0	0	0	0	0	16	0.
Cat (Felis catus)	0	0	0	0	0	0	0	0	0	0	0	0	О	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)	О	0	0	0	0	0	0	0	0	0	0	0	О	0	0.0
Ferret (Mustela putorius furo)	О	0	0	0	0	0	0	0	0	0	0	0	О	0	0.0
Other carnivore (other Carnivora)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Horse and other equids (Equidae)	0	0	0	0	0	0	0	0	0	0	0	0	0	О	0.
Pig (Sus scrofa domesticus)	О	0	0	0	287	0	0	0	0	0	0	0	О	287	2.0
Goat (Capra aegagrus hircus)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Sheep (Ovis aries)	О	0	0	0	0	0	28	0	0	0	0	0	53	81	0.7
Cattle (Bos primigenius)	0	213	0	0	0	0	346	0	0	0	586	0	0	1,145	10.
Other mammal (other Mammalia)	0	0	0	0	0	0	0	0	0	0	0	0	О	0	0.0
Bird															
Domestic fowl (Gallus domesticus)	О	0	0	0	0	0	0	0	0	0	0	1,360	94	1,454	13.4
Quail (Coturnix coturnix)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Other bird (other Aves)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Reptile (Reptilia)	О	0	О	0	0	0	0	0	0	0	0	0	О	0	0.0
Amphibian															
Rana (temporaria and pipiens)	0	0	0	0	0	0	0	0	0	0	0	0	О	0	0.
Xenopus (laevis and tropicalis)	О	0	0	0	0	0	0	0	0	0	0	0	О	0	0.0
Other amphibian (other Amphibia)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Fish															
Zebrafish (Danio rerio)	0	0	0	0	0	0	0	0	0	0	0	0	О	0	o.
Other fish (other Pisces)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.
Cephalopod (Cephalopoda)	О	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	2,919	498	172	724	287	100	1,718	38	1,587	544	586	1,400	312	10,885	100.
% of total	26.8	4.6	1.6	6.7	2.6	0.9	15.8		14.6	5.0	_	12.9	2.9	100.0	

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

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Northern	Iroland	201E

	Translational/applied research													
Species of animal	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					
Mammal														
Mouse (Mus musculus)	1,118	1,110	570		284	2	, ,	235	(
Rat (Rattus norvegicus)	0	0	0		0	0		12	C					
Guinea-pig (Cavia porcellus)	0	0	0		0	0	0	0	(
Hamster (Syrian) (Mesocricetus auratus)	0	0	0		0	0	0	0	C					
Hamster (Chinese) (Cricetulus griseus)	0	0	0		0		0	0	(
Mongolian Gerbil (Meriones unguiculatus)	0	0	0	0	0	0	0	0	(
Other rodent (other Rodentia)	0	0	0	0	0	0	0	0	(
Rabbit (Oryctolagus cuniculus)	0	0	0	0	0	0	0	0	(
Cat (Felis catus)	О	0	0		0			0	(
Beagle (Canis lupus familiaris)	0	0	0	0	0	0	0	0	(
Other dog (other Canis)	0	0	0	0	0	0	0	0	(
Ferret (Mustela putorius furo)	0	0	0	0	0	0	0	0						
Other carnivore (other Carnivora)	0	0	0	0	0	0	0	0						
Horse and other equids (Equidae)	0	0	0	0	0	0	0	0						
Pig (Sus scrofa domesticus)	0	0	63	0	0	0	0	0						
Goat (Capra aegagrus hircus)	0	0	0	0	0	0	0	0						
Sheep (Ovis aries)	0	0	0	0	0	0	0	0						
Cattle (Bos primigenius)	0	0	0	0	0	0	0	0						
Other mammal (other Mammalia)	0	0	0	0	0	0	0	0						
Bird														
Domestic fowl (Gallus domesticus)	0	0	0	0	0	0	0	0						
Quail (Coturnix coturnix)	0	0	0	0	0	0	0	0						
Other bird (other Aves)	0	0	0	0	0	0	0	0						
Reptile (Reptilia)	0	0	0	0	0	0	0	0						
Amphibian														
Rana (temporaria and pipiens)	0	0	0	0	0	0	0	0						
Xenopus (laevis and tropicalis)	0	0	0		0	0	0	0						
Other amphibian (other Amphibia)	0	0	0	0	0	0	0	0						
ish														
Zebrafish (Danio rerio)	0	0	0	0	0	0	0	0						
Other fish (other Pisces)	0	0	0	0	0	0	0	0						
ephalopod (Cephalopoda)	o	0	0	0	0	0	0	О						
otal	1,118	1,110	633	146	284	2	75	247						
6 of total	22.7	22.6	12.9		5.8			5.0	0.					

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

Northern Ireland 2015										
				Translational/ap	plied research	1				
Species of animal	Human Sensory Organ Disorders (skin, eyes and ears)	Human Endocrine/ Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Animal Welfare	Diagnosis of diseases	Plant diseases	Non-regulatory toxicology and ecotoxicology	Total	% of total
Mammal										
Mouse (Mus musculus)	709	0	0	10	0	0	C	0	4,259	86.6
Rat (Rattus norvegicus)	50	88	0	0	0	0	C	0	150	3.1
Guinea-pig (Cavia porcellus)	0	0	0	0	0	-	C		0	0.0
Hamster (Syrian) (Mesocricetus auratus)	0	0	0	0	0	-	C		0	0.0
Hamster (Chinese) (Cricetulus griseus)	0	0	0	0	0	-	C		0	0.0
Mongolian Gerbil (Meriones unguiculatus)	0	0	0	0	0	-	C		0	0.0
Other rodent (other Rodentia)	0	0	0	0	0	-	(0	0.0
Rabbit (Oryctolagus cuniculus)	0	0	0	0	0	0	C	0	o	0.0
Cat (Felis catus)	0	0	0	50	0	0	C	0	50	1.0
Beagle (Canis lupus familiaris)	0	0	0	36	0	-	Ċ		36	0.7
Other dog (other Canis)	0	0	0	0	0				0	0.0
Ferret (Mustela putorius furo)	0	0	0	0	0	0	C	0	0	0.0
Other carnivore (other Carnivora)	0	0	0	0	0	0	C	0	0	0.0
Haras and other equide (Fauides)		_	_		_	_	_		_	
Horse and other equids (Equidae) Pig (Sus scrofa domesticus)	0	0	0	0	0		(0	0.0
Goat (Capra aegagrus hircus)	0	0	0	76 0	0		(139 0	2.8
Sheep (Ovis aries)	0	0	0	0	0		(86	0.0 1.7
Cattle (Bos primigenius)		0	0	183	0		(183	3.7
				,						3.7
Primate										
New World monkey										
Marmoset and tamarin	0	0	0	0	0	0	C	0	0	0.0
Old World monkey										
Cynomolgus monkey (Macaca fascicularis)	0	0	0	0	0		(0	0.0
Rhesus monkey (Macaca mulatta)	0	0	0	0	0	0	C	0	0	0.0
Other mammal (other Mammalia)	0	0	0	0	0	0	C	0	0	0.0
Bird										
Domestic fowl (Gallus domesticus)	0	0	0	0	0	0	C		o	0.0
Quail (Coturnix coturnix)	0	0	0	0	0				o	0.0
Other bird (other Aves)	0	0	0	0	0		Ċ		0	0.0
Reptile (Reptilia)	0	0	0	0	0	0	C	0 0	0	0.0
Amphibian										
Rana (temporaria and pipiens)	0	0	0	0	0		(0	0.0
Xenopus (laevis and tropicalis)	0	0	0	0	0		(0	0.0
Other amphibian (other Amphibia)	0	0	15	0	0	0	C	0	15	0.3
Fish										
Zebrafish (Danio rerio)	0	0	0	0	0	0	C	0	o	0.0
Other fish (other Pisces)	0	0	0	0	0		Č		o	0.0
Cephalopod (Cephalopoda)	0	0	0	0	0		C		0	0.0
Total	759	88	15	355	0		C	i	4,918	100.0
% of total	15.4	1.8	0.3	7.2	0.0	1.7	0.0	0.0	100.0	

Table 7.1 Experimental procedures by species of animal: regulatory use

Northern Ireland 2015	Ro	outine Production			Quality	/ control			Toxicity and		
		Monoclonal						Other efficacy	other safety		
Species of animal	Blood based	antibody	0.1	Batch safety	Pyrogenicity	Batch potency	Other quality		testing	Total	% of total
<i>'</i>	products	production	Other	testing	testing	testing	controls	testing	including		
	'	(ascites)			Ü	· ·			pharmacology		
Mammal											
Mouse (Mus musculus)	14	0	0	0	0	0	0	0	5	19	2.4
Rat (Rattus norvegicus)	0	0	0	0	0		0	0	0	ó	0.0
Guinea-pig (Cavia porcellus)	0	0	0	0	0	0	0	0	o	О	0.0
Hamster (Syrian) (Mesocricetus auratus)	0	0	0	0	0	0	0	0	0	О	0.0
Hamster (Chinese) (Cricetulus griseus)	0	0	0	0	0	0	0	0	0	О	0.0
Mongolian Gerbil (Meriones unguiculatus)	0	0	0	0	0	0	0	О .	0	o	0.0
Other rodent (other Rodentia)	0	0	0	0	0	0	0	0	0	О	0.0
Rabbit (Oryctolagus cuniculus)	53	0	0	0	0	0	0	0	0	53	6.7
, , ,											•
Cat (Felis catus)	0	0	0	0	0	0	0	0	63	63	7.9
Beagle (Canis lupus familiaris)	0	0	0	0	0	0	0	0	74	74	9.3
Other dog (other Canis)	0	0	0	0	0	0	0	0	0	o	0.0
Ferret (Mustela putorius furo)	0	0	0	0	0	0	0	0	0	О	0.0
Other carnivore (other Carnivora)	0	0	0	0	0	0	0	0	0	О	0.0
Horse and other equids (Equidae)	0	0	0	0	0	0	0	0	0	О	0.0
Pig (Sus scrofa domesticus)	0	0	0	0	0	0	0	0	104	104	13.1
Goat (Capra aegagrus hircus)	0	0	0	0	0	0	0	0	0	О	0.0
Sheep (Ovis aries)	19	0	0	0	0	0	0	0	344	363	45.8
Cattle (Bos primigenius)	0	0	0	0	0	0	0	0	117	117	14.8
Other mammal (other Mammalia)	0	0	0	0	0	0	0	0	0	0	0.0
Bird											
Domestic fowl (Gallus domesticus)	0	0	0	0	0	0	0	О О	0	o	0.0
Quail (Coturnix coturnix)	0	0	0	0	0	0	0	0	0	О	0.0
Other bird (other Aves)	0	0	0	0	0	0	0	0	0	o	0.0
Reptile (Reptilia)	0	0	0	0	0	0	0	0	0	0	0.0
Amphibian											
Rana (temporaria and pipiens)	0	0	0	0	0	0	0	О .	0	o	0.0
Xenopus (laevis and tropicalis)	0	0	0	0	0		0	0	0	o	0.0
Other amphibian (other Amphibia)	0	0	0	0	0		0	0	0	О	0.0
Fish (S. I. (S. I. I.)											
Zebrafish (Danio rerio)	0	0	0	0	0		0	0	0	0	0.0
Other fish (other Pisces)	0	0	0	0	0	0	0	0	0	0	0.0
Cephalopod (Cephalopoda)	О	0	0	0	0	0	0	0	О	0	0.0
Total	86	0	0	0	0	0	0	0	707	793	100.0
% of total	10.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	89.2	100.0	

					Testing by	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 leg islation	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												i
Mouse	0	14	0	0	0	0	5	0	0	О	19	2.4
Rat	0	0	0	0	0	0	0	0	0	О	0	0.0
All other rodent	0	0	0	0	0	0	0	0	0	О	0	0.0
Rabbit	0	53	0	0	0	0	0	0	0	О	53	6.7
Cat	0	63	0	0	0	0	0	0	0	О	63	7.9
Dog	0	74	0	0	0	0	0	0	0	О	74	9.3
Ferret	0	0	0	0	0	0	0	0	0	О	0	0.0
Other carnivore	0	0	0	0	0	0	0	0	0	О	0	0.0
Horse and other equid	0	0	0	0	0	0	0	0	0	О	0	0.0
Pigs	0	104	0	0	0	0	0	0	0	О	104	13.1
All other ungulates	0	142	0	0	0	0	338	0	0	О	480	60.5
All other mammal	0	0	0	0	0	0	0	0	0	О	0	0.0
Bird	0	0	0	0	0	0	0	0	0	О	0	0.0
Reptile, amphibian	0	0	0	0	0	0	0	0	0	О	0	0.0
Fish	0	0	0	0	0	0	0	0	0	О	0	0.0
Cephalopod	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	0	450	0	0	0	0	343	0	0	0	793	100.0
% of total	0.0	56.7	0.0	0.0	0.0	0.0	43.3	0.0	0.0	0.0	100.0	i l

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

	Le	gislative requirem	ent		
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)	19	0	0	19	2.4
Rat (Rattus norvegicus)	0	0	0	0	0.0
Guinea-pig <i>(Cavia porcellus)</i>	0	0	0	0	0.0
Hamster (Syrian) (Mesocricetus auratus)	0	0	0	0	0.0
Hamster (Chinese) (Cricetulus griseus)	0	0	0	0	0.0
Mongolian Gerbil (Meriones unguiculatus)	0	0	0	0	0.0
Other rodent (other Rodentia)	0	0	0	0	0.0
Rabbit (Oryctolagus cuniculus)	53	0	0	53	6.7
Cat (Felis catus)	63	0	0	63	7.9
Beagle (Canis lupus familiaris)	74	0	0	74	9.3
Other dog (other Canis)	0	0	0	0	0.0
Ferret (Mustela putorius furo)	0	0	0	0	0.0
Other carnivore (other Carnivora)	0	0	0	0	0.0
Horse and other equids (Equidae)	0	0	0	О	0.0
Pig (Sus scrofa domesticus)	104	0	0	104	13.1
Goat (Capra aegagrus hircus)	0	0	0	0	0.0
Sheep (Ovis aries)	363	0	0	363	45.8
Cattle (Bos primigenius)	117	0	0	117	14.8
Bird					
Domestic fowl (Gallus domesticus)	0	0	О	o	0.0
Quail (Coturnix coturnix)	0	0	О	o	0.0
Other bird (other Aves)	0	0	0	o	0.0
Reptile (Reptilia)	0	0	0	О	0.0
Amphibian					
Rana (temporaria and pipiens)	0	0	О	О	0.0
Xenopus (laevis and tropicalis)	0	0	О	0	0.0
Other amphibian (other Amphibia)	0	0	0	o	0.0
Fish					
Zebrafish (Danio rerio)	0	0	О	o	0.0
Other fish (other Pisces)	0	0	О	o	0.0
Cephalopod (Cephalopoda)	o	0	0	o	0.0
Total	793		0	793	100.0
% of total	100.0	0.0	0.0	100.0	

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

		d sub-acute					Other typ	oe of regulat	ory test or p	orocedure			
Species of animal	LD50 and LC50	Other lethal methods	Non-lethal methods	Skin irritation/ corrosion	Skin sensitisation	Eye irritation/ corrosion	Repeated dose toxicity	Carcinogenicity	Genotoxicity	Reproductive toxicity	Developmental toxicity	Safety testing in food and feed area	Target animal safety
Mammal													
Mouse	О	0	0	О	0	0	0	0	0	0	0	5	О
Rat	0	0	0	О	0	0	0	0	0	0	0	0	О
All other rodent	0	0	0	О	0	0	0	0	0	0	0	0	О
Rabbit	0	0	0	О	0	0	0	0	0	0	0	0	О
Cat	О	0	0	0	0	0	0	0	0	0	0	0	0
Dog	0	0	0	О	0	0	0	0	0	0	0	0	О
Ferret	О	0	0	0	0	0	0	0	0	0	0	0	0
Other carnivore	0	0	0	О	0	0	0	0	0	0	0	0	0
Horse and other equid	0	0	0	0	0	0	0	0	0	0	0	0	0
Pig	О	0	0	О	0	0	0	0	0	0	0	36	0
All other ungulate	0	0	0	0	0	0	0	0	0	0	0	382	0
All other mammal	О	0	0	0	0	0	0	0	0	0	0	0	0
Bird	0	0	0	0	0	0	0	0	0	0	0	0	0
Reptile, amphibian	О	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	0	0	0	423	0
% of total	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	59.8	0.0

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

Northern Ireland 2015

	Other type	of regulato	ry test or p	rocedure			Ecoto	xicity			Other type		
Species of animal	Neurotoxicity	Kinetics	Pharmo- dynamics	Phototoxicity	Acute toxicity	Chronic toxicity	Reproductive toxicity	Endocrine activity	Bioaccumulation	Other	of toxicity or safety test	Total	% of total
Mammal													
Mouse	0	0	0	0	О	0	0	C	0	0	0	5	0.7
Rat	О	0	0	0	О	0	0	C	0	0	0	0	0.0
All other rodent	0	0	0	0	О	0	0	C	0	0	0	0	0.0
Rabbit	О	0	0	0	О	0	0	C	0	0	0	0	0.0
Cat	0	63	0	0	О	0	0	C	0	0	0	63	8.9
Dog	0	74	0	0	О	0	0	C	0	0	0	74	10.5
Ferret	0	0	0	0	О	0	0	C	0	0	0	0	0.0
Other carnivore	0	0	0	0	О	0	0	C	0	0	0	0	0.0
Horse and other equid	0	0	0	0	О	0	0	C	0	0	0	0	0.0
Pig	0	44	0	0	О	0	0	C	0	0	24	104	14.7
All other ungulate	0	0	0	0	О	0	0	C	0	0	79	461	65.2
All other mammal	0	0	0	0	О	0	0	C	0	0	0	0	0.0
Bird	0	0	0	0	О	0	0	C	0	0	0	0	0.0
Reptile, amphibian	0	0	0	0	О	0	0	C	0	0	0	0	0.0
Fish	О	0	0	0	О	0	0	C	0	0	0	0	0.0
Cephalopod	0	0	0	0	О	0	0	C	0	0	0	0	0.0
Total	0	181	0	0	0	0	0	C	0	0	103	707	100.0
% of total	0.0	25.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	14.6	100.0	

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 status¹

			Genetic status			
Mouse	Actual severity	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	% of total
	Sub threshold	71	387	0	458	8.7
	Non – recovery	0	0	О	О	0.0
Mauga	Mild	16	2,626	226	2,868	54.2
wouse	Moderate	28	1,827	44	1,899	35.9
	Severe	0	0	64	64	1.2
	Total	115	4,840	334	5,289	100.0
	Sub threshold	0	0	0	0	0.0
	Non – recovery	0	0	О	О	0.0
.	Mild	0	0	0	О	0.0
Rat	Moderate	43	0	0	43	0.8
	Severe	0	0	0	О	0.0
	Total	43	0	o	43	o.8
	Sub threshold	71	387	0	458	8.6
	Non – recovery	0	0	0	0	0.0
AU	Mild	16	2,626	226	2,868	53.8
All species	Moderate	71	1,827	44	1,942	36.4
	Severe	0	0	64	64	1.2
	Total	158	4,840	334	5,332	100.0

^{1.} Some species were not involved in the creation/breeding of genetically altered animals in 2015. Therefore, these species are not listed in this table.

Table 9.1 Creation of new lines of genetically altered animals (not used in experimental procedures) by species of animal, severity and genetic status¹

		Basic res	earch by geneti	c status		ional/applied re y genetic status		Tota	l by genetic sta	tus		
Species of animal	Actual severity	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	% of total
	Sub threshold	0	0	0	0	0	0	0	0	О	0	0.00
	Non – recovery	О	О	0	0	0	0	0	0	О	0	0.00
Mouse	Mild	15	233	226	0	1365	0	15	1598	226	1839	49.78
Wouse	Moderate	28	292	0	0	1535	0	28	1827	0	1855	50.22
	Severe	0	0	0	0	0	0	0	0	0	О	0.00
	Total	43	525	226	0	2900	0	43	3425	226	3694	100.00
	Sub threshold	0	0	0	0	0	0	0	0	0	0	0.00
	Non – recovery	0	0	0	0	0	0	0	0	О	О	0.00
Rat	Mild	0	0	0	0	0	0	0	0	О	О	0.00
Kal	Moderate	43	0	0	0	0	0	43	0	0	43	100.00
	Severe	0	0	0	0	0	0	0	0	О	o	0.00
	Total	43	0	0	0	0	0	43	0	o	43	100.00
	Sub threshold	0	0	0	0	0	0	0	0	0	0	0.00
	Non – recovery	0	0	0	0	0	0	0	0	О	О	0.00
All species	Mild	15	233	226	0	1365	0	15	1598	226	1839	49.21
MII Species	Moderate	71	292	0	0	1535	0	71	1827	0	1898	50.79
	Severe	0	0	0	0	0	0	0	0	0	О	0.00
	Total	86	525	226	0	2900	0	86	3425	226	3737	100.00

^{1.} Some species were not involved in the creation/breeding of genetically altered animals in 2015. Therefore, these species are not listed in this table.

Table 9.2 Creation of new lines of genetically altered animals (not used in experimental procedures) by species of animals and severity: basic research¹

							Ba	sic Resear	ch							
Species of animal	Actual severity	Oncology	Cardiovascular Blood and Lymphatic System	Nervous System	Respiratory System	Gastrointestinal System including Liver	Musculoskeletal System	Immune System	Urogenital/ Reproductive System	Sensory Organs (skin, eyes and ears)	Endocrine System/ Metabolism	Multisystemic	Ethology/ Animal Behaviour/ Animal Biology	Other	Total	% of total
	Sub threshold	О	0	0	0	0	0	0	0	0	0	0	0	О	О	0.0
	Non – recovery	О	0	0	0	0	0	0	0	0	0	0	0	О	О	0.0
Mouse	Mild	О	226	0	0	0	0	127	0	0	0	0	0	121	474	59.7
Mouse	Moderate	0	0	0	0	0	0	0	0	320	0	0	0	О	320	40.3
	Severe	О	0	0	0	0	0	0	0	0	0	0	0	О	О	0.0
	Total	0	226	0	0	0	0	127	0	320	0	0	0	121	794	100.0
	Sub threshold	0	0	0	0	0	0	0	0	0	0	0	0	О	О	0.0
	Non – recovery	0	0	0	0	0	0	0	0	0	0	0	0	О	О	0.0
Rat	Mild	0	0	0	0	0	0	0	0	0	0	0	0	О	О	0.0
, and	Moderate	0	0	0	0	0	0	0	0	43	0	0	0	О	43	100.0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0	О	О	0.0
	Total	0	0	0	0	0	0	0	0	43	0	0	0	0	43	100.0
All species	Sub threshold	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
	Non – recovery	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
	Mild	0	226	0	0	0	0	127	0	0	0	0	0	121	474	56.6
	Moderate	0	0	0	0	0	0	0	0	363	0	0	0	0	363	43.4
	Severe	0	0	0	0	0	0	0	0	0	0	0	0	О	О	0.0
	Total	0	226	0	0	0	0	127	0	363	0	0	0	121	837	100.0

^{1.} Some species were not involved in the creation/breeding of genetically altered animals in 2015. Therefore, these species are not listed in this table.

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Table 9.3 Creation of new lines of genetically altered animals (not used in experimental procedures) by species of animal and severity: translational/applied research¹

								1	Franslatio	nal/applied	l research									
Species of animal	Actual severity	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 Organ Disorders (skin, eyes and ears)	Human Endocrine/ Metabolism Disorders	Other Human Disorders	Animal Diseases and Disorders	Animal Welfare	Diagnosis of diseases	Plant diseases	Non- regulatory toxicology and ecotoxicology	Total	% of total
	Sub threshold	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
	Non – recovery	О	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	О	0.0
Mouse	Mild	1,365	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1,365	47.1
Mouse	Moderate	1,535	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1,535	52.9
	Severe	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	О	0.0
	Total	2,900	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2,900	100.0

^{1.} Mice (Mus musculus) were the only species involved in the creation of new lines of genetically altered animals in 2015. Therefore, all other species and species totals are excluded from this table.

Table 10 Maintenance of established lines of genetically altered animals (not used in experimental procedures) by species of animal, severity and genetic status¹

Horaicin netana 2013						
			Genetic status			
Species of animal	Actual severity	Not genetically altered	Genetically altered without a harmful phenotype	Genetically altered with a harmful phenotype	Total	% of total
Mouse	Sub threshold	71	387	0	458	28.7
	Non – recovery	О	0	0	0	0.0
	Mild	1	1,028	0	1,029	64.5
	Moderate	0	0	44	44	2.8
	Severe	0	0	64	64	4.0
	Total	72	1,415	108	1,595	100.0

^{1.} Mice (*Mus musculus*) were the only species involved in the maintenance of established lines of genetically altered animals in 2015. Therefore, all other species and species totals are excluded from this table.

	Number of	project licer	nces where o	ountable¹ pr	ocedures we	re completed	d in 2015 by	number of p	rocedures	Number			Number of	procedures
				Number of	procedures					of project	Number			
Type of licensed establishment	1 to 50	51 to 100	101 to 200	201 to 400	401 to 600	601 to 800	801 to 1,000	More than 1,000	Total	licences where only non- countable¹ procedures were completed in 2015	of project licences where no procedures were completed in 2015	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	12	3	7	8	3	2	3	5	43	0	27	70	17,615	78.3
NHS hospitals	О	0	0	0	О	О	0	0	О	О	О	О	О	0.0
Government departments	0	0	0	1	0	0	0	0	1	0	0	1	341	1.5
Other public bodies	0	0	0	0	0	0	0	0	0	О	О	o	0	0.0
Non-profit- making organisations	8	7	1	4	0	o	0	1	21	2	20	43	3,409	15.1
Commercial organisations	4	0	0	0	2	0	0	0	6	0	4	10	1,143	5.1
Total	24	10	8	13	5	2	3	6	71	2	51	124	22,508	100.0

^{1.} 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 2015).

Number of designated places at 31 December

Northern Ireland

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Scientific procedure establishments	5	5	5	5	5	5	5	5	4	4	4
Scientific procedure and breeding establishments	0	0	0	0	0	0	О	0	0	0	О
Scientific procedure breeding and supplying establishments	5	5	5	5	3	3	3	3	4	4	4
Scientific procedure and supplying establishments	0	0	0	0	0	0	o	0	0	0	О
Breeding and supplying establishments	1	1	1	1	1	1	1	1	1	1	1
Total designated places	11	11	11	11	9	9	9	9	9	9	9

Table 13 Personal Licensees: 2005-2015

Number of personal licences at 31 December

2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
535	607	523	561	565	585	582	590	480	480	548

Appendix

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

Introduction

1. 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

- 2. 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.
- 3. 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.
- 4. 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

- 5. 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.
- 6. 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.
- 7. 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 now required to complete an accredited training course.
- 8. 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.
- 9. During 2015, there were a total of 548 personal licences in force. Personal licences continue to be in force until revoked but they must be reviewed at least every five years.

Establishment Licences

- 10. 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; 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.
- 11. 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

- 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.
- 13. 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.
- 14. During 2015 the Inspectorate made 98 visits to establishments.

The Animals in Science Committee (ASC)

15. 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

- 16. 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. Four such documents have been published:
 - Guidance on the operation of the Animals (Scientific Procedures) Act 1986 (2000; HC 321);
 - Code of practice for the housing and care of animals bred, supplied or used in scientific procedures December 2014;
 - Code of Practice for the Humane Killing of Animals under Schedule 1 to the Animals (Scientific Procedures) Act 1986 (1997; HC 193).

Education and training

- 17. 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.

18. 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

- 19. 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).
- 20. A total of 128 personal licence applications, amendments and cancellations as well as 75 project licence applications and amendments were processed during the year. One hundred percent (100%) were processed within the targets.

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