

Statistics of Scientific Procedures on Living Animals Great Britain 2004

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HOME OFFICE

Statistics of Scientific Procedures on Living Animals

GREAT BRITAIN 2004

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STATISTICS OF SCIENTIFIC PROCEDURES ON LIVING ANIMALS GREAT BRITAIN 2004

INTRODUCTORY NOTES

1. The statistics in this publication relate to experiments or other scientific procedures on living animals that were subject to the provisions of the Animals (Scientific Procedures) Act 1986 during the year from 1 January 2004. The system of control under the 1986 Act is explained in detail in Appendix A. Under this Act any scientific procedure carried out on any living vertebrate animal, or one species of octopus (Octopus vulgaris), which is likely to cause that animal pain, suffering, distress or lasting harm is a regulated procedure requiring licence authority. Recognised veterinary, agricultural or animal husbandry practice and the administration of medicines under an Animal Test Exemption granted under the Medicines Act 1968 are excluded from the controls of the 1986 Act. Statistics of scientific procedures on living animals are collected and published annually. They are structured to comply with European Union requirements, but the data provided are far more extensive than required by Europe.

Collection procedures

2. A return of scientific procedures is required each year from every person who holds a project licence for part or all of the year. The statistics are compiled from a detailed form returned by project licence holders at the end of each year, or on termination of the licence where this occurred during the year. A copy of the current form and the instructions relating to its completion can be found at Appendix B. This return, completed by each project licence holder, provides details of the species of animal used, the main purpose of the procedure and other details as described in paragraphs 12-19 below. In these statistics each procedure (which may consist of several stages) for a given purpose on an animal is counted as one returnable procedure for the year in which it commenced. A study involving a procedure using a number of animals is counted once for each animal. Where an animal which has recovered fully from a completed procedure is used again for a further procedure, this is counted as a separate procedure, but the animal itself is not re-counted. The circumstances in which this re-use of an animal is permitted are limited.

3. Licence holders are required, as a condition of their licence, to submit a return even if no work has been undertaken (nil returns). A list of licensees is drawn up at the end of the year prior to the start of the collection process, and a record is kept of all licensees from whom returns have been received so that those who fail to make a return can be reminded of their obligation under the Animals (Scientific Procedures) Act 1986. It is not always possible to obtain every single return even though failure to submit is likely to result in the licence being revoked.

4. To ensure that the published data are as complete as possible the Home Office will not publish the statistics unless the number of missing returns represents less than 0.5 per cent of all the returns expected, even though experience has shown that the missing returns are likely to be nil returns.

5. Details of the work of individual project licence holders are not identifiable in this publication.

Accuracy

6. Verification and subsequent publication of these statistics are done by the Science and Research Group (SRG) of the Home Office.

7. To complete the return, project licence holders are asked to classify their procedures according to a standard coding list. The current classification system dates from 1995, and was modified in 1999 in those areas relating to source of animals, production and breeding, toxicology and legislation. Fuller details are given in paragraphs 13, 14 (vii), 15, 16, 19 A (ii) and 19 B (ii) below. Licensees make returns by completing a form using specified codes. A full list of the codes used can be found in the copy of the form, at Appendix B. During the collection and verification process, forms that have been incorrectly coded are referred back to the licensees for correction. Incorrect coding might be either codes which are wrong (i.e. outside the appropriate code range for the particular row) or which fail a cross-validation check (i.e. where two codes in different rows are incompatible).

8. Throughout the collection process and right up to the point of publication, the Animals (Scientific Procedures) Inspectorate (ASPI) scrutinise the returns and output tables to check that the returns are consistent with the terms of the licences which have been granted. This is done by means of reports and tables, which are provided by SRG to ASPI. During this period Inspectors may contact licensees to discuss and confirm coding, and inform SRG of any amendments which may be necessary.

Description of statistical tables

9. Project licence holders are asked to answer 15 questions about the procedures performed (see form at Appendix B), 12 of which identify individual characteristics explained more fully in paragraphs 12-19 below. The flowchart on page 23 shows the relationship between the tables and the data in Part A.

10. Part B covers information on project licence holders, their place of employment and numbers of procedures.

11. Part C presents historical data for varying periods, depending on the table. For some tables, comparable figures are available only from 1995 onwards.

References to previous years' publications are given on the inside back cover.

PART A TABLES - PROCEDURES IN 2004

As a result of a review of the published tables in 2001, Tables 6, 7, 14 and 17 no longer appear. Although this leaves gaps in the table numbering, the existing numbering has been retained to preserve continuity from previous years. The sequence of tables published in this year's report is the same as that published since 2001.

Species of animal

12. All tables in Part A are classified by species of animal. The full classification is used in Tables 1, 1a, 5, 5a, 10 and 10a, but the other tables use a condensed classification. All the tables except 1a, 5a and 10a give the number of procedures. Tables 1a, 5a, and 10a give the actual number of animals used for the first, and usually only, time in 2004 classified according to their first use. The list of species or categories of animals is selective to avoid undue complications; when 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 of the tables, rows which are completely zero have been omitted and if a species is not mentioned it is because the row or rows pertaining to that species is blank.

Genetic status of animal

13. Tables 2 (source), 3 (genetic status), and 5 (non-toxicological work by field of research) are subdivided to give more information about animals with abnormal genetic constitutions. Table 2 shows procedures using all animals; Table 2.1 shows the number of procedures using animals with harmful (but naturally occurring) genetic defects and table 2.2 shows the number of procedures using genetically modified animals. Table 5 follows the same pattern. Table 3 is subdivided into three supplementary tables (3.1, 3.2 and 3.3) to present in detail the use of normal animals, animals with harmful mutations, and genetically modified animals respectively, in breeding programmes or research.

Primary purpose (Table 1)

14. The use of animals for regulated procedures is limited by section 5(3) of the Act to one of the following primary purposes:

- (i) fundamental biological research; carried out with the primary intention of increasing knowledge of the structure, function and malfunction of man and other animals, or plants. Such studies may be aimed solely at an increase in knowledge, application of that knowledge being beyond the scope of the investigation, or with a view to providing a practical solution to a medical or veterinary problem once the issues are more clearly defined and understood. This category includes physiological, pathological, pharmacological, genetic and biochemical studies, including toxicological evaluation.
- (ii) applied studies human medicine or dentistry, and veterinary medicine; consisting of research into, development of and quality control of products or devices, including toxicological evaluation and safety or efficacy testing.
- (iii) protection of man, animals or the environment; by toxicological or other safety or environmental evaluation. This category is intended to cater for toxicological work which is not related either to fundamental research or to the solution of medical and veterinary problems as such (see (i) and (ii) above), but also includes some non-toxicological procedures. This category is further divided into a number of subgroups (listed in Tables 10 and 10a). These are largely self-explanatory but the following notes may be helpful in understanding the figures:
 - (a) while any one substance may be used in industry or in the home, or may be an environmental pollutant, a herbicide or a pesticide, the project licence holder classifies the procedure in accordance with the particular context of the procedure and the expected primary use of the product;
 - (b) animal pesticides (as distinct from plant pesticides) are not included amongst the types of substances listed, because a substance intended to kill pests which infest or attack animals would be regarded as a veterinary product. These are included in the appropriate body-system group covered by primary purposes described in (ii) above;
 - (c) many of the procedures recorded under this category are required by UK law or by the laws and regulations of countries in which it is intended to use the substance concerned;
 - (d) the term 'food additives' covers substances deliberately added to food as preservatives, artificial colourants or flavouring agents but not studies on the nutritive value of food, accidental contamination or infection of food, or medicines administered to animals or humans in food.
- (iv) education and training; these categories include procedures carried out under project licences for the purposes of education or training under the 1986 Act. They also include killing of animals by methods not included in Schedule 1 to the 1986 Act, if the killing takes place for educational purposes at a designated establishment. Such killing may be authorised to provide, for example, tissues subsequently used for education or training. The use of animals for the acquisition of manual skills is currently permitted only for training in microvascular surgery, and at present this is always carried out under general anaesthesia, without recovery.
- (v) **forensic enquiries;** may refer to animal use in human or veterinary enquiries relevant to potential legal proceedings.
- (vi) direct diagnosis; investigation of disease including investigating suspected poisoning. This caters for procedures carried out under the 1986 Act for the purpose of diagnosing disease in an individual human or animal patient or a group of such patients. There is no research function: these are essentially applied studies, predominantly involving the production of biological reagents, for example antibodies and clotting factors.

(vii) breeding; a category for recording the production and breeding of animals with harmful genetic defects, and genetically modified animals. The numbers recorded in this category include those animals which are identified as possessing a harmful mutation or are genetically modified, but not used subsequently on procedures which are recorded elsewhere in the tables. The numbers also include some genetically normal animals which were subjected to regulated procedures such as tissue sampling or hormonal administration for the purpose of regulated breeding programmes (see also Tables 3, 3.1, 3.2, 3.3).

Source of animals (Tables 2, 2.1, 2.2)

15. Sections 7 and 10(3) of the Act require, unless a specific exemption is granted, that certain animals, listed in Schedule 2 to the Act, be obtained from designated breeding or supplying establishments certified as such by the Secretary of State. The species so listed during 2004 were: mouse, rat, guinea-pig, hamster, gerbil, rabbit, cat, dog, ferret, primate and quail (Coturnix coturnix); also pigs (if genetically modified), and sheep (if genetically modified). Normal pigs and normal sheep remain outside the scope of this schedule. The source of these species is tabulated according to whether it is within the UK, within the remainder of the EU, within certain Council of Europe (but non-EU) countries who are signatories to convention ETS 123, or elsewhere. Animals which originate from non-designated sources, such as overseas breeding centres, but which are acquired by the project licence holder from a designated supplying establishment in the UK, are reported under the heading "Animals acquired from other designated breeding or supplying establishments in the UK."

Table 2 lists numbers of procedures by source of animal, as described above; tables 2.1 and 2.2 list procedures by source for animals with a harmful (but naturally-occurring) genetic defect, and genetically modified animals, respectively. In columns 3–6 of these tables, use of Schedule 2-listed species from non-designated sources in the UK, or from Europe or elsewhere, is subject to prior approval by the Home Office. Such use would be justified on the basis of scientific need or lack of availability of appropriate animals from designated breeding or supplying establishments.

Stage of development, genetic status, and breeding (Tables 3, 3.1, 3.2, 3.3)

16. Stage of development

Details of procedures on animals in foetal, larval or embryonic form are collected but not shown in any of the published tables because it may be 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.

Genetic status

Only the number of animals in which a harmful genetic defect actually manifested itself has been recorded for spontaneously arising mutants. All genetically modified animals are recorded. Additional information on counting animals in those categories is provided in Annex A at the end of Appendix B.

Table 3.1 shows the use of genetically normal animals in breeding programmes for both animals with harmful mutations and genetically modified animals. The number of procedures is shown for: normal animals used to generate founder genetically modified (GM) animals (which themselves will be further used in breeding programmes), normal animals within GM breeding colonies, and normal animals within breeding colonies of animals with naturally-occurring harmful mutations.

Tables 3.2 and 3.3 show the use of animals with harmful mutations and genetically modified animals respectively in breeding programmes or research. The structure of these two tables is similar. They show, respectively for harmful mutant and GM animals: procedures undertaken for maintenance of the breeding colony (i.e. primary purpose is shown as "breeding" and row 11 is coded B64 or B62 as appropriate); procedures undertaken for research analysis *post mortem* (primary purpose is *not* breeding, and row 11 coded B64 or B62, as above); further regulated procedures, following on from the breeding programme (row 11 coded B65 or B63); procedures used for production (row 11 coded B50–56); and procedures for toxicological (safety evaluation) purposes (row 11 coded A30–50). For an explanation of these codes, see Appendix B at the end of this publication.

Breeding

The breeding of animals with harmful genetic defects or genetically modified animals is a regulated procedure under a project licence. Animals which are identified as 'harmful mutants' or 'genetically modified' may be used for further breeding or used subsequently in procedures. The numbers also include some genetically normal animals which were subjected to regulated procedures such as tissue sampling or hormonal administration for the purpose of regulated breeding programmes.

The classifications of procedures concerned with breeding distinguish between:

- (a) animals used to generate founder genetically modified animals for novel transgenic lines, chimeras or clones;
- (b) genetically modified animals generated by recognised husbandry methods for maintenance of a breeding colony;
- (c) genetically modified animals used in research programmes not concerned with breeding;
- (d) animals with a harmful mutation generated by recognised husbandry methods for maintenance of breeding colonies;
- (e) animals with a harmful mutation used in research programmes not concerned with breeding.

Fuller details of these classifications will be found in Appendix B at List B, row 11.

Target body system (Table 4a)

17. Some of the headings in the tables are self-explanatory but, for the others, further explanation is given below.

Abbreviated title	Description: studies in which interest centres on:
Nervous	The central or peripheral nervous systems, other than the special senses
Senses	Sight, hearing, smell, or taste
Alimentary	The alimentary (including liver) and excretory systems
Musculo-skeletal	The skeletal or muscle system
Immune and reticulo-endothelial	The understanding and operation of the immune system
Other system	A single body system not separately listed in the table
Multiple systems	More than one system of primary interest
System not relevant	The system or systems affected were not predictable or not relevant

Use of anaesthesia (Table 4b)

From the 2001 publication onwards, use of anaesthesia for both toxicological and non-toxicological procedures has been combined into one simplified table. It replaced tables 7 and 17 of previous years' publications.

18. The codes for anaesthesia distinguish procedures involving one or more stages in which there was anaesthesia with recovery, from procedures in which the only anaesthesia was terminal. They also include the use of local or regional anaesthesia. The categories are:

- (a) no anaesthesia used throughout the procedure; this will include procedures without anaesthesia even where the subject animal may have been killed by use of an anaesthetic overdose at the end of the procedure. It also includes studies of potential anaesthetic agents;
- (b) general anaesthesia with recovery;
- (c) local or regional anaesthesia;
- (d) general anaesthesia without recovery, at the end of the procedure only;
- (e) general anaesthesia without recovery, throughout the procedure.

The killing of an animal by the administration of an overdose of an anaesthetic agent (a recognised humane method as cited in Schedule 1 of the Act) is not a regulated procedure and is not recorded as such in the above table.

The use of neuromuscular blocking agents (NMBA) is uncommon and for this reason such use is not shown in the table (except as a footnote), but is described in the text.

Type of procedure

19. The tables are divided into two groups:

- (a) fundamental and applied studies other than toxicology (Tables 5–9);
- (b) toxicity tests, or other safety or efficacy evaluation (Tables 10–17).

If the purpose was non-toxicological, the licensee was asked to specify the field of research, the nature of the procedure with regard to production and breeding and whether the technique was identified as being of particular interest.

If the purpose of the procedure was toxicological, the licensee was asked to report on the field of safety testing or efficacy evaluation, the type of test or procedure, and the legislative requirements (if any) under which the procedure was performed.

The two strands of reporting are mutually exclusive (as shown in the flowchart and appendix B) and it is not possible, for instance, to identify procedures using a technique of particular interest if the purpose of the procedure was toxicological.

A Fundamental and applied studies other than toxicology

This group of tables is sub-divided into three main areas of interest:

(i) **Field of research** (Tables 5, 5a, 5.1 and 5.2)

The headings are self-explanatory, but the following should be noted:

- (a) pharmaceutical research and development excludes anti-cancer agents, where work is listed separately later in the table under 'cancer research';
- (b) ecology excludes work done in toxicology and other safety evaluation;
- (c) tobacco and alcohol research lists only those procedures done for research on the effects of tobacco or alcohol, and not those where these substances are used as experimental tools or standards; note also that tobacco safety procedures would be reported in table 10.

(ii) **Production of biological materials** (Table 8)

Production:	procedures for production and maintenance of infectious agents (excluding those causing
	neoplasms);
	procedures for production and maintenance of vectors, e.g. parasites;
	procedures for production and maintenance of neoplasms;
	the ascites model for the production of monoclonal antibodies;
	initial immunisation for subsequent in vitro or in vivo production of monoclonal antibodies;
	procedures for production of polyclonal antibodies;
	procedures for production of other biological material, e.g. plasma, tissues.

(iii) **Techniques of particular interest** (Table 9)

This table provides a selective list which identifies those procedures in which a technique is of itself of particular interest as, for example, the application of a substance to the eye or exposure to ionising radiation. The procedures recorded in this table do not include those undertaken for toxicology or safety evaluation. However, few of these techniques would be used in routine regulatory toxicology or safety assessments.

B Toxicity tests, or other safety or efficacy evaluation

(i) **Safety and efficacy evaluation** (Tables 10, 10a)

Most of the subdivisions have been described in paragraph 10 (iii) above with regard to general safety or efficacy evaluation but the category also includes work done for pharmaceutical safety and efficacy evaluation, and some other purposes as follows:

efficacy evaluation (acute, subacute and chronic); absorption, distribution, metabolism, excretion (ADME) and residue tests; nutritional evaluation; quality control; toxicology research; tobacco safety (note: tobacco research is recorded in Table 5 – see above); medical device safety; method development, and other tests.

(ii) Legislative requirements (Table 11)

This identifies medical/dental and veterinary categories which include procedures used in the initial development and selection of such products, those required to satisfy specific legislation (medical and non-medical) such as the Medicines Act 1968 and/or equivalent overseas or international legislation or regulations for purposes such as the intention of registration or the intention of presenting batch quality control data; and those carried out for other reasons. The legislation is divided into seven groups:

- (a) United Kingdom legislation only;
- (b) legislation specific to one EU country only (excluding the UK);
- (c) general EU requirements, including the European Pharmacopoeia;
- (d) non-EU member country of Council of Europe legislation;
- (e) legislation of other countries;
- (f) any combination of (a) (e);
- (g) purposes other than legislative requirements.

The following are examples of specific legislative requirements which may be included:

Medicines Act 1968;

Workplace safety, e.g. Health and Safety at Work Act 1974, COSHH Regulations; Substances used in agriculture, e.g. Control of Pesticides Regulations 1986; EU Pesticides Directives; Substances used in foodstuffs, e.g. Food Safety Act 1990.

(iii) Specific types of toxicity tests (Table 12)

acute and subacute dose ranging or limit setting lethal toxicity tests; acute quantitative lethal toxicity tests; acute and subacute non-lethal clinical sign toxicity tests; subchronic and chronic toxicity tests; carcinogen/teratogen/mutagen tests; other reproductive toxicity tests; tests for clinical signs in the eye; tests for clinical signs on the skin, including irritation or sensitisation; toxicokinetics, pyrogenicity, biocompatibility and other toxicology tests.

(iv) Tables showing some selected work in greater detail

There are three further tables which examine some aspects of toxicological work in greater detail (see appendix B for full details of the codes):

Table 13:	non-pharmaceuticals (list A, row 10, codes A01-A06);
Table 15:	pharmaceuticals (list A, row 10, codes A11-A14);
Table 16:	other safety or toxicology (list A, row 10, codes A21-A25).

(Table 14 on cosmetic safety has been discontinued since all such use ceased prior to 1999.)

Tree tables (Tables 18a-h)

20. These show, by means of 'trees', how procedures carried out on certain species of animals which are of particular interest are broken down into their various categories. The species illustrated in this way are: cats, dogs, horses, new-world primates, old-world primates, and rabbits. Two further tables were introduced in 1999 to illustrate the use of genetically modified animals, and animals with harmful genetic defects.

PART B - PROJECT LICENCE HOLDERS AND DESIGNATED PLACES

Type of designated place (Table 19)

21. 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.

PART C - HISTORICAL AND TIME-SERIES TABLES

22. Tables 20–27 summarise some selected aspects of the annual statistics collected since the introduction of the Animals (Scientific Procedures) Act 1986 on 1 January 1987. For the reasons explained below, not all the tables refer to the same time period.

23. Some of the historical tables which appeared in publications prior to 1995 have been discontinued because of the lack of comparability with data for 1995 onwards, when the present system for collecting and presenting data was introduced. Footnotes are given in those tables which have been retained to explain aspects of the discontinuities.

24. Two tables (21 and 25) have been adapted to reflect the way data have been reorganised: Table 21 carries information about legislative requirements from 1995 only, because earlier data are no longer comparable, and Table 25 has replaced tobacco and alcohol safety data with data for pharmaceutical and other safety, but figures for earlier years are still shown because in this case data in the rest of the table are comparable.

25. Three tables show data only from 1995: Table 24 on non-toxicology procedures by field of research, Table 26 on procedures by primary purpose, and Table 27 on procedures by primary purpose and genetic status. There are no comparable figures for earlier years.

MAIN POINTS

- 1. The number of scientific procedures started in 2004 was just over 2.85 million, a rise of about 63,000 (2.3 per cent) on 2003.
- 2. Mice, rats and other rodents were used in the majority of procedures 85 per cent of the total. Most of the remaining procedures used fish (7 per cent), and birds (4 per cent).
- 3. Dogs, cats, horses and non-human primates, afforded special protection by the Act, were collectively used in less than 1 per cent of the procedures. The number of such animals used for the first time rose slightly from 9,100 in 2003 to 9,200 mainly due to an increase in the use of dogs. Since 1995 there has been a 28 per cent decrease in the combined use of these groups.
- 4. The number of procedures using non-human primates was 4,208, down 591 from 2003, a 12 per cent fall; and with pharmaceutical R & D (research and development) and safety evaluation accounting for 3,157 (75 per cent) of the 2004 procedures. Since 1995 there has been a 31 per cent fall in the numbers of primates used for the first time.
- 5. Over 99 per cent of procedures carried out on animals listed in Schedule 2 of the Act used animals acquired from designated sources in the United Kingdom.
- 6. Genetically normal animals were used in 1,673,000 regulated procedures, a decrease of 76,000 (4 per cent) from 2003. Their use represents 59 per cent of all procedures for 2004 (compared with 63 per cent in 2003 and 84 per cent in 1995).
- 7. Species with harmful, but naturally-occurring, genetic mutations were used in 268,000 regulated procedures, representing 9 per cent of all procedures for 2004. The majority of these were rodents (85 per cent).
- 8. Genetically modified animals were used in 914,000 regulated procedures representing 32 per cent of all procedures for 2004 (compared with 27 per cent in 2003 and 8 per cent in 1995). The majority of these were rodents (96 per cent).
- 9. Just under one third (32 per cent) of the genetically modified animals were used in scientific procedures other than the maintenance of breeding colonies.
- 10. About 40 per cent of all procedures used some form of anaesthesia to alleviate the severity of the interventions. For many of the remaining procedures the use of anaesthesia would have increased the adverse effects of the procedure.
- 11. Non-toxicological procedures accounted for about 85 per cent of the procedures carried out in 2004, with the main areas of use being for immunological studies, pharmaceutical research and development, anatomy and cancer research. This contrasts with 75 per cent of procedures being for a non-toxicological purpose in 1995.
- 12. Procedures for toxicological purposes accounted for 15 per cent of all procedures started in 2004; this contrasts with 25 per cent of procedures being for a toxicological purpose in 1995 an absolute decrease of about 241,700 procedures.
- 13. About 70 per cent of toxicological procedures were for pharmacological safety and efficacy evaluation in 2004.
- 14. About 80 per cent of toxicological procedures used rodent species. Non-human primates were used in less than three quarters of one per cent of the toxicological procedures.
- 15. Eighty six per cent of toxicological procedures were performed to conform to legal or regulatory requirements.

COMMENTARY

OVERALL PICTURE

Procedures started in 2004

The number of scientific procedures started in 2004 was just over 2.85 million (Table 1), a rise of about 63,000 (2.3 per cent) compared to 2003. There has been a significant reduction in the annual number of experiments or scientific procedures since 1976, this trend has levelled out in recent years but the figure for 2004 was the highest since 1992. The overall level of scientific procedures is determined by a number of factors, including the economic climate and global trends in scientific endeavour.

Some 2.78 million animals were used for the first time in procedures started in 2004 (Table 1a). This was about 57,000 (2.1 per cent) more than in 2003, broadly reflecting the number of procedures started.



Figure 1: Experiments or procedures commenced each year, 1946-2004⁽¹⁾

Species used (Tables 1 and 1a, Table 20 and Figure 2)

The species of animals involved in the largest numbers of procedures in 2004 were mice (67 per cent of procedures), rats (16 per cent), fish (7 per cent), and birds (4 per cent). Domestic fowl accounted for nearly 90 per cent of all birds used. These proportions are all broadly similar to those in recent years.

Dogs (0.28 per cent of all procedures in 2004), cats (0.03 per cent) and non-human primates (0.15 per cent) were involved in relatively small numbers of procedures (a combined total of 13,045 in 2004), and the total use of these three groups fell by 90 procedures compared with the 2003 figure.

Despite the overall rise in the number of procedures in 2004, there were falls in procedures using most species (see below), but the principal increase in 2004 was in procedures involving mice (up 102,500 - 6 per cent), mainly due to their increased use in both fundamental and breeding procedures. Other species showing increases on the 2003 figures were fish (up 20,600), amphibia (up 3,200), sheep (up 2,900), dogs (up 924), hamsters (up 630) and mammals not separately categorised in the tables, (up 660).

The increase in use of mice and fish in 2004 was mainly associated with breeding, but some of the rise was also associated with fundamental biological research. The use of amphibia has increased mainly for the conduct of fundamental studies. The rise in the use of sheep is mainly associated with applied research in veterinary medicine. The use of dogs also rose, but numbers of procedures have fluctuated in recent years and the current rise is within that general range, and was across all purposes. The large increase reported last year of some 6,500 procedures using quail (not *C. coturnix*) was reversed in 2004; such isolated short-lived increases in the use of particular species occur from time to time and are usually related to a specific piece of research or other scientific use.

There was a decrease in use of new world primates by about 15 per cent. The use of these species has fluctuated in recent years, but there is a definite long-term downward trend. The number of procedures involving old-world primates also decreased, by about 11 per cent, but the long-term trend in this case is more difficult to determine since there have been marked fluctuations over the last ten years. Many primates are re-used, since many of the procedures in which they are involved are of only mild effect, for which anaesthesia is not required. Most of this work is for pharmaceutical research, development or safety.

In 2004 the 'other carnivore' category included badgers, mink and seals, all used for research relevant to those species. The 'other ungulate' category, which appears only in some years, included only one species in 2004, used for a single programme of work. The 'other mammals' included species such as bats, marsupials and one type of shrew.

There were decreases in procedures using most species, but notably rats (down 31,000, or 6 per cent), rodents other than mice or hamsters (down 10,000 or 22 per cent), rabbits (down 3,600, 14 per cent), cattle (down 2,550, 16 per cent), and fowl (down 8,300, 8 per cent). The decrease in use of non-*Coturnix coturnix* quail has already been mentioned.

No procedures were performed in 2004 on greyhound dogs, camelids, prosimians, baboons, great apes, gibbons, non-specified new-world primates and non-specified old-world primates, or *Octopus vulgaris*, the single cephalopod species protected by the Act. The government stated in November 1997 that it would no longer issue licences to use great apes in scientific procedures. No great apes have been used since the current legislation (the 1986 Act) was introduced in 1987.

Where there was no use of a species, the species might not be listed in tables other than Tables 1, 1a, 5, 5a, 10 and 10a.



Figure 2: Procedures by species of animal and primary purpose of procedure, 2004

Primary purpose (Tables 1 and 1a, Tables 26 and 27, Figures 2 and 2A)

In 2004, the main purposes for performing scientific procedures were for breeding, fundamental biological research, and applied studies into human medicine or dentistry. These accounted for 983,000 (34 per cent), 881,000 (31 per cent), and 672,000 (24 per cent) of the total number of procedures respectively.

Breeding procedures accounted for much of the overall rise in procedures in 2004; see figure 2A. These procedures were up 80,000 (part of a continuing rise). There were also rises in fundamental biological research (up 48,000); procedures for this purpose have been fluctuating for a number of years, as have applied studies into veterinary medicine, which rose by 5,700 or 4 per cent.

There was a further decline in procedures for the protection of man, animals or the environment (down 37,000, 25 per cent). Procedures for this purpose are now only just over half the level reported eight years ago. Procedures for applied studies for human medicine were down 22,000 (3 per cent) on the 2003 figure; a steady decline in this purpose seems to be flattening. Decreases were also reported for direct diagnosis of disease, down 10,500 (19 per cent); an earlier decline halted and now annual figures for this purpose seem to be fluctuating. The other purposes reported in Tables 1 and 1a recorded small falls, all in line with existing trends.





Figure 2A: Breeding, and other procedures, 1995-2004

Source (Tables 2, 2.1 and 2.2)

In 2004, 86 per cent of all procedures were performed on animals listed in Schedule 2 to the Act (mouse, rat, guinea pig, hamster, gerbil, rabbit, cat, dog, ferret, non-human primate, pigs (if genetically modified), sheep (if genetically modified), and quail (*Coturnix coturnix*)).

In total, 99 per cent (2.43 million) of procedures carried out on animals listed in Schedule 2 used animals acquired from designated establishments in the United Kingdom, 60.5 per cent from the user's own establishment, and 39.5 per cent from another designated establishment. There is an established trend towards using animals sourced from the licensee's own establishment (rather than obtaining them from a designated supplier), and the changes recorded in 2004 follow that trend. The number of procedures involving Schedule 2 listed animals obtained from sources outside the EU in 2004 fell by 2,250 to 13,600 and of these, almost all (13,340) were performed on animals obtained from outside Europe (68 per cent of which were mice). Thirty six per cent of all procedures performed on non-human primates used animals acquired from designated sources within the United Kingdom. Acquisition from abroad is due to a lack of available animals of either a suitable strain or suitable health status for the particular purpose.

From Tables 2, 2.1 and 2.2, it can be seen that just under half of procedures on species listed in Schedule 2 that were obtained from sources outside the UK, were performed on either harmful mutant or genetically modified animals. They were almost all mice, and the remainder were rats. Three quarters of harmful mutant and 94 per cent of genetically modified animals were obtained from within the licensee's own designated establishment.

The use of animals in Schedule 2 acquired from non-designated sources in the UK was duly authorised as properly justified under Section 10(3) of the Act. The rodents from non-designated sources in the UK are mainly those involved in studies requiring animals from or in the wild.

The dogs from non-designated sources within the UK were 'other dogs', i.e. neither beagles nor greyhounds. The research programmes required animals representative of the general pet population which are not available from the usual designated sources, and which were used for studies relevant to the specific breed or type of dog. There was a rise in 2004 of 169 procedures using imported dogs; this number tends to fluctuate from year to year.

Some 399,000 procedures, up 6,100 (1.5 per cent) on 2003, were performed on species not listed in Schedule 2. This number has shown fluctuations in recent years.

Genetic status (Tables 3, 3.1, 3.2, 3.3, Table 27, figure 2B)

Genetically normal animals (Tables 3, 3.1)

About 59 per cent of procedures started in 2004 involved normal animals, down 75,500 on 2003. In the longer term, the use of genetically normal animals has decreased from 2.27 million in 1995 to 1.67 million, a drop of 26 per cent over this period. Table 3.1 shows normal animals used only in breeding programmes. Nearly all these animals were mice (97 per cent), the remainder being rats, pigs, sheep, fish, birds, and amphibians. Comparison with 2003 shows similar use to that year.

Animals with a naturally-occurring harmful genetic defect (Tables 3, 3.2)

Some 267,000 procedures (9 per cent of all procedures) started in 2004 involved animals with a naturally occurring harmful genetic defect, 11,000 fewer than in 2003. Use of such animals has risen from 8 per cent of all procedures in 1995 to just under 10 per cent now. The figures fluctuate slightly but there is a slight rising trend. The animals used in 2004 were mostly mice (74 per cent), rats (11 per cent), and fish (14 per cent), although there were a few procedures using other species. Other than procedures associated with maintenance of breeding colonies, the work with mice and rats was split reasonably evenly between fundamental biological research and applied studies (though rats tend to be used more for the latter). The fish and amphibia were bred and/or used mainly for fundamental research. The procedures involving dogs were for studies of naturally-occurring eye diseases relevant to those species, and man. The pattern of species use was very similar to that in 2003. About 38 per cent of these animals were used for scientific purposes additional to breeding; fewer than one half of one per cent were used in toxicology.



Figure 2B: Procedures involving normal, mutant, and genetically modified, animals, 1995-2004

Genetically modified animals (Tables 3, 3.3, Figure 2B)

The use of genetically modified (GM) animals was identified as a separate category for the first time in 1990; this category accounted for some 914,000 procedures in 2004, 150,000 (32 per cent) more than in 2003. Nearly a third of all procedures in 2004 involved genetically modified animals, and 96 per cent of these procedures involved mice, most of the remainder being fish. Moreover, GM and mutant animals (see above) accounted for over half of all mouse use (56 per cent) in 2004. There was an increase in GM mouse use across almost all areas, while GM rat use rose slightly, reversing the decrease noted last year. Thirty seven GM pigs were used (for breeding) in 2004, but no GM sheep use was noted. There was a decline in the number of procedures using GM birds (fowl), but marked rises in the use of amphibians (up around 500, or 35 per cent), and fish, use of which doubled from 16,000 last year to nearly 32,000 in 2004.

About 68 per cent of GM animals (623,000) were used solely to maintain breeding colonies, a similar proportion to last year, and 30 per cent (278,000) were used for further scientific purposes. Fewer than one fifth of one per cent were used in toxicology procedures. There was a decline in the generation of founder colonies and in use of GM animals for toxicology, but rises for other purposes.

The regulated use of GM animals has more than quadrupled since 1995 and in percentage terms now represents about 32 per cent of all scientific procedures, compared with 8 per cent in 1995. This increase has however been offset by the decline in the use of genetically normal animals.

Target body system (Table 4a)

In 2004, about 56 per cent of all procedures were directed towards a particular body system. The largest single category was the immune system, accounting for 18 per cent, or 509,000 procedures. The next largest was the nervous system (14 per cent, 405,000 procedures). In both cases rodents were the main species used; in the former case mainly mice, but in the latter case mice and rats were used in approximately equal numbers. There were increases in use in 2004 for immune (up 21,000), respiratory (up 6,000), special senses (up 2,000) and cardiovascular (up 700) systems. Other uses have fallen except for those categorized as relating to multiple body systems or where a body system is not relevant. About 19 per cent of all procedures in 2004 were directed towards more than one body system, and just over a quarter were procedures in which the body system was not relevant.

Use of anaesthesia (Table 4b, Table 22)

Procedures are permitted without anaesthesia or analgesic only when the administration of an anaesthetic or analgesic is judged to be more traumatic than the procedure itself, or when anaesthesia is incompatible with the object of the procedure. Just under 60 per cent of procedures did not use anaesthesia. Local anaesthesia was used in 312,000 procedures (almost the same number as in 2003, and about 11 per cent of the total), mainly in mice (299,000 – usually for tissue collection for genetic analysis). Anaesthesia without recovery was used in 269,000 procedures, about 9.4 per cent of the total (up 3,100 from the year 2003).

Neuromuscular blocking agents (NMBA) were reported in 3,800 procedures, fewer than one in every 700 procedures, all of these in conjunction with general anaesthesia. About three quarters of these procedures were carried out under general anaesthesia without recovery. Around 56 per cent of these procedures were performed on rats, and much of the remainder on mice and other rodents.

FUNDAMENTAL AND APPLIED STUDIES OTHER THAN TOXICOLOGY, REGULATORY OR SAFETY PURPOSES

The attention of readers is drawn to paragraph 15 of the introductory notes above where the method of recording procedures for toxicology and regulatory purposes, against those for non-toxicology purposes, is explained.

Some 2.42 million procedures, in which 2.35 million animals were used for the first time, were conducted for purposes of fundamental and applied studies other than toxicology, safety or other regulatory purposes in 2004. There was a rise of 75,000 in the number of such procedures and of 68,000 in the number of animals used, compared with 2003, broadly reflecting the rise in the overall number of procedures. Although use of most species fell, this was more than offset by the increases in the use of mice (up 90,000, mostly for breeding purposes) and fish (up 24,000). Of the procedures started in 2004, 1.72 million (71 per cent) were performed on mice and 330,000 (14 per cent) on rats; 98,000 (4 per cent) on birds (mainly domestic fowl) and 145,000 (6 per cent) on fish. A total of 2,300 procedures used dogs, just under 800 used cats and 1,040 used non-human primates.

Field of research (Tables 5, 5a, 5.1 and 5.2, Table 24)

Of the various fields of research, the largest single category was immunology, which accounted for 484,000 procedures (20 per cent of all non-toxicology procedures, and up 62,000 or two percentage points on the 2003 figure), mainly on rodents, though a wide range of species was used. Pharmaceutical research and development (393,000), cancer research (275,000) and anatomy (254,000) represented around 16, 11 and 10 per cent of the total respectively. A range of species was used in pharmaceutical research; mice and rats accounted for all but 4 per cent of the procedures carried out for cancer research and rodents, fish and amphibia were the main species used for anatomy research. Physiology and genetics were the only other fields where the number of procedures was greater than 5 per cent of all non-toxicology procedures.

The main changes compared with 2003 were: anatomy (up 26,000, an 11 per cent rise, following a rising trend); biochemistry (up 7,600), immunology (up 62,000, continuing a rising trend), clinical medicine (up 7,300, or 64 per cent), genetics (up 21,000, a strongly rising trend), molecular biology (up 17,000), and nutrition (up 6,900). There were several smaller rises in other disciplines. Decreases were reported in procedures for physiology (down 16,000 or 8 per cent, but within a rising trend), pathology (down 9,500), microbiology (down 13,400), parasitology (down 20,000, a drop of 18 per cent, continuing the fall from a peak in 2002), and animal science (down 13,000, reversing the rise in 2003). No procedures were carried out for research on the effects of tobacco; there has been no research of this kind since 2001.

Animals with harmful genetic defects (Table 5.1) were used across a wide range of disciplines, but none were used for dentistry, zoology, botany, animal science, ecology, or research related to the use of tobacco or alcohol. The principal disciplines for which such animals were used were: cancer research (88,000 or a third of all procedures involving animals with harmful mutations); anatomy (50,000, or 19 per cent); immunology (27,000 or 10 per cent); genetics (26,400, 10 per cent), and 'other' use (i.e. disciplines not otherwise specified), 34,600 or 13 per cent. Mice, rats and fish were the main species used.

There was a broadly similar spread of disciplines involving genetically modified animals (Table 5.2). The greatest use was for immunology (270,000 or 30 per cent of procedures using GM animals), cancer research (107,000 or 12 per cent) and anatomy, which includes developmental biology (127,000 or 14 per cent). Procedures for all disciplines showed increases from 2003 except for psychology, parasitology, clinical medicine and animal science. No procedures using GM animals were performed for the disciplines of dentistry, clinical surgery, zoology, botany, ecology, or tobacco research.

Production of biological materials (Table 8)

In 2004 some 286,500 procedures, 15,000 more than in 2003, were performed for the purposes of production of biological materials. Of these, about 30 per cent were for the production of infectious agents and, of this particular group, 63 per cent used birds and a further 32 per cent used mice. Vectors, neoplasms and polyclonal antibodies accounted for a further 12 per cent; here, rodents were the main animals used except for polyclonal antibody production, where a wider range of species was used. The remaining 56 per cent of production procedures were to obtain other biological material such as tissues or blood products, also using a wide range of species.

In November 1997, the Government confirmed that the production of monoclonal antibodies by the ascites method could only be considered if *in vitro* attempts at production had failed, or the use of animals was justified for specific diagnostic or therapeutic products. The coding of the returns form was changed in 1999 to distinguish between procedures for the immunisation of animals used in monoclonal antibody production, (for which there are no generally applicable replacement alternatives), and those where the ascites model has been used. The immunisation method to produce tissues for *in vitro* use (using mostly mice) showed a drop of 970 to 3,400. No procedures have been performed since 2001 using the ascites model.

Techniques of particular interest (Table 9)

Among non-toxicological work, certain procedures have been identified as being of particular interest. These have been described above in paragraph 15A(iii) of the introductory notes. About 159,000 procedures, representing 7 per cent of non-toxicological procedures, fell into this category in 2004, about 4,250 fewer than the number reported in 2003. The general trend is downwards since this category of procedure was separately identified in 1995, but the trend has flattened since around 2000. There were some increases, principally in procedures involving interference with the organs of special sense (up 4,000). There were also decreases, including procedures involving injection into the brain (down 4,000), psychological stress (down 7,600), and inhalation (down 6,000). Physical trauma procedures used mainly rodents, and included work for pain and other neuronal injury studies, tissue repair studies, and atheroscelerosis. Aversive training mainly involved mice, rats and birds. The thermal injury category included mainly tissue repair studies.

TOXICOLOGY OR OTHER SAFETY OR EFFICACY EVALUATION

(Tables 10, 10a, 21, 25 and Figure 3)

Procedures for the purpose of toxicology or safety and efficacy evaluation accounted for 435,500, or just over 15 per cent, of the total number of procedures carried out in 2004. This was about 12,000 fewer than in 2003. The decrease was reflected in a similar fall (10,750) in the number of animals used for the first time, which in 2004 was 425,200. Toxicology procedures continue to form an ever smaller proportion of scientific procedures overall; in 2004 they represented only 15 per cent, compared with 25 per cent in 1995.

Species

Of toxicology procedures started in 2004, 202,000 (46 per cent) used mice; a further 135,000 (31 per cent) used rats, and other rodents were used in 12,100 procedures (3 per cent). Some 49,500 (11 per cent of the total) used fish; 16,100 used rabbits; birds were used in 7,500 procedures; and dogs (beagles) in 5,800. Other species accounted for just under 2 per cent of all toxicology procedures; 3,200 used non-human primates (principally old-world species) but only 26 used cats. Species for which there was a fall in the number of toxicological procedures in 2004 included: rats (down 8,500, or 6 per cent); guinea pigs (down 2,400), rabbits (down 1,400), old world monkeys (down 480), birds (down 11,000) and fish (down 3,300). There were some species with an increase in use: the main instance was procedures on mice which rose 12,400, or 6.5 per cent; also dogs (up 730), sheep (up 170), cattle (up 170) and new world monkeys (up 100). There was actually an overall decrease of 169 in the number of individual non-human primates used for the first time, a decrease of 261 in old world monkeys being offset by an increase of 92 in new world monkeys. As in previous years, the non-human primates, dogs and cats were used mainly for pharmaceutical safety.



Figure 3: Procedures (toxicology) by species of animal, purpose of test, legislative requirement and type of test, 2004

Only 1,548 procedures involving genetically modified animals were carried out for toxicology, and all the animals so used were mice (see Table 3.3). This represents just over one in 600 of all genetically modified animals used, and is somewhat less than the proportion reported a year ago. There were 1,010 procedures for toxicology involving animals with harmful genetic defects (all mice); this represented about one procedure in every 270 involving these animals, about the same proportion as last year (Table 3.2).

Purposes

Pharmaceutical safety, efficacy evaluation, residue studies and quality control accounted for 70 per cent of toxicology procedures in 2004. The next most common purposes were safety evaluation of substances used in industry (8 per cent), in agriculture (6.5 per cent), and evaluation of environmental pollution (7 per cent).

Decreases were reported in some types of procedures, but particularly those concerned with the safety of substances used in agriculture (down 12,000), pharmaceutical efficacy testing (down 8,200, following a long-term declining trend) and, to a lesser extent, foodstuffs and additives (down 7,200), toxicology research (down 4,250, following a slowly declining trend), non-specific toxicology (down 3,100), and procedures connected with environmental pollution (down 3,800). A few categories showed a rise in the number of procedures; those for pharmaceutical quality control were up 14,000 (18 per cent on 2003); pharmaceutical safety testing (up 13,000), and pharmaceutical ADME and residue testing, up 4,700. Except where stated in this paragraph, most of the movements are within fluctuations noted over the last ten years.

In November 1997 the Government announced that no further licences would be issued for cosmetic finishedproduct testing, and that existing licences had been amended to exclude this type of work. This was extended in November 1998 to ingredients intended primarily for cosmetics. As a consequence no procedures were performed for either of these purposes in 2004. Since 1995 there has been no safety testing of tobacco or tobacco products and there are no licences in force authorising procedures of this kind.

Legislative requirements (Table 11, Table 21, Figure 3)

Of the total of 436,000 toxicology or safety procedures in 2004, 86 per cent were performed to comply with legislation or other regulations. Only 19,800 procedures (4 per cent) were performed to satisfy UK legislation alone, the slight fall following the prevailing general downward trend; about 43,700 (10 per cent – see pie chart in Fig. 3) were performed to satisfy the requirements of either a single EU country (excluding the UK) or the EU in general; and 14,600 (3 per cent) for other international legislation. The majority of procedures performed to fulfil legislative requirements (300,000, or 69 per cent) were used to satisfy a combination of the above requirements. The remaining 59,000 procedures, 14 per cent of toxicology and safety work (a fall of 15,000 procedures from 2003, reversing the rise noted last year, and continuing the general downward trend), were performed for purposes other than direct legislative or regulatory requirements.

Type of test (Tables 12, 13, 15, 16, Figure 3)

See explanatory notes for List A, Row 11 in Appendix C for more details of the type of test or procedure.

From 1999 the category of procedures relating to acute lethal toxicity tests was subdivided into: acute lethal (LD50), acute lethal concentration (LC50) and other types of acute limit-setting tests. In 2004 acute quantitative lethal toxicity tests accounted for 84,000 procedures or 19 per cent of all toxicology work. Tests were reported in this category for the following purposes: pharmaceutical efficacy; pharmaceutical quality control; method development; non-specific toxicity tests; and a smaller number of procedures for the safety of substances in agriculture and industry, and for toxicology research. Very nearly all these procedures used mice. None of these procedures were LD50 tests carried out according to the previous OECD Guideline 401. The acute lethal toxicity tests involved testing of biopharmaceuticals including veterinary biologicals, and food safety tests. Acute lethal concentration tests accounted for 20,100 procedures (5 per cent of all toxicology), and acute limit-setting lethal toxicity tests another 18,700 procedures (4 per cent). There was an overall decrease in the use of procedures for acute safety testing from 144,000 in 2003 to 138,000 in 2004, but numbers of individual types of test have tended to fluctuate in recent years.

A further 43,400 procedures (10 per cent of toxicology procedures) were carried out for subacute limit-setting or subacute toxicity tests. This was 5,200 more than in 2003. Of the remaining tests, other, non-specified, toxicological tests (in which a wide range of species was used, with the majority being mice, rats and other rodents) accounted for the greatest single proportion with 117,600 procedures (27 per cent of the total), a rise of about 2,800 on 2003. The present 'other' category is comprised mostly of procedures concerning pharmaceutical safety testing not otherwise described, other basic or applied toxicology research, and the acquisition of tissues for further *in vitro* studies.

There were about 8,500 procedures carried out on rabbits for pyrogenicity testing which will continue as a necessary safety test required by regulatory bodies as there is no validated alternative for the evaluation of noncrystalloid substances for intravenous injection into humans; a further 800 procedures were carried out on rabbits to test for clinical signs in the eye (300 fewer than in 2003); 27,000 procedures (almost half the number reported last year), of which 85 per cent were on rats, to test for reproductive toxicity; and 2,700 procedures on rodents to test for skin sensitization, mainly on mice and guinea pigs used for the safety testing of products used in agriculture and industry. Procedures for skin sensitisation tests were down 75 per cent from 2003.

Further detailed analysis of safety testing is contained in Tables 13, 15 and 16. Each of these tables takes one of the three purposes shown in the columns in Table 11, and examines procedures by species by each of the types of test shown in the columns of Table 12. For example, Tables 13, 15 and 16 show that the 23,100 procedures carried out on rats for reproductive toxicity other than teratogenic testing (Table 12) is split mainly between safety testing of pharmaceuticals (see Table 15), and non-pharmaceuticals (Table 13), with comparitively few on other safety and toxicity testing (Table 16).

Two of these three tables show a fall in the number of procedures against the comparable figures for 2003: environmental and industrial safety down 25,200, other safety down 10,500, but pharmaceutical safety up 23,500.

Rodenticide trials

It is impractical to collect accurate figures on the number of animals affected in field trials of rodenticidal substances. No field trials were reported to have been started in 2004.

Use of animals in CITES list

Returns were required on the use of animals listed in Appendix 1 of the Convention on International Trade in Endangered Species of Flora and Fauna (CITES) or in Annex C.1 to the Council Regulation (EEC)3626/82 (see the notes to the return form in Appendix C). There were 47 procedures performed in 2004 on animals in this category, all on wild birds.

TREE TABLES (Tables 18a-h)

These tables show the relationship between the purpose of the procedures and the target body system for six species in which there is special interest (Tables 18a-f). The species presented in these tables are: cats, dogs, horses, new-world (non-human) primates, old-world (non-human) primates, and rabbits. Two further tables illustrate the use of genetically modified animals (Table 18g) and animals with a harmful genetic defect (Table 18h). Additional information on use is provided where appropriate.



RETURNS, PROJECT LICENSEES AND DESIGNATED PLACES

Figure 4: Project licence holders and procedures started in 2004, by type of designated place (note: only those project licence holders reporting procedures in 2004 are included)

Returns (Table 19)

Returns were received in respect of 3,550 project licences in 2004. Returns were received from all but a very few licensees. Just under 2,600 licensees reported starting procedures in 2004, some 250 fewer than in 2003. Of these, about 2,000 (77 per cent, similar to the proportion in 2003), reported starting more than 50 procedures. The holders of about 950 project licences (27 per cent of all licensees) reported starting no procedures in 2004 (Table 19). This was also very similar to the position in 2003.



Millions of procedures

Figure 5: Procedures by type of establishment, 1987-2004. The graph shows the two types of institution responsible for the largest number of procedures (and therefore that have most impact on the overall number of procedures started each year).

Project licensees and designated places (Table 19, Table 23, Figures 4 and 5)

Sixty eight per cent of the projects on which procedures were started in 2004 were based at universities or other academic establishments (including medical schools) but they accounted for only just over 42 per cent of the number of procedures. Projects at commercial organisations accounted for almost exactly a third of procedures started in 2004 (down three percentage points on 2003) but represented only an eighth of the total number of active projects.

Throughout the period 1981 to 1992 university licensees performed between one-fifth and one-quarter of all experiments or procedures, but since 1992 this has slowly risen to over 42 per cent. The proportion of procedures carried out by commercial licensees has fallen from 60 per cent in 1987 to 33 per cent in 2003 (Table 23; see also Figure 5). The number of procedures reported by universities or other higher educational establishments overtook that reported by commercial organisations for the first time in 2000, and is now clearly ahead (see Figure 5).

The fall in the number of procedures carried out by commercial licensees was largely responsible for the overall fall in the total number of procedures until a few years ago, but the rise in the number of procedures conducted in universities and non-governmental public bodies clearly contributed to the overall rise in the number of procedures in 2004 (see Table 23). The number of procedures started in public health laboratories has tended to fall in recent years, as have those in NHS hospitals (many of the latter are classified as university departments for the purposes of these statistics). There is an overall rising trend in procedures conducted in non-governmental public bodies, but a recent rise in procedures reported by the not-for-profit sector appears to have peaked in 2001, although the overall trend is still very slightly upwards.

Historical tables

Tables 20-27 (q.v.) show longer-term trends in scientific procedures.

Organisation Chart: Relationship between the tabels in part A, 2004



Notes

Tree tables and tables in parts B and C are separate from this relationship.

GM = genetically modified

Tables 6, 7, 14, and 17 have been discontinued as being either superfluous or having been superseded by other tables.

Detailed descriptions of the terms used in the tables will be found in the Introductory Notes, at page onwards.

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Great Britain 2004	-								Number o	f procedures
Species of animal				Primary pui	pose of the pro	cedure				Total
	Fundamental biological	Applied studies -	Applied studies -	Protection of man, animals	Education	Training	Forensic enquiries	Direct diagnosis	Breeding	
	research	human medicine or dentistry	veterinary medicine	or environment						
Mammal										
Mouse	601,327	350,634	24,491	24,599	971	I	I	7,539	909,577	1,919,138
Rat	126,524	267,402	1,086	44,293	561	863	'	340	23,658	464,727
Guinea pig	2,751	22,297	1,404	217	140	1	'	292	I	27,101
Hamster	2,328	2,298	410	ı	I	ı	ı	ı	I	5,036
Gerbil	1,775	1,927		I	I	'	ı	I	ı	3,702
Other rodent	1,431	I	114	91	I	I	I	I	I	1,636
Rabbit	1,869	13,209	2,118	2,534	61	I	I	1,728	217	21,736
Cat	207	I	612	I	I	I	I	I	ı	819
Dog										
Beagle	120	7,027	261	147	ı	'	ı	244	I	7,799
Greyhound	•	I	•	I	ı	'	'	ı	I	'
Other including cross-bred dogs	21	7	191	I	I	1	'	'	ı	219
Ferret	169	828	2	ı	13	'	ı	26	I	1,038
Other carnivore	601	I	152	76	I	I	I	I	1	829
Horse, donkey and cross-bred equids	356	I	280	ъ С	16	'	40	7,820	I	8,517
Pig	2,923	525	5,759	107	17	'	'	1,798	53	11,182
Goat	322	43	24	4	I	'	'	2	I	395
Sheep	6,670	567	13,141	ı	Ð	'	ო	20,868	29	41,283
Cattle	3,439	0	10,156	19	~	'	'	ო	I	13,620
Deer	132	I	14	'	ı	'	'	'	I	146
Camelid	1	I		ı	I	'	'	'	I	'
Other ungulate	I	I	I	ო	I	I	I	I	I	ю
Primate										
Prosimian	I	I		I	I	'	ı	I	I	'
New World monkey										
marmoset, tamarin	239	747	I	I	I	I	I	0	I	995
Squirrel, owl, spider monkey	1	4	I	I	I	I	I	I	I	40
Other New World monkey	I	I	I	I	I	1	I	I	'	I

Great Britain 2004									Number	of procedures
Species of animal				Primary pr	irpose of the pro	ocedure				Total
	Fundamental	Applied	Applied	Protection of	Education	Training	Forensic	Direct	Breeding	
	biological	studies -	studies -	man, animals			enquiries	diagnosis		
	research	human	veterinary	or						
		medicine or	medicine	environment						
		dentistry								
Old World monkey										
Macaque	76	2,521	ı	575	I	ı	I	-	I	3,173
Baboon	I	I	I	'	I	'	I		I	•
Other Old World monkey	I	I	ı	'	I	I	I		I	ı
Ape										
Gibbon	I	I	I	'	I	'	I		I	·
Great ape	I	I	I	'	I	'	I		ı	
Other mammal	2,272	6 2 2	I	82	I	1	I		I	2,393
Bird										
Domestic fowl (Gallus domesticus)	21,607	210	68,366	1,571	I	'	I	1,712	565	94,031
Turkey	1,401	50	282	'	I	'	I	194	I	1,927
Quail (Coturnix coturnix)	20	I	I	'	I	'	I		I	02
Quail (spp.other than Coturnix coturnix)	60	ı	I	506	ı	'	I		I	566
Other bird	7,489	I	371	182	I	'	I	670	I	8,712
Reptile										
Any reptilian species Amphibian	52	1,294	I	ω	I	I	I	I	I	1,354
Any amphibian species	16,029	I	I	613	963	I	I	I	590	18,195
Anv fish species	78.637	020	27 154	38 449	I	1	I	2 101	47 951	194 562
Cephalopod		2	2	$\hat{\mathbf{b}}$				Î		100,-0-
Octopus vulgaris	1							•	'	1
Total	880,897	671,937	156,388	114,081	2,748	863	43	45,347	982,640	2,854,944

Table 1 Scientific procedures by species of animal and primary purpose of the procedure (Continued)

Table 1a Animals by species of animal and primary purpose of the procedure

Great Britain 2004

Great Britain 2004									Numb	er of animals
Species of animal				Primary purp	ose of the proc	edure				Total
	Fundamental biological	Applied studies -	Applied studies -	Protection of man, animals	Education	Training	Forensic enquiries	Direct diagnosis	Breeding	
	research	human	veterinary	or)		
		medicine or dentistry	medicine	environment						
Mammal										
Mouse	593,880	350,329	24,491	24,599	971	ı	'	7,539	908,301	1,910,110
Rat	124,847	261,333	1,086	44,293	561	863	I	340	23,658	456,981
Guinea pig	2,751	22,186	1,404	217	140	I	I	264	1	26,962
Hamster	1,876	2,298	410	I	'	I	I	'	I	4,584
Gerbil	1,727	1,927	'	I	'	ı	I	'	ı	3,654
Other rodent	1,431	I	114	91	I	I	I	I	I	1,636
Rabbit	1,622	7,195	1,449	2,514	54	'	'	1,661	217	14,712
Cat	191	'	307	I	I	I	ı	1	I	498
Dog										
Beagle	00	4,911	237	141	ı	I	ı	88	I	5,476
Greyhound	I	'	'	I	'	ı	I	I	1	I
Other including cross-bred dogs	21	7	66	I	ı	I	I	'	ı	94
Ferret	169	818	0	ı	13	ı	I	17	ı	1,019
Other carnivore	601	I	146	68	I	I	I	I	I	815
Horse, donkey and cross-bred equids	99	'	173	5	16	I	'	62	ı	339
Pig	2,906	477	5,485	107	17	ı	I	1,797	53	10,842
Goat	291	43	24	ო	'	ı	I	0	ı	363
Sheep	6,431	553	13,076	ı	5	ı	ო	466	29	20,563
Cattle	2,499	I	3,262	19	~	I	I	ю	I	5,784
Deer	132	I	14	I	I	I	I	I	I	146
Camelid	I	I	ı	I	I	I	I	I	I	I
Other ungulate	I	I	I	n	I	I	I	ı	I	ო
Primate										
Prosimian	I	1	ı	I	ı	I	I	1	ı	1
New World monkey										
marmoset, tamarin	228	510	'	I	I	I	I	თ	I	747
Squirrel, owl, spider monkey	I	1	'	I	I	ı	I	1	I	'
Other New World monkey	I	I	I	I	I	1	I	I	•	'

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Great Britain 2004									Num	er of animals
Species of animal				Primary puri	oose of the proc	edure				Total
	Fundamental	Applied	Applied	Protection of	Education	Training	Forensic	Direct	Breeding	
	biological	studies - buman	studies - weteringry	man, animals or			enquiries	diagnosis		
		medicine or	medicine	environment						
		dentistry								
Old World monkey										
Macaque	60	1,590	'	394	'	I	I	-	ı	2,045
Baboon	'	I	'	'	'	ı	1	1	'	
Other Old World monkey	I	I	ı	I	ı	I	I	I	I	'
Ape										
Gibbon	I	1	'	I	'	I	I	I	'	'
Great ape	I	·	'	I	'	I	I	I	'	
Other mammal	2,272	0° C	'	74	'	I	I	I	1	2,385
Bird										
Domestic fowl (Gallus domesticus)	21,042	210	68,366	1,571	'	I	I	1,710	565	93,464
Turkey	1,401	9	282	I	'	I	I	29	'	1,718
Quail (Coturnix coturnix)	70	'	'	I	'	I	I	I	'	20
Quail (spp,other than Coturnix coturnix)	60	'	'	506	'	I	I	I	'	566
Other bird	7,397	1	315	182	'	I	I	660	'	8,554
Reptile										
Any reptilian species	52	3	ı	Ø	ı	I	I	I	I	82
Amphibian										
Any amphibian species	8,836	I	I	609	963	I	I	I	521	10,929
Fish										
Any fish species	78,637	270	27,126	38,449	I	I	'	2,096	46,973	193,551
Cephalopod										
Octopus vulgaris	I	1	T	I	I	I	1	I	I	T
Total	861,595	654,724	147,835	113,853	2,741	863	ю	16,761	980,317	2,778,692

her of procedures	Total		1,919,138	464,727	27,101	5,036	3,702	21,736	819	8,018	1,038	37	ı	4,208	70	399,314	2,854,944
NUN		Animals not listed in schedule 2	1	I	I	I	I	I	I	I	I	I	I	I	I	399,314	399,314
		Animals acquired from other sources	9,097	517	106	I	Q	124	I	836	5	I	I	2,674	I	ı	13,364
		Animals acquired from Council of Europe countries who are signatories to ETS123	213	I	I	I	I	I	I	I	I	I	I	I	I	1	213
	Source	Animals acquired from sources within the EU (outside the UK)	3,774	1,932	162	743	46	3	250	86	I	I	I	I	I	ı	6,996
		Animals acquired from non- designated sources in the UK	60	228	I	I	I	21	I	118	I	I	I	I	I	ı	427
		Animals acquired from another designated breeding or supplying establishment in the UK	543,255	365,753	26,024	3,191	2,559	14,422	70	4,683	956	I	I	716	70	I	961,699
		Animals acquired from within own designated establishment	1,362,739	96,297	808	1,102	1,092	7,166	499	2,295	77	37	I	818	I	ı	1,472,931
Great Britain 2004	Species of animal		Mouse	Rat	Guinea pig	Hamster	Gerbil	Rabbit	Cat	Dog	Ferret	Pig (genetically modified)	Sheep (genetically modified)	Primate	Quail (Coturnix coturnix)	Animals not listed	Total

Table 2 Scientific procedures by Schedule 2 listed species and source of animals

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(1) The "animals not listed in Schedule 2" here were 347 domestic fowl, 1,075 amphibia and 37,906 fish.

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(genetically modified animals) Great Britain 2004

Great Britain 2004								Number of procedures
Species of animal				Source				Total
	Animals acquired from within own designated establishment	Animals acquired from another designated breeding or supplying establishment in the UK	Animals acquired from non- designated sources in the UK	Animals acquired from sources within the EU (outside the UK)	Animals acquired from Council of Europe countries who are signatories to ETS123	Animals acquired from other sources	Animals not listed in schedule 2 ⁽¹⁾	
Mouse	855,299	15,449	I	1,991	167	4,545	I	877,451
Rat	2,578	28	I	149	I	ю	I	2,758
Guinea pig	I	I	I	I	I	I	I	I
Hamster	I	I	I	I	I	I	I	ı
Gerbil	I	I	I	I	I	I	I	I
Rabbit	I	I	I	I	I	I	I	ı
Cat	I	I	I	I	I	I	I	I
Dog	I	I	I	I	I	I	I	I
Ferret	I	I	I	I	I	I	I	ı
Pig (genetically modified)	37	I	I	I	I	I	1	37
Sheep (genetically modified)	I	I	I	I	I	I	I	I
Primate	I	I	I	I	I	I	I	I
Quail (Coturnix coturnix)	I	I	I	I	I	I	I	ı
Animals not listed	ı	1	I	I	I	1	33,777	33,777
Total	857,914	15,477	I	2,140	167	4,548	33,777	914,023

(1) The "animals not listed in Schedule 2" here were 114 domestic fowl, 1,859 amphibia and 31,804 fish.

Table 3 Scientific procedures by species of animal, primary purpose and genetic status

Great Britain 2004				Number of	procedures
Species of animal	Primary purpose of procedure	Normal animal	Genetic status Animal with harmful genetic defect	Genetically modified animal	Total
Mouse	Fundamental biological research Applied studies Safety	311,956 309,874 24,548	45,263 40,124 30	244,108 25,127 21	601,327 375,125 24,599
	Other uses Breeding Total	7,786 188,465 842,629	77 113,564 199,058	647 607,548 877,451	8,510 909,577 1,919,138
Rat	Fundamental biological research Applied studies Safety	122,882 262,188 44,246	2,318 6,300 -	1,324 - 47	126,524 268,488 44,293
	Other uses Breeding Total	1,764 2,049 433,129	- 20,222 28,840	- 1,387 2,758	1,764 23,658 464,727
Guinea pig	Fundamental biological research Applied studies Safety Other uses Breeding	2,751 23,701 217 432			2,751 23,701 217 432
Hamster	Total Fundamental biological research Applied studies	27,101 2,328 2,708		-	27,101 2,328 2,708
	Other uses Breeding Total		-	-	- - - 5,036
Gerbil	Fundamental biological research Applied studies Safety Other uses Breeding	1,775 1,927 - -			1,775 1,927 - -
Other rodent	Total Fundamental biological research Applied studies Safety Other uses Breeding	3,702 1,431 114 91 - -			3,702 1,431 114 91 - -
Rabbit	Total Fundamental biological research Applied studies Safety Other uses Breeding	1,636 1,867 15,208 2,534 1,789	- 2 119 - - 217		1,636 1,869 15,327 2,534 1,789 217
Cat	Total Fundamental biological research Applied studies Safety Other uses Breeding	21,398 207 612 - -	338 - - - - -		21,736 207 612 - -
Dog - Beagle	Total Fundamental biological research Applied studies Safety Other uses Breeding	819 120 7,288 147 244 -			819 120 7,288 147 244
Dog - Other	Total Fundamental biological research Applied studies Safety Other uses Breeding	7,799 21 191 - -	- 77		7,799 21 198 - -
Ferret	Total Fundamental biological research Applied studies Safety Other uses	212 169 830 - 39	7		219 169 830 - 39
	Breeding Total	- 1,038	-	-	- 1,038

Table 3 Scientific procedures by species of animal, primary purpose and genetic status(Continued)

Great Britain 2004	1	1		Numb	per of procedures
Species of animal	Primary purpose of procedure	Nerverl	Genetic status	O a matting all a	Total
		Normal	Animal With	Genetically	
		animai	narmiul genetic	animal	
			delect	animai	
Other carnivore	Fundamental biological research	601	-	-	601
	Applied studies	152	-	-	152
	Safety	/6	-	-	76
	Other uses	-	-	-	-
	Total	- 820	-	-	- 829
Horse Donkey etc	Fundamental biological research	356	_	-	356
	Applied studies	280	_	-	280
	Safety	5	_	-	5
	Other uses	7,876	-	-	7,876
	Breeding	-	-	-	-
	Total	8,517	-	-	8,517
Pig	Fundamental biological research	2,923	-	-	2,923
	Applied studies	6,284	-	-	6,284
	Safety	107	-	-	107
	Other uses	1,815	-	-	1,815
	Breeding	16	-	37	53
	Total	11,145	-	37	11,182
Goat	Fundamental biological research	322	-	-	322
	Applied studies	67	-	-	67
	Safety	4	-	-	4
	Other uses	2	-	-	2
	Breeding	205	-	-	- 205
Shoop	Fundamental biological research	6 670	-	-	6 670
Sheep		13 708		_	13 708
	Safety		_	_	
	Other uses	20.876	-	-	20.876
	Breeding	29	-	-	29
	Total	41,283	-	-	41,283
Cattle	Fundamental biological research	3,439	-	-	3,439
	Applied studies	10,158	-	-	10,158
	Safety	19	-	-	19
	Other uses	4	-	-	4
	Breeding	-	-	-	-
	Total	13,620	-	-	13,620
Deer	Fundamental biological research	132	-	-	132
	Applied studies	14	-	-	14
	Safety	-	-	-	-
	Brooding	-	-	-	-
		146			146
Other ungulate	Fundamental biological research	-	-	-	-
	Applied studies	-	-	-	-
	Safety	3	-	-	3
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	3	-	-	3
Marmoset, Tamarin	Fundamental biological research	239	-	-	239
	Applied studies	747	-	-	747
	Safety	-	-	-	-
	Other uses	9	-	-	9
	Breeding	-	-	-	-
	Total	995	-	-	995
Squirrel, Owl or Spider monkey	Fundamental biological research	-	-	-	-
	Applied studies	40	-	-	40
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total		-	-	- 40
Macaque	Fundamental biological research	76	-		76
	Applied studies	2.521		_	2.521
	Safety	575	_	-	575
	Other uses	1		-	1
	Breeding	-	-	-	-
	Total	3,173	-	-	3,173

Table 3 Scientific procedures by species of animal, primary purpose and genetic status (Continued)

Great Britain 2004				Numb	per of procedures
Species of animal	Primary purpose of procedure		Genetic status		Total
		Normal	Animal with	Genetically	
		animal	harmful genetic	modified	
			defect	animal	
Other mammal	Fundamental biological research	2,272	-	-	2,272
	Applied studies	39	-	-	39
	Safety	82	-	-	8 2
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	2,393	-	-	2,393
Domestic fowl	Fundamental biological research	21,607	-	-	21,607
	Applied studies	68,576	-	-	68,576
	Safety	1,571	-	-	1,571
	Other uses	1,712	-	-	1,712
	Breeding	104	347	114	565
	Total	93,570	347	114	94,031
Turkey	Fundamental biological research	1,401	-	-	1,401
	Applied studies	332	-	-	332
	Safety	-	-	-	-
	Other uses	194	-	-	194
	Breeding	-	-	-	-
	Total	1.927	-	-	1.927
Quail (Coturnix coturnix)	Fundamental biological research	70	-	-	70
,	Applied studies	_	-	-	-
	Safety	-	-	-	-
	Other uses	_	_	-	_
	Breeding	-	-	-	-
	Total	70	-	-	70
Quail (spp_other than	Fundamental biological research	60	-	-	60
Cotumix cotumix)	Annlied studies	-	_	_	-
	Safety	506	_	_	506
		-	_	_	-
	Breeding		_	_	-
	Total	566			566
Other bird	Fundamental biological research	7 489	-	_	7 489
	Annlied studies	371	_	_	371
	Safety	182	_	_	182
		670		_	670
	Breeding	-	_	_	-
	Total	8 712		-	8 712
Rentile	Fundamental biological research	52	_	-	52
Replie	Annlied studies	1 294	_	_	1 294
	Safety	8		_	1,204
					-
	Breeding			_	_
	Total	1 354	_	-	1 354
Amphibian	Fundamental biological research	13 459	1 075	1 495	16 029
Априман	Applied studies	10,400	1,075	1,400	10,025
	Safety	613	_	_	613
		963		_	963
	Breeding	226		364	590
	Total	15 261	1 075	1 859	18 195
Fish	Fundamental biological research	53 511	20.070	5.056	78 637
Fish		27.164	20,070	260	27 424
	Applied studies	38 //9		200	27,424
	Other uses	2 101		-	2 101
	Breeding	2,101	17 836	26 / 89	2,101
	Total	10/ 850	37 000	20,400 31 804	10/ 567
All spacios	Fundamental biological response	5c0 19c	57,300	251,004	820 207
nii species		756 300	00,120 AG 550	201,903	829 325
	Sofoty	112 002	40,000	20,007	114 094
	Other uses	113,363	30	00 647	114,001
	Brooding	40,277	152 196	625 020	49,001
ΤΟΤΑΙ		1 673 350	152,100 267 571	033,930 011 022	2 85/ 0//
101/L		1,075,550	201,371	514,025	2,004,044

Species not listed had no procedures
Table 3.1 Procedures using genetically normal animals for the production and breeding of genetically modified or harmful mutant animals

104 Tal	Generation of founder	Normal animals within genetically modified	Normal animals within	Number of procedures Totals
	genetically modified animals	genetically modified breeding colonies	narmtul mutant preeding colonies	
	88,058	93,428	6,979	188,465
	871	1,148	30	2,049
	I	I	I	ı
	I	I	I	ı
	I		I	
	I	I	I	
	I	I	I	
	I	1	I	
	I	ı	I	ı
	16		I	16
	29	ı	I	29
	I	I	I	
	ı	ı	I	
	I	I	•	
	•	1	I	
	104	I	•	104
	226	I	I	226
	3,532		95	3,627
	92,836	94,576	7,104	194,516

Great Britain 2004					Nu	mber of procedures
Species of animal	Maintenance of breeding colony	Used for further non-regulated scientific purpose	Used in further regulated procedures	Used in production and other procedures ⁽²⁾	Used in safety evaluation studies (3)	Totals
Mouse	113,647	8,709	46,146	29,546	1,010	199,058
Rat	20,222	401	6,466	1,751	ı	28,840
Other rodent	'	I	ı	I	ı	
Rabbit	217	I	119	N	ı	338
Cat	'	I	I	I	I	·
Dog	'	I	7	I	I	7
Ferret	1	I	I	I	I	ı
Other carnivore	'	I	I	I	I	·
Horse and other equids	1	I	I	I	I	I
Other ungulate	'	I	ı	I	ı	
New World monkey	1	I	I	I	I	·
Old World monkey	1	I	•	I	I	
Other mammal	1	I	I	I	I	ı
Bird	347	I	I	I	I	347
Reptile / Amphibian	1	564	I	511	I	1,075
Fish	17,836	2,789	17,281	I		37,906
Total	152,269	12,463	70,019	31,810	1,010	267,571

Table 3.2 Procedures using harmful mutant animals in breeding procedures or research

See Annex A of Appendix B
 Includes production of various biological materials (codes B50-B56 in Appendix B); also includes procedures not concerned with production (code B79)
 Reported using A codes in rows 10-12 (see Appendix B)

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Great Britain 2004						ž	umber of procedures
Species of animal	Generation of founder animals	Maintenance of breeding colony	Used for further non-regulated scientific purpose	Used in further regulated procedures	Used in production and other procedures ⁽²⁾	Used in safety evaluation studies (3)	Total
Mouse	12,201	595,347	108,330	100,950	59,075	1,548	877,451
Rat	30	1,357	850	270	251	I	2,758
Other rodent	I		I	•	I	I	
Rabbit	I	I	I	I	I	I	
Cat	I	I	I	I	I	I	
Dog	I	ı	I	I	I	I	
Ferret	ı	,	I	ı	'	ı	
Other carnivore	1	,	'		ı	'	
Horse and other equids	ı	,	I	ı	ı	I	
Pig	ı	37	ı	•	'	ı	37
Sheep	1		'		ı	'	
Other ungulate	I	,	I	ı	ı	I	
New World monkey	I	,	I	ı	ı	I	
Old World monkey	ı	,	I	·	ı	I	
Other mammal	•	ı	·	•	I	'	•
Bird	56	58	·		ı	1	114
Reptile / Amphibian	229	135	222	988	285	'	1,859
Fish	690	25,798	4,984	•	332	'	31,804
Total	13,206	622,732	114,386	102,208	59,943	1,548	914,023
(1) See Annex A of Appendix B						-	

(2) Includes production of various biological materials (codes B50-B56 in Appendix B); also includes procedures not concerned with production (code B79)
 (3) Reported using A codes in rows 10-12 (see Appendix B)

Great Britain 2004												Number of	procedures
Species of animal						Body sy	stems						Total
	Respiratory	Cardiovascular	Nervous	Senses	Alimentary	Skin	Musculo - skeletal	Reproductive	Immune and reticulo - endothelial	Other system	Multiple systems	System not relevant	
Mammal													
Mouse	37,883	45,524	197,204	11,365	31,900	37,678	30,151	160,816	449,669	25,434	359,301	532,213	1,919,138
Rat	24,980	25,370	182,062	2,336	12,441	2,082	7,848	27,018	12,498	21,571	82,895	63,626	464,727
Other rodent	9,202	1,758	6,538	446	826	575	258	83	6,817	251	5,581	5,140	37,475
Rabbit	209	1,103	74	165	156	1,390	332	3,040	2,955	896	8,350	3,066	21,736
Cat	'	'	150	41	21	71	'		22	'	508	9	819
Dog	235	748	24	7	118	16	1	'	235	126	3,886	2,623	8,018
Ferret	401	119	60	101	68	'		'	238	17	10	24	1,038
Other carnivore	'	ო	ı	4	'	ı	œ	'	'	'	144	634	829
Horse, donkey and cross-bred equids	6	191	ı	'	60	14	'	121	22	5,435	195	2,389	8,517
Other ungulate	925	1,704	787	1	2,794	364	275	1,903	17,024	18,977	6,323	15,553	66,629
Primate													
New World monkey	'	100	140	7		I	ı	111	30	4	182	461	1,035
Old World monkey	'	93	213	9	~	'		19	124	'	737	1,980	3,173
Other mammal	'	654	39	'	24	1,037		5	'	552	'	82	2,393
Bird	1,140	2,719	5,079	305	9,185	698	1,250	361	4,997	56,317	6,971	16,284	105,306
Reptile, amphibian	'	429	718	77	36	'	951	11,730	'	1,339	2,686	1,583	19,549
Fish	2,951	684	12,288	783	2,176	7,465	3,990	13,523	14,617	185	62,816	73,084	194,562
Total	78,016	81,199	405,376	15,679	59,806	51,390	45,063	218,730	509,248	131,104	540,585	718,748	2,854,944

Table 4a Scientific procedures by species of animal and target body system

Great Britain 2004						Number of procedures
Species of animal			Type of an	iaesthesia		Total
	No anaesthesia	General anaesthesia, with recovery	Local anaesthesia	General anaesthesia at end of procedure, without recovery	General anaesthesia throughout, without recovery	
Mouse	1,153,043	353,133	299,005	84,842	29,115	1,919,138
Rat	254,884	124,852	1,663	44,705	38,623	464,727
Other rodent	19,932	8,135	421	4,384	4,603	37,475
Rabbit	16,128	922	880	2,366	1,440	21,736
Cat	597	40	I	22	160	819
Dog	5,383	880	386	603	766	8,018
Ferret	360	523	I	13	142	1,038
Other carnivore	224	605	I	I	I	829
Horse and other equids	605	10	7,886	I	16	8,517
Other ungulates	62,645	2,448	875	194	467	66,629
New World monkey	884	119	I	4	28	1,035
Old World monkey	2,624	499	I	17	33	3,173
Other mammal	1,121	2	1,270	I	I	2,393
Bird	51,911	339	I	52,972	84	105,306
Reptile / Amphibian	14,994	3,324	I	27	1,204	19,549
Fish	125,425	66,698	I	1,923	516	194,562
Total	1,710,760	562,529	312,386	192,072	77,197	2,854,944

Table 4b Scientific procedures by species of animal and level of anaesthesia

Neuromuscular blocking agents (NMBA) were used in 3,832 procedures in 2004. All of these procedures involved the use of general anaesthesia.

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Table 5 Scientific	

Great Britain 2004

Number of procedures

Species of animal							Field of resear	ch					
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Mammal													
Mouse	157,698	126,102	40,421	16,115	34,100	440,433	34,738	24,787	36,151	184,570	13,155	3,781	332
Rat	12,813	43,868	11,471	10,361	2,926	7,700	689	1,365	24,929	185,901	1,671	3,429	1,915
Guinea pig	'	807	4		17	445	1,236	26	2,159	12,348	I	'	'
Hamster	112	312	125		1	69	179	1,102	2	365	'	'	50
Gerbil	16	9	I	497	'	27	73	244		2,589	I	'	'
Other rodent	'	б	'	65		'	114	15	'	'	I	'	'
Rabbit	26	798	246		84	2,069	645	69	159	850	123	22	64
Cat		111	ı		'	63	'	16	32	194	26	43	'
Dog													
Beagle		32	ı		•	251	'	ı	'	1,519	ı		'
Greyhound	'	'		'		'	'	'		'	'	'	'
Other including cross-bred dogs	I	I	I	•		ı	1	I	21	1	I	7	'
Ferret	13	66	'	57		226	167	'	23	388	24	'	'
Other carnivore	1	'		40		5	'	'		'	'	'	'
Horse, donkey and cross-bred equids	16	151	I	4		168	7,962	I	52	19	I	14	'
Pig	63	183	I	47	137	4,639	332	I	7	236	9	101	42
Goat	1	43	1	'	23	4	24	165	14	'	I	1	4
Sheep	287	1,084	371	31	1,042	637	20,870	601	10	97	212	11,254	164
Cattle	59	880	I		28	8,863	069	126		221	ı	30	'
Deer			ı	9	14	1		ı		'	1		'
Camelid	ı	ı	I	,		I	1	I	ı	'	I	'	'
Other ungulate	1	1	I	,	1	I	1	ı	1	1	I	'	'
Primate													
Prosimian	1	1	ı			'	'	I	'	'	ı	'	'
New World monkey	I	I	I			I	'						
marmoset, tamarin		92	I	99	9	30	I	I	49	223	I		'
Squirrel, owl, spider monkey	1	1	1	'		'	'	'		40	1	'	'
Other New World monkey	'	1	'	1	1	1	'	'	I	1	'	1	'

Great Britain 2004												Number of pi	ocedures
Species of animal							Field of resear	ch					
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Old World monkey													
Macaque	ю	44	4	J	'	66	16	1	5	328	I	I	
Baboon	I	ı	'	ı		'	ı	'	'		ı	'	
Other Old World monkey	'		I		'	1		'	1	'	I		'
Ape													
Gibbon	I	I	1	I	'	I	I	1	'	I	I	I	'
Great ape	I	I	I	I	'	I	I	I	1	I	I	I	'
Other mammal	ı	29	ı	'		'	'	ı	39	'	ı	'	
Bird													
Domestic fowl (Gallus domesticus)	291	1,148	143	6,002	1,120	7,796	9,379	55,573	I	246	I	I	'
Turkey	ı	1	'	1	693	18	236	88	'	182	1	ı	
Quail (<i>Coturnix coturnix</i>)	02	I	I		'	I	I	1	I	I	I	1	'
Quail (spp. other than Coturnix coturnix)	I	09	'	ı		'	ı	'	'		ı	'	
Other bird	I	653	ı	644	50	926	81	72	1	ı	I	I	
Reptile													
Any reptilian species	I	52	ı			I	ı	'	ı	ı	ı	I	'
Amphibian													
Any amphibian species	12,715	1,586	1,024			ı	ı	Ю	88	590	ı	I	'
Fish													
Any fish species	69,605	6,243	I	739	4,556	9,785	4,256	2,479	'	2,099	35	I	'
Cephalopod													
Octopus vulgaris	T				'	ı					1		
Total	253,787	184,392	53,809	34,683	44,796	484,303	81,687	86,731	63,740	393,005	15,252	18,681	2,571

Table 5 Scientific procedures (non-toxicology) by species of animal and field of research (Continued)

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Great Britain 2004													Number o	f procedures
Species of animal							Field of resea	rch						Total
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	
Mammal														
Mouse	'	139,445	106,076	264,799	1,434	95	9	13,878	119	4,722	73,575	'	825	1,717,357
Rat	21	1,874	1,980	8,553	3,687	I	14	ı	ı	273	4,538	'	108	33 0,0 86
Guinea pig	'	I	т	1	'	I		ı	51	ı	1	1	'	17,096
Hamster	'	ı	230	10	244	166		'	4	'	'	'		2,970
Gerbil	'	I	'	200	1	ı		'	'	'	'	'	I	3,702
Other rodent	'	I	'	I	32	I		ı	1,377	'	'	'	ı	1,612
Rabbit	'	I	40	91	'	I	6	2	82	-	256	'	1	5,636
Cat	'	I	'	'	308	1		'	'	'	'	'	I	793
Dog														
Beagle	'		1	116		•		1	1	1	124		'	2,042
Greyhound	'	ı	'	1		ı	'	ı	ı	ı	'	'	'	'
Other including cross-bred dogs	'	99	'	1	125	I		'	'	'	'	'		219
Ferret	'	I	'	I	'	I		'	'	'	1	'	1	266
Other carnivore	'	ı	'	'	~	ı		ю	774	'	'	'		823
Horse, donkey and cross-bred equids	'	I	'	1	43	I		'	'	40	'	'		8,469
Pig	'		15	'	1,739	'		1,792	I	216	1	'	1	9,555
Goat	'	ı	'	'	77	ı		'	'	'	'	'		354
Sheep	'	469	'	I	827	I		2,605	'	131	•	'	1	40,692
Cattle	'	22	'	'	152	ı		208	13	1,039	'	'		12,331
Deer	'	78	'	'		I		48	ı	ı	1	'	'	146
Camelid	'	I	'	I		I		ı	1	ı	1	'	'	'
Other ungulate	'	I	'	'	'	ı		ı	Ю	ı	ı	ı	'	Ю
Primate														
Prosimian	'	I	'	ı	'	I		ı	ı	ı	'	I	'	,
New World monkey														
marmoset, tamarin	1	I	'	26	'	I		I	I	1	1	I	'	492
Squirrel, owl, spider monkey	1	I	'	I	'	I		I	ı	ı	ı	I	1	40
Other New World monkey		1	1	'	'	1		1		1	1	1	1	'

Great Britain 2004													Number of	procedures
Species of animal							Field of resea	ch						Total
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	
Old World monkey														
Macaque	'	'	'	1		I		1	'	'	'	'		508
Baboon		I	1	•	'	•		I	1	'	1	'	'	
Other Old World monkey			I		'	•		I	I	'		'	'	
Ape														
Gibbon	'	'	'	I	'	I	ı	'	'	1	'	I	'	'
Great ape	I	'	ı	'	'	I		1	1	'	'	'	'	'
Other mammal	'	485	1,758	I	'	I		I	82	'	'	'	'	2,393
Bird														
Domestic fowl (Gallus domesticus)		954	5		3,886			252	93	249	'	'	'	87,137
Turkey	I	'	ı	ı	614	I	ı	ı	I	38	'	'	'	1,869
Quail (Coturnix coturnix)	'	'	ı	I	'	I		1	ı	'	'	'	'	02
Quail (spp. other than Coturnix coturnix)	I	1	I	•	'	I		I	I	1	1	'	'	60
Other bird	ı	932	ı		34	706		I	4,536	'	'	'	'	8,634
Reptile														
Any reptilian species	I	I	I	1	1	I	I	I	Ø	1	1		1	60
Amphibian Anv amphibian species	,	45	678	521	1	ı	2	,	943		I	ı	I	18.195
Fish .														
Any fish species	'	1,307	83	902	6,092	7,174		2,052	27,666	Q	'	'	'	145,082
Cephalopod														
Octopus vulgaris	1	1	,	T	'	I	T	1	,	,	'	I	'	'
Total	21	145,677	110,868	275,221	19,295	8,141	31	20,840	35,751	6,715	78,493	I	933	2,419,423

Table 5 Scientific procedures (non-toxicology) by species of animal and field of research (Continued)

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Animals

Great Britain 2004												Number	of animals
Species of animal							Field of researc	h					
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Mammal													
Mouse	156,409	124,845	39,958	16,115	34,000	440,302	34,738	24,787	33,323	183,536	13, 139	3,781	332
Rat	12,813	43,643	11,471	9,557	2,926	7,700	689	1,289	24,683	179,672	1,671	3,368	1,915
Guinea pig	'	807	4	1	17	445	1,208	26	2,159	12,245	'	I	
Hamster	112	312	125	I	ı	69	179	800	2	365	'	I	50
Gerbil	16	9	'	449	ı	22	73	244	'	2,589	'		
Other rodent	'	თ	'	65	'	'	114	15	'	'	'	I	
Rabbit	26	798	67	•	84	2,059	586	30	159	808	112	22	64
Cat	1	111	1		'	36	'	I	32	194	26	43	
Dog													
Beagle	'	32	1	•	'	235	'	I	'	743	'	I	•
Greyhound	'	I	'	I	'	'	'	'	'	'	'	I	
Other including cross-bred dogs	•	I	ı	I	ı	'	•	'	21	'	'	7	,
Ferret	13	66	I	57	'	226	158	1	23	384	18		'
Other carnivore	'	1	'	40	'	5	'	'	'	'	'	ı	
Horse, donkey and cross-bred equids	16	20	'	4	'	თ	183	'	'	19	'	13	
Pig	63	183	1	47	134	4,365	332	I	5	224	9	101	42
Goat	'	12	'	ı	23	4	24	165	14	'	'	ı	4
Sheep	286	1,036	371	31	1,031	545	532	601	10	83	212	11,227	164
Cattle	59	849		I	28	2,002	690	126	'	219	'	30	
Deer	'	I	1	9	14	'	'	I	'		'	I	•
Camelid		I	1	1	'	'		'	'	1	'	I	
Other ungulate	'	I	1	•	'	'	'	ı	'	,	ı	I	
Primate													
Prosimian	1	I	1		'	'	1	I	'		I	I	
New World monkey													
marmoset, tamarin	'	81	'	99	9	29	•	'	49	37	'	I	•
Squirrel, owl, spider monkey	I	I	I	I	'	ı	•	I	•	1	ı	I	
Other New World monkey	,				'	-,		,	'		,		

Great Britain 2004												Number	of animals
Species of animal							Field of researd	ч;					
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical	Therapeutics	Clinical	Clinical
										R&D		medicine	surgery
Old World monkey													
Macaque	e	28	4	თ		68	16	'	5	53	'	'	'
Baboon	1	'	I	'		1	I	'	1		1	'	'
Other Old World monkey	•	I	ı	'		'	1	'	'	,	'	'	'
Ape													
Gibbon	I	'	I	'	'	I	1	'	I	I	I	'	'
Great ape	'	'	'	'	1	'	'	'	1	1	'	'	'
Other mammal	1	29	1	'		1	I	'	98	'	1	1	'
Bird													
Domestic fowl (Gallus domesticus)	86	1,148	143	6,002	760	7,795	9,379	55,573	1	245	1	1	'
Turkey	I	'	'	'	693	18	82	88	'	127	'	'	'
Quail (Coturnix coturnix)	70	'	1			1	I	'	'	'	'	'	'
Quail (spp,other than Coturnix coturnix)	1	60	1	'		1	I	'	'	1	'	'	'
Other bird	•	570	ı	644	50	886	81	72	'	'	1	'	'
Reptile													
Any reptilian species	•	52	ı	'		ı	ı	1	I	ı	I	ı	'
Amphibian													
Any amphibian species	6,988	1,345	180	1		I	I	ю	60	590	I	1	'
Fish													
Any fish species	68,627	6,243	I	739	4,556	9,785	4,251	2,479	1	2,099	35	'	'
Cephalopod													
Octopus vulgaris	1	'		1			'	1				1	
Total	245,587	182,318	52,323	33,831	44,322	476,660	53,315	86,298	60,584	384,233	15,219	18,592	2,571

Table 5a Animals (non-toxicology) by species of animal and field of research (Continued)

Great Britain 2004													Num	per of animals
Species of animal							Field of resear	ch						Total
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	
Mammal														
Mouse	1	139,371	105,460	263,814	1,434	95	9	13,878	119	4,722	73,575	I	590	1,708,329
Rat	21	1,874	1,980	8,553	3,687	'	14	ı	,	273	4,538		108	322,445
Guinea pig	1	I	Ю	•	'	'	ı	1	51		'		'	16,965
Hamster	'	'	230	10	244	16	'	'	4		'		'	2,518
Gerbil	1	I	'	200	'	'	ı	1			'		'	3,654
Other rodent	1	I	'	•	32	'	ı	ı	1,377	ı	1		'	1,612
Rabbit	'	'	40	91	'	'	6	2	82	-	249	'	'	5,290
Cat	'	1	'		50	'	1	'		'	ı		'	492
Dog														
Beagle	'	ı	'	14	'	'	'	1			7	I	'	1,031
Greyhound	1	I	'	ı	'	'	'	1			'	I	'	'
Other including cross-bred dogs	'	99	'	'	'	'	'	'			'	'	'	94
Ferret	'	'	'	'	'	'	'	'			'	1		978
Other carnivore	1	I	'	•	-	'	ı	ო	766	ı	1		'	815
Horse, donkey and cross-bred equids	'	ı	'		43	'	ı	ı	,	ı	'		'	307
Pig	'	1	15		1,727	'	1	1,792		216	ı		'	9,252
Goat	'	ı	'		77	'	ı	ı	,	ı	'		'	323
Sheep	1	469	'	•	772	'	ı	2,546		56	'		'	19,972
Cattle	1	22	'	ı	103	'	'	168	13	221	'	I	'	4,530
Deer	'	78	'		'	'	ı	48	,	ı	'		'	146
Camelid	'	ı	'	1	'	'	'	1			'	I	'	'
Other ungulate	1	I	'	ı	'	'	'	1	e		'	I	'	ო
Primate														
Prosimian	I	I	1	I	'	'	'	1	I	I	1	I	'	,
New World monkey														
marmoset, tamarin	I	1	•	26	'	'	1	1		I	I			294
Squirrel, owl, spider monkey	I	I	I	i	I	ı	I	I	I	I	I	I		ı
Other New World monkey	'	'			-	ı	'	-	'	'	-	-		

Table 5a Animals (non-toxicology) by species of animal and field of research (Continued)

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Table 5a Animals (non-toxicology) by species of animal and field of research (Continued)

Table 5.1 Scientific procedures (non-toxicology) by species of animal and field of research (animals with a harmful genetic defect)

Number of procedures

Great Britain 2004

Species of animal							Field of resear	ch					
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Mammal													
Mouse	11,424	8,647	699	10	3,570	26,567	385	730	685	2,523	493	244	23
Rat	598	5,006	4,947	445	113	816	'	53	337	5,904	13	1,485	'
Other rodent	'	ı	'	'	'	ı			-	ı	'	'	'
Rabbit	'	ı	1	ı	2	'			-	119	ı	1	'
Cat	'	ı	'	'	'	ı			-	ı	'	'	'
Dog													
Other including cross-bred dogs	1	ı	I	ı	'	'	I	I	-	ı	ı	7	'
Other mammal	ı	ı	ı	ı	'	I	ı	ı	'	ı	'	I	ı
Bird													
Domestic fowl (Gallus domesticus)	1	ı	ı	ı	'	1	I		-	ı	ı	I	'
Amphibian													
Any amphibian species	1,075	ı	I	I	'	'	I	I	-	ı	ı	1	'
Fish													
Any fish species	37,256	'	ı	'	'	'	ı	ľ	'	220	'	I	'
Total	50,353	13,653	5,616	455	3,685	27,383	385	783	1,022	8,766	506	1,736	23

Table 5.1 (Continued)

Great Britain 2004

Number of procedures

Species of animal							Field of resear	ch						Total
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	
Mammal														
Mouse	'	23,889	2,930	85,118	75	I	ı	1	I	11	30,055	I	'	198,048
Rat	'	1,736	'	3,056	'		1	1	'	'	4,331		'	28,840
Other rodent	1	ı	'	'	'	I	1	1		1	'	1	'	
Rabbit	1	ı	'	'	'	I	1	1		'	217	I	'	338
Cat	'	I	'	'	'	I	ı	1	I	1	I	I	'	'
Dog														
Other including cross-bred dogs	'	I	'	'	'	I	'	1	1	'	I	I	'	7
Other mammal	'	'	ı	'		ı	'	'	'	'	'	1	ı	'
Bird														
Domestic fowl (Gallus domesticus)	•	347	1	'	'		1	1	'	1	1		'	347
Amphibian														
Any amphibian species	'	'	1	'	I	1	•	'	•	•	'	1	1	1,075
Fish														
Any fish species	'	430	ı	1	'		ı	I	I	ı	I	'	'	37,906
Total	'	26,402	2,930	88,174	75	ı	I	,	ı	11	34,603	ı	'	266,561
				-						-			-	

Table 5.2 Scientific procedures (non-toxicology) by species of animal and field of research (genetically modified animals)

Great Britain 2004												Number of	procedures
Species of animal							Field of resear	ch					
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical	Therapeutics	Clinical	Clinical
										R&D		medicine	surgery
Mammal													
Mouse	94,323	83,515	27,433	8,548	19,550	269,534	9,156	281	22,292	47,974	4,409	1,156	'
Rat	661	914	4	ı	208	'	'			'	24	ı	'
Other rodent	'	'	I	I	•	'	'			1	1	I	'
Rabbit	'	'	ı	I	•	'	'		'	ı	ı	I	'
Pig	37	'	I	I	'	'	'			ı	I	I	'
Sheep	'	'	'	ı	ı	ı	'			ı	'	ı	'
Bird													
Domestic fowl (Gallus domesticus)	'	'	I	1	•	'				'	'	'	
Amphibian	1	ı	I	I	I	I	'		,	I	ı	I	'
Any amphibian species	1,859	ı	ı	ı	I	'	'			'	ı	ı	'
Fish													
Any fish species	30,061	1	'		'	1	1		'	318	I		
Total	126,941	84,429	27,437	8,548	19,758	269,534	9,156	281	22,292	48,292	4,433	1,156	I
							1						

Table 5.2 (Continued)

Great Britain 2004													Numbe	of procedures
Species of animal							Field of resear	rch						Total
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	
Mammal														
Mouse	I	56,228	68,278	107,290	286			13,177		3,288	39,149		36	875,903
Rat	1	I	726	1	190	'	I	'		31	I	I	•	2,758
Other rodent	'	I	I	ı	'	'	ı	ı		'	ı	I		'
Rabbit	1	I	'	1		'		'		'	ı	ı		
Pig		I	'	1	'	1		'		'	ı	'		37
Sheep	'	I	I	'	'	'	I	ı	I	'	I	I		ı
Bird														
Domestic fowl (Gallus domesticus)	'	114	I	'	'	'	ı	ı		'	ı	I		114
Amphibian	1	ı	'	1		'		'		'	ı	ı		
Any amphibian species		I	I	I	'	ı	I	I	I	1	I	I	'	1,859
Fish														
Any fish species		290	I		'		I	1,135	I	1	I		'	31,804
Total	'	56,632	69,004	107,290	476	ı		14,312		3,319	39,149	I	36	912,475

n of biological materials
ind productio
es of animal a
gy) by speci
(non-toxicolo
: procedures
Table 8 Scientific

Great Britain 2004

Great Britain 2004							-	Nur	nber of procedures
Species of animal				Production				Other ⁽¹⁾	Total
	Infectious agents	Vectors	Neoplasms	Monoclonal antibodies (ascites model)	Monoclonal antibodies (initial immunisation)	Polyclonal antibodies	Other biological materials		
Mouse	28,396	2,714	11,932	-	2,646	13,077	83,282	1,575,310	1,717,357
Rat	1,661	130	740	•	662	158	25,231	301,504	330,086
Other rodent	1,044	582	'		10	317	439	22,988	25,380
Rabbit	20	68	'		45	2,887	412	2,204	5,636
Cat	I	16	ı		ı	ı	I	777	793
Dog	I	ı	ı		I	ю	684	1,574	2,261
Ferret	I	ı	ı	•	I	55	330	612	661
Other carnivore	I	ı	ı		ı	ı	I	823	823
Horse and other equids	I	ı	ı		I	ı	5,491	2,978	8,469
Other ungulate	542	2	ı	•	63	603	32,039	29,832	63,081
New World monkey			'		I	'	46	486	532
Old World monkey	I	ı	ı		I	-	13	494	508
Other mammal	I	ı	ı	•	I	ı	I	2,393	2,393
Bird	54,943		'			562	4,504	37,761	97,770
Reptile / Amphibian	I	ı	ı	•	I	ı	8,696	9,559	18,255
Fish	1,155				I		280	143,647	145,082
Total	87,761	3,512	12,672	ı	3,426	17,663	161,447	2,132,942	2,419,423
	_	_			_		_		

(1) Includes breeding procedures which are now detailed in Tables 3.1 - 3.3

Great Britain 2004										Num	per of procedures
Species of animal				Techniqu	ies of particular i	nterest				All other	Total
	Interference with organs of special sense	Injection into brain	Interference with brain	Psychological stress	Aversive training	Radiation	Inhalation	Thermal injury	Physical trauma	techniques	
Mouse	11,200	11,321	4,934	3,461	2,783	10,097	23,318	64	3,864	1,646,315	1,717,357
Rat	10,465	80	19,107	3,962	2,334	821	10,375	20	12,355	270, 56 7	330,086
Other rodent	477	226	463	497	'	I	6,343	27	138	17,209	25,380
Rabbit	60	I	e	ı	I	I	101	I	17	5,455	5,636
Cat	116	I	45	ı	'	I	'	I		63 2	793
Dog	7	I	•	I	'	I	78	I		2,176	2,2 61
Ferret	99	I	•	ı	I	I	248	I		683	266
Other carnivore	I	I		I	40	I	'	I	ı	783	823
Horse and other equids	I	I	1	I	'	I	'	I	I	8,469	8,469
Other ungulate	ю	28	130	162	'	I	21	12	120	62,605	63,081
New World monkey	I	I	67	21	I	16	'	I		428	532
Old World monkey	12	1	27	ı	ı	ı	•	I		469	508
Other mammal	I	I	•	ı	'	I	'	I		2,393	2,393
Bird	21	430	2	552	4,609	I	1	I		92,156	97,770
Reptile / Amphibian	52	I		I	'	I	1	I	ı	18,203	18,255
Fish	I	1	I	380	I	1	'	1	83	144,619	145,082
Total	22,479	12,085	24,778	9,035	9,766	10,934	40,484	123	16,577	2,273,162	2,419,423

Table 9 Scientific procedures (non-toxicology) by species of animal and techniques of particular interest

Table 10 Scientific procedures (toxicology) by species of animal and toxicological purpose

Great Britain 2004

Number of procedures

Species of animal			Toxic	cology or other se	ifety/efficacy eval	luation		
				General safety/e	fficacy evaluation	ſ		
	Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	Finished cosmetics	Cosmetics ingredients
Mammal								
Mouse	72	2,644	8,089	95	20	I	I	I
Rat	9	20,686	15,651	65	474	240	I	ı
Guinea pig	ı	108	'	20	ı	·	I	ı
Hamster	'	I	·	'		ı	'	
Gerbil	'	•	•	'		•	ı	'
Other rodent	24	I	•	'	ı	I	I	·
Rabbit	ı	677	1,589	12	ı	·	I	ı
Cat	'	ı	'	'			ı	·
Dog								
Beagle	'	137	'	'		ı	ı	'
Greyhound	'	I	·	'		ı	'	
Other including cross-bred dogs	ı	'	'	1	ı	·	I	ı
Ferret	ı	ı		'			'	
Other carnivore	'	'	'	'	'	'	1	ı
Horse, donkey and cross-bred equids	ı	ı		'			'	
Pig	1	212	•	'	·	·	ı	·
Goat	1	4	'	'			ı	'
Sheep	ı	ı	'	'	'	ı	ı	ı
Cattle	1	88	'	'			'	'
Deer	ı	ı		'			'	
Camelid	1	ı	'	'			'	'
Other ungulate	ı	'	'	ı	ı	I	ı	ı
Primate								
Prosimian	'	ı		'			'	
New World monkey	'	I	·	'	•	ı	'	
marmoset, tamarin	1	ı	'	'			'	'
Squirrel, owl, spider monkey	ı	ı	'	'		ı	ı	ı
Other New World monkey	1	I	'	1		ı	ı	I

Table 10 Scientific procedures (toxicology) by species of animal and toxicological purpose (Continued)

ain 2004
Great Brit

Number of procedures

Species of animal			Toxi	cology or other sa	fety/efficacy eval	uation		
				General safety/e	fficacy evaluation	_		
	Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	Finished	Cosmetics
							cosilletics	lligredierits
Old World monkey								
Macaque	ı	ı	•	'	'	'	'	'
Baboon	ı	I		'	•	'	ı	'
Other Old World monkey	I	'		'	•		ı	'
Ape								
Gibbon	I	'	•	'	•	'	ı	
Great Ape	I	ı	•	1	'	'		'
Other mammal	I	I		'	·	'	I	•
Bird								
Domestic fowl (Gallus domesticus)	I	937		'	'		ı	'
Turkey	ı	ı	•	'	'	'	'	'
Quail (Coturnix coturnix)	I	'		'	1	'	ı	'
Quail (spp,other than Coturnix coturnix)	169	337	•	'	•	'	ı	
Other bird	I	78		'	'	'	1	'
Reptile								
Any reptilian species	I	'	1	'	1	'	I	ı
Amphibian								
Any amphibian species	ı	ı	'	'	'	'	'	'
Fish								
Any fish species	28,786	2,242	8,328	80	104	42	'	'
Cephalopod								
Octopus vulgaris	•	•	-	I	•	I	•	•
Total	29,057	28,252	33,657	272	598	282	I	I

Great Britain 2004									Number	of procedures
Species of animal				Toxicology or o	ther safety/effic:	acy evaluation				Total
	Pharn	naceutical safe	ty/efficacy evalu	ation			Other purposes			
	Safety testing	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other	
Mammal										
Mouse	54,191	18,701	81,746	10,492	12,408		839	4,205	8,279	201,781
Rat	65,063	148	2,177	19,528	5,221		99	3,102	2,214	134,641
Guinea pig	2,288	1,847	5,551	ŋ	73		6	19	ı	10,005
Hamster	1,721	245	Q	84	'		ı	10	ı	2,066
Gerbil	•	'	•	'	'		ı	•	'	
Other rodent	·	'	•	'	'		ı	•	'	24
Rabbit	9,553	830	2,622	101	136		295	183	'	16,100
Cat	9	20	'	ı	'	ı	ı	ı	ı	26
Dog										
Beagle	4,346	4	'	1,168	59		ı	38	Ð	5,757
Greyhound	ı	•	1	ı	'		ı	•	ı	
Other including cross-bred dogs	•	'	'	'	'			•	'	
Ferret	Ø	'	'	15	'	'	'	18	'	41
Other carnivore	9	'	'	1	'	'		'	'	9
Horse, donkey and cross-bred equids	7	36	'	5	'		·	•	'	48
Pig	585	576	'	201	18		•	25	10	1,627
Goat	•	'	'	'	'		37	•	'	41
Sheep	200	184	20	133	'		54	•	'	591
Cattle	409	673	50	69	'	'		'	'	1,289
Deer	'	'	'	'	'	'	'	'	'	
Camelid	'	'	'	'	'	'	1	'	'	
Other ungulate		'	'	'	'			'	'	
Primate										
Prosimian	I	I	I	ı	1	I	I	I	I	I
New World monkey										
marmoset, tamarin	424	12	I	67	1	'	I	I	ı	503
Squirrel, owl, spider monkey	I	I	I	ı	ı	I	I	I	I	I
Other New World monkey	•	•	•	•	•	•	•	•	•	•

Table 10 Scientific procedures (toxicology) by species of animal and toxicological purpose (Continued)

Great Britain 2004 Species of animal				Toxicology or o	ther safety/effic	acy evaluation			Number	of procedures Total
	Pham	naceutical safe	ty/efficacy evalu	ation			Other purposes			
	Safety testing	Efficacy	Quality control	ADME and	Toxicology	Tobacco	Medical	Method	Other	
		testing		residue	research	satety	device safety	development		
Old World monkey										
Macaque	1,775	'	ı	288	ı	·	I	590	12	2,665
Baboon	'	'	'	1	'	'	'	ı	ı	'
Other Old World monkey	ı	'	ı	ı	ı	·	I	I	I	'
Ape										
Gibbon	ı	'	'	ı	'	'	'	ı	ı	'
Great Ape	ı	'	ı	ı	'	'	ı	I	I	'
Other mammal	ı	'	'	ı	'	'	'	ı	ı	'
Bird										
Domestic fowl (Gallus domesticus)	973	4,626	92	266	'	'	ı	I	I	6,894
Turkey	I	'	ı	58	'	ı	ı	I	I	58
Quail (Coturnix coturnix)	ı	'	ı	ı	'	'	ı	I	I	'
Quail (spp,other than Coturnix coturnix)	ı	'	'	ı	'	'	'	ı	ı	506
Other bird	ı	'	ı	ı	'	'	ı	I	I	78
Reptile										
Any reptilian species	ı	'	ı	ı	1,294	'	ı	I	I	1,294
Amphibian										
Any amphibian species	I	ı	I	I	ı	I	I	I	I	'
Fish										
Any fish species	3,502	5,947	ı	449	'	'	ı	ı	ı	49,480
Cephalopod										
Octopus vulgaris	•		I	•			I	I	•	
Total	145,057	33,849	92,264	32,933	19,209	ı	1,381	8,190	10,520	435,521

Table 10 Scientific procedures (toxicology) by species of animal and toxicological purpose (Continued)

Table 10a Animals (toxicology) by species of animal and toxicological purpose

Great Britain 2004

Number of animals

Great ditialiti ∠004							NN	moer of animals
Species of animal			Toxic	cology or other se	ıfety/efficacy eval	uation		
				General safety/e	fficacy evaluatior	-		
	Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	Finished cosmetics	Cosmetics ingredients
Mammal								
Mouse	72	2,644	8,089	95	20	I	I	ı
Rat	9	20,686	15,651	65	474	240	ı	
Guinea pig	I	108	1	20	I	ı	I	•
Hamster	ı	'	I	I	I	ı	I	
Gerbil	I	'	I	I	I	ı	I	
Other rodent	24	'	·	ı	ı	•	ı	•
Rabbit	1	771	1,577	12		'	ı	•
Cat	I	'	'	·	·	'	ı	•
Dog								
Beagle	I	137	I	I	I	ı	I	
Greyhound	I	'	I	I	I	ı	I	
Other including cross-bred dogs	1	'	1	I	I	ı	I	
Ferret	I	1	I	I	I	I	I	·
Other carnivore	I	ı	'			'	ı	•
Horse, donkey and cross-bred equids	I	'	'	·	·	'	ı	•
Pig	1	212	'	•		•	ı	•
Goat	1	r	'			•	ı	•
Sheep	ı	ı	'			•	ı	'
Cattle	'	88	'		·	•	'	•
Deer	'	'	'		·	•	'	•
Camelid	1	'	·	·	I	•	ı	•
Other ungulate	1	ı	'			•	ı	
Primate								
Prosimian	ı	ı	'			•	ı	'
New World monkey								
marmoset, tamarin	ı	1	'			1	ı	•
Squirrel, owl, spider monkey	'	'	'	•		'	1	'
Other New World monkey	•	'	'			'	I	•

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Great Britain 2004

Number of animals

Species of animal			Toxi	cology or other sa	ifety/efficacy eval	uation		
				General safety/e	fficacy evaluation	_		
	Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	Finished cosmetics	Cosmetics ingredients
Old World monkey								
Macaque	I	ı	•	I	'	•	I	
Baboon	I	ı	·	ı	'	ı	I	
Other Old World monkey		I	'	ı	1	1	•	
Ape								
Gibbon	1	ı	'	ı	1	ı	I	'
Great Ape	I	ı	•	I	'	•	I	
Other mammal	I	ı		I	'	'	I	'
Bird								
Domestic fowl (Gallus domesticus)	1	937	'	ı	ı	ı	I	'
Turkey	1	ı	'	ı	1	'	I	'
Quail (<i>Coturnix coturnix</i>)	•		'	1	'	'	I	'
Quail (spp,other than <i>Coturnix coturnix</i>)	169	337	'	1	'	'	ı	'
Other bird	I	78	•	I	'	1	I	
Reptile								
Any reptilian species	1	ı	'	ı	1	'	I	'
Amphibian								
Any amphibian species	I	•	•	1	1	1	I	'
Fish								
Any fish species	28,786	2,242	8,328	80	104	42	I	'
Cephalopod								
Octopus vulgaris	•	-		I	I	1	•	ı
Total	29,057	28,243	33,645	272	598	282	I	ı

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Great Britain 2004									Num	oer of animals
Species of animal				Toxicology or of	ther safety/effic:	acy evaluation				Total
	Pharm	aceutical safe	ty/efficacy evalu	ation			Other purposes			
	Safety testing	Efficacy	Quality control	ADME and	Toxicology	Tobacco	Medical	Method	Other	
		testing		residue	research	safety	device safety	development		
Mammal										
Mouse	54,191	18,701	81,746	10,492	12,408		839	4,205	8,279	201,781
Rat	65,005	148	2,177	19,512	5,221	'	66	3,080	2,205	134,536
Guinea pig	2,280	1,847	5,551	໑	73		90	19	ı	9,997
Hamster	1,721	245	9	84	'	•	ı	10	I	2,066
Gerbil	1	'	'	'	'		ı	'	ı	•
Other rodent	1	'	ı	'	'		ı	ı	I	24
Rabbit	5,040	830	568	101	136	1	204	183	I	9,422
Cat	9	'	ı	'	'	1	I	ı	I	9
Dog										
Beagle	3,944	'	ı	316	38			თ	-	4,445
Greyhound	1	•	1	'	1	•	ı	ı	ı	•
Other including cross-bred dogs	1		ı	'	'		1	ı	ı	•
Ferret	00		ı	15	1		1	18	ı	41
Other carnivore	'	'	'	'	'	'		'	1	'
Horse, donkey and cross-bred equids	7	20	'	5	'	'		'	1	32
Pig	565	576	I	197	18	•	ı	12	10	1,590
Goat	1	•	1	'	1	•	37	ı	I	40
Sheep	200	184	28	133	1		54	ı	ı	591
Cattle	387	660	50	69	ı	·	I	ı	I	1,254
Deer	'	'	1	'	'		1	'	1	•
Camelid	'	'	'	'	'	'	1	'	1	'
Other ungulate	'	'	ı	'	'			ı	'	'
Primate										
Prosimian	'	'	ı	1	1		ı	ı	ı	'
New World monkey										
marmoset, tamarin	390	11	I	52	1	I	I	ı	I	453
Squirrel, owl, spider monkey	I	I	I	I	ı	I	I	ı	I	ı
Other New World monkey	ı	ı	ı	1	1	1	ı	ı	I	ı

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Great Britain 2004									Num	ber of animals
Species of animal				Toxicology or o	ther safety/effic	acy evaluation				Total
	Pharm	naceutical safet	y/efficacy evalua	ation			Other purposes			
	Safety testing	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other	
Old World monkey										
Macaque	1,387	I	'	55	'	1	'	406	11	1,859
Baboon	'	'	'	'	'	'	'	'	'	'
Other Old World monkey	ı	•	1	I	'			I	1	·
Ape										
Gibbon	ı		'	ı	'			I	ı	
Great Ape	ı	1	ı	ı	ı	ı		I	ı	ı
Other mammal	'	•	'	'	'	'		ı	'	'
Bird										
Domestic fowl (Gallus domesticus)	973	4,626	92	266	'	ı	ı	I	ı	6,894
Turkey	'	'	ı	58	'	'	'	ı	'	58
Quail (Coturnix coturnix)	ı		'	ı	'			I	ı	•
Quail (spp,other than <i>Coturnix coturnix</i>)	I	I	ı	I	ı	ı	ı	I	I	506
Other bird	'	'	'	'	'	'	'	'	'	78
Reptile										
Any reptilian species	I	I	ı	I	8	ı	ı	I	I	22
Amphibian										
Any amphibian species	ı	I	I	I	'	1	1	ı	I	'
Fish										
Any fish species	3,502	5,947	'	449	'	1	1	I	I	49,480
Cephalopod										
Octopus vulgaris	I	-	•		•	-	-	I	ı	ı
Total	139,606	33,795	90,210	31,813	17,916	I	1,290	7,942	10,506	425,175

Table 11 Scientific procedures (toxicology) by species of animal, type of legislation and

toxicological purpose

Great Britain 2004				Nun	her of procedures
Species	Legislative requirements	–	oxicological purpose		Total
		Safety testing other than cosmetics	Pharmaceutical safety	Other safety / Toxicology	
Mouse	UK requirements only	242	931	2,373	3,546
	One EU country only (not UK)	91	1	1	91
	EU requirements, incl. European Pharmacopoeia	1,148	10,630	4,710	16,488
	Requirements of (non-EU) Council of Europe	•		357	357
	Requirements of other countries	1,055	618	628	2,301
	Any combination of above	7,930	141,857	4,030	153,817
	Non-legislative purposes	454	11,094	13,633	25,181
	Total	10,920	165,130	25,731	201,781
Rat	UK requirements only	51	1,155	84	1,290
	One EU country only (not UK)	73	1	•	73
	EU requirements, incl. European Pharmacopoeia	5,392	1,354	•	6,746
	Requirements of (non-EU) Council of Europe	•	•	255	255
	Requirements of other countries	5,106	1,165	536	6,807
	Any combination of above	24,764	69,529	2,956	97,249
	Non-legislative purposes	1,736	13,713	6,772	22,221
	Total	37,122	86,916	10,603	134,641
Other rodent	UK requirements only	•	4,821	45	4,866
	One EU country only (not UK)	I	•	15	15
	EU requirements, incl. European Pharmacopoeia	I	1,925	30	1,955
	Requirements of (non-EU) Council of Europe	I	•	•	
	Requirements of other countries	20	466	•	486
	Any combination of above	•	4,430	19	4,449
	Non-legislative purposes	132	109	83	324
	Total	152	11,751	192	12,095
Rabbit	UK requirements only	9	1,217	93	1,316
	One EU country only (not UK)	15		•	15
	EU requirements, incl. European Pharmacopoeia	348	6,135	5	6,488
	Requirements of (non-EU) Council of Europe	e		•	e
	Requirements of other countries	460	12	10	482
	Any combination of above	1,494	5,730	275	7,499
	Non-legislative purposes	54	12	231	297
	Total	2,380	13,106	614	16,100
Cat	UK requirements only	•	•	•	
	One EU country only (not UK)	•	1	'	
	EU requirements, incl. European Pharmacopoeia	•	•	'	•
	Requirements of (non-EU) Council of Europe	I	I	•	
	Requirements of other countries	1	•	•	
	Any combination of above	•	20	•	20
	Non-legislative purposes	•	9		9
	Total	•	26	•	26

Table 11 Scientific procedures (toxicology) by species of animal, type of legislation and toxicological

purpose (Continued)

Great Britain 2004				nN	nber of procedures
Species	Legislative requirements	–	oxicological purpose		Total
		Safety testing other than cosmetics	Pharmaceutical safety	Other safety / Toxicology	
Dog	UK requirements only	•	•	•	
	One EU country only (not UK)	•	•	•	
	EU requirements, incl. European Pharmacopoeia	•	•	•	
	Requirements of (non-EU) Council of Europe	'	'	•	
	Requirements of other countries	16	4	•	20
	Any combination of above	109	4,874	17	5,000
	Non-legislative purposes	12	640	85	737
	Total	137	5,518	102	5,757
Ferret	UK requirements only	•	•	•	
	One EU country only (not UK)	•	•	•	
	EU requirements, incl. European Pharmacopoeia	•	•	•	
	Requirements of (non-EU) Council of Europe	•	•	•	
	Requirements of other countries	•	•	•	
	Any combination of above	•	œ	•	80
	Non-legislative purposes	•	15	18	33
	Total	•	23	18	41
Other carnivore	UK requirements only	•	9	'	9
	One EU country only (not UK)	I	•	•	•
	EU requirements, incl. European Pharmacopoeia	•		•	
	Requirements of (non-FU) Council of Furope	•	•	•	
	Requirements of other countries		1		1
	Any combination of above	1	'	'	ı
	Non-legislative purposes		1	'	
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	EU requirements, incl. European Pharmacopoeia	•	21	•	21
	Requirements of (non-EU) Council of Europe	•	•	•	
	Requirements of other countries	•	•	•	•
	Any combination of above	•	20	•	20
	Non-legislative purposes	•	•		
	Total	•	48	•	48
Other ungulate	UK requirements only	-	100	-	100
	One EU country only (not UK)	'	'	'	
	EU requirements, incl. European Pharmacopoeia	42	1,591	•	1,633
	Requirements of (non-EU) Council of Europe	•	•	•	
	Requirements of other countries	9	26	99	98
	Any combination of above	256	1,282	19	1,557
	Non-legislative purposes	•	101	59	160
	Total	304	3,100	144	3,548

Table 11 Scientific procedures (toxicology) by species of animal, type of legislation and toxicological purpose (Continued)

Great Britain 2004		-		Ž	Imber of procedures
Species	Legislative requirements		Foxicological purpose		Total
		Safety testing other	Pharmaceutical safetv	Other safety / Tovicology	
			6200	68000000-	
New World monkey	UK requirements only	1	•	1	•
	One EU country only (not UK)	'	•	•	•
	EU requirements, incl. European Pharmacopoela	I	I	I	
	Requirements of other countries				
	Any combination of above	1	485	I	485
	Non-legislative purposes	1	18		18
	Total	1	503	1	503
Old World monkey	UK requirements only	•	•	•	•
	One EU country only (not UK)	•			
	EU requirements, incl. European Pharmacopoeia	'			
	Requirements of (non-EU) Council of Europe	I	I	I	·
	Requirements of other countries	1	•	I	ı
	Any combination of above	I	2,018	593	2,611
	Non-legislative purposes	'	45	6	54
	Total		2,063	602	2,665
Other mammal	UK requirements only	•	-	•	•
	One EU country only (not UK)	'		•	
	EU requirements, incl. European Pharmacopoeia	'			
	Requirements of (non-EU) Council of Europe	I	I	I	
	Requirements of other countries	•	•	•	
	Any combination of above	•	•	•	
	Non-legislative purposes	•			
	Total	-	-	•	
Bird	UK requirements only	•	166	I	166
	One EU country only (not UK)	I	I	I	
	EU requirements, incl. European Pharmacopoeia	90	755	1	785
	Requirements of (non-EU) Council of Europe	1	•	•	
	Requirements of other countries	71		•	71
	Any combination of above	1,251	5,094	•	6,345
	Non-legislative purposes	169	-	•	169
	Total	1,521	6,015	-	7,536
Reptile / Amphibian	UK requirements only	1	-	1,294	1,294
	One EU country only (not UK)	•	•	I	
	EU requirements, incl. European Pharmacopoeia	•	•	•	•
	Requirements of (non-EU) Council of Europe	'	•	•	•
	Requirements of other countries	'	•	•	•
	Any combination of above	'	•	•	•
	Non-legislative purposes	•			
	Total	1	•	1,294	1,294

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		Safety testing other than cosmetics	Pharmaceutical safety	Other safety / Tovicology	
			6000	600000	
Fish	UK requirements only	5,441	I	'	5,441
	One EU country only (not UK)	67	1	1	67
	EU requirements, incl. European Pharmacopoeia	5,426	3,869	1	9,295
	Requirements of (non-EU) Council of Europe			•	
	Requirements of other countries	3,755	•	•	3,755
	Any combination of above	15,337	5,661	•	20,998
	Non-legislative purposes	9,556	368	•	9,924
	Total	39,582	9,898		49,480
Cephalopod	UK requirements only	•	•	•	•
	One EU country only (not UK)	•	1	•	•
	EU requirements, incl. European Pharmacopoeia	•	'		
	Requirements of (non-EU) Council of Europe	•	'		
	Requirements of other countries	•	'		•
	Any combination of above	•	'		
	Non-legislative purposes	•	•		
	Total	•	•	•	•
All species	UK requirements only	5,740	8,403	3,889	18,032
	One EU country only (not UK)	246	•	15	261
	EU requirements, incl. European Pharmacopoeia	12,386	26,280	4,745	43,411
	Requirements of (non-EU) Council of Europe	r	•	612	615
	Requirements of other countries	10,489	2,291	1,240	14,020
	Any combination of above	51,141	241,008	7,909	300,058
	Non-legislative purposes	12,113	26,121	20,890	59,124
TOTAL		92,118	304,103	39,300	435,521

Great Britain 2004									Z	umber of pr
Species of animal				Type of t	oxicological test or pr	ocedure				
	Acute lethal toxicity	Acute lethal concentration	Acute limit setting	Acute non - lethal clinical sign	Subacute limit- setting or dose ranging	Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Te
Mouse	83,811	1,400	4,285	5,417	4,519	5,388	5,839	8,068	4,353	
Rat	27	2,064	2,267	9,077	9,521	12,845	12,865	6,641	6,319	
Other rodent	175	I	630	206	164	198	I		'	
Rabbit	1			219	272	28	254		1	
Cat	1	I	•	9	1	ı	I		'	
Dog	1			171	498	1,598	1,598		1	
Ferret	ı	1		ı	ı	,	,		'	
Other carnivore	I	ı		ı	I	ı	I	'	1	
Horse and other equids	I	I	ı	I	I	ı	I		ı	
Other ungulate	I	I	ı	2	8	36	34		ı	
New World monkey	I	ı	9	50	18	150	64		1	
Old World monkey	I	I	I	40	185	680	576		1	
Other mammal	I	I	ı	I	I	1	I		1	
Bird	100	60	225	62	I	542	I		1	
Reptile / Amphibian	1	I	I	I	I	I	I	ı	I	
Fish	'	16,593	11,325	I	4,820	1,919	184		99	
Cephalopod	1	I	•	I	•	ı	I			
Total	84,113	20,117	18,738	15,250	20,005	23,384	21,414	14,709	10,738	

Table 12 Scientific procedures (toxicology) by species of animal and type of toxicological test: all purposes

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Great Britain 2004										NU	mber of procedures
Species of animal				Type of t	oxicological test or pro	ocedure					Total
	Other reproductive toxicity	In eyes	For skin Irritation	For skin sensitisation	Toxicokinetics	Pyrogenicity	Biocompatibility	Enzyme induction for <i>in vitro</i> tests	Immunotoxicology	Other toxicology	
Mouse	1,445	1	12	2,526	16,383	1	400	12	5,074	51,878	201,781
Rat	23,126	1	9	ı	15,027	I	26	294	234	31,664	134,641
Other rodent	I	ı	I	190	132	I	ı	I	25	10,375	12,095
Rabbit	42	803	1,319	I	204	8,488	148	I	~	1,346	16,100
Cat	I	ı	I	ı	I	I	I	I	I	20	26
Dog	I	I	I	I	840	I	I	I	I	1,052	5,757
Ferret	I	ı	ı	ı	I	I	I	ı	ı	41	41
Other carnivore	I	1	I	ı	I	I	I	I	I	Q	Q
Horse and other Equids	I	ı	ı	1	I	I	I	1	ı	48	48
Other ungulate	I	ı	ı	8	240	I	35	1	384	2,801	3,548
New World Monkey	I	1	ı	1	159	I	I	1	ı	56	503
Old World Monkey	I	I	I	I	207	I	I	I	I	977	2,665
Other mammal	I	1	1	ı	I	I	I	1	1	I	ı
Bird	I	1	1	ı	217	I	I	1	1	6,330	7,536
Reptile / Amphibian	I	I	I	I	ı	I	I	1	I	1,294	1,294
Fish	2,755	I	ı	ı	1,825	I	I	319	1	9,674	49,480
Cephalopod	-			-						-	
Total	27,368	803	1,337	2,724	35,234	8,488	609	625	5,718	117,562	435,521

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Great Britain 2004									Nu	mber of procedures
Species of animal				Type of to	oxicological test or p	rocedure				
	Acute lethal toxicity	Acute lethal concentration	Acute limit setting	Acute non - lethal clinical sign	Subacute limit- setting or dose ranging	Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Teratogenicity
Mouse	'		4	468	98			928	2,650	
Rat	27	1,147	2,155	5,164	2,600	3,034	2,640	500	814	248
Other rodent	1	ı		108			,		1	'
Rabbit	1	'		10	50				1	384
Dog	ı	I		2	38	I	96		'	ı
Horse and other equids	'	'		1		1			'	'
Other ungulate	1	1		1		I	ı		1	'
Bird	100	60	225	62		30	1		1	'
Reptile / Amphibian	I	I	ı	I	ı	I	I	ı	I	I
Fish	'	16,509	11,275	ı	148	1,919	184		66	ı
Total	127	17,716	13,659	5,814	2,934	4,983	2,920	1,428	3,530	632

Table 13: Scientific procedures (toxicology) by species of animal and type of toxicological test: safety testing of substances other than pharmaceuticals (continued)

Number of procedures

Species of animal				Type of te	oxicological test or pr	ocedure					Total
	Other reproductive toxicity	In eyes	For skin Irritation	For skin sensitisation	Toxicokinetics	Pyrogenicity	Biocompatibility	Enzyme induction for <i>in vitro</i> tests	Immunotoxicology	Other toxicology	
Mouse	1			1,884	72				4,523	293	10,920
Rat	14,730	I	I	I	397	I	ı	160	ı	3,506	37,122
Other rodent	'	ı	ı	20		'	,		'	24	152
Rabbit	'	718	1,218	I	'	ı	'	1			2,380
Dog	'	I	I	I	'	ı	'	1		1	137
Horse and other equids	'	I	I	I	'	I		1	1	I	,
Other ungulate	'	1	1	ı	19	'		1	'	285	304
Bird	'	I	I	I	7	I	,	ı		1,037	1,521
Reptile / Amphibian	I		I	I	I			ı	I	ı	ı
Fish	2,755	ı	ı	ı	1,575	ı		319	1	4,832	39,582
Total	17,485	718	1,218	1,904	2,070	I	,	479	4,523	9,978	92,118

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Great Britain 2004									NU	mber of procedures
Species of animal				Type of t	oxicological test or pr	rocedure				
	Acute lethal toxicity	Acute lethal concentration	Acute limit setting	Acute non - lethal clinical sign	Subacute limit- setting or dose ranging	Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Teratogenicity
Mouse	75,416	1	4,277	4,869	4,421	5,388	5,839	7,140	1,663	971
Rat	ı		112	3,409	6,871	9,805	10,225	6,029	4,514	2,390
Other rodent	102	,	630	86	164	198	ı	1	I	·
Rabbit	ı	'	I	209	222	28	254	1	1	2,592
Cat	ı	,	ı	Q	I	ı	ı	I	ı	,
Dog	ı	,	I	169	460	1,598	1,502	I	ı	ı
Ferret	I	1	I	I	1	I	I	I	I	I
Other carnivore	ı		ı	ı	1	1	ı	ı	ı	·
Horse and other equids	ı		ı	ı	1	1	ı	ı	ı	
Other ungulate	ı		I	7	8	36	34	I	ı	ı
New World monkey	ı		9	50	18	150	64	I	ı	ı
Old World monkey	ı		I	40	185	680	576	I	ı	ı
Bird	ı		I	I	I	512	I	I	I	ı
Fish	1	84	50	ı	4,672	I	ı	ı	I	·
Total	75,518	84	5,075	8,852	17,021	18,395	18,494	13,169	6,177	5,953
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2 Table 15: Scientific procedures (toxicology) by species of animal and type of toxicological test: safety testing of pharmaceuticals (continued)

ber of procedures	Total		165,130	86,916	11,751	13,106	26	5,518	23	9	48	3,100	503	2,063	6,015	9,898	304,103
ШN		Other toxicology	38,589	21,616	10,322	1,197	20	988	23	9	48	2,407	56	375	5,293	4,842	85,782
		Immunotoxicology	152	ı	25	ı	ı	I	1	I	I	384	1	1	I	1	561
		Enzyme induction for <i>in vitro</i> tests	12	69	1	1	1	I	ı	1	1	ı	ı	ı	I		81
		Biocompatibility		I	I	44	ı	I	I	I	I	I	I	I	I	1	44
	Type of toxicological test or procedure	Pyrogenicity		I	I	8,399	I	I	I	I	I	I	I	I	I	I	8,399
		Toxicokinetics	14,514	13,770	132	72	1	801	I	ı	1	221	159	207	210	250	30,336
		For skin sensitisation	462	'	80	'	'	1	ı	I	1	8	ı	ı	I	ı	550
		For skin Irritation	12	Q	I	23	I	ı	I	I	I	I	I	I	I	I	41
		In eyes		ı	ı	24	ı	I	I	I	I	I	I	I	I	1	24
		Other reproductive toxicity	1,405	8,100	ı	42	1	I	I	I	ı	I	I	I	I	1	9,547
Great Britain 2004	Species of animal		Mouse	Rat	Other rodent	Rabbit	Cat	Dog	Ferret	Other carnivore	Horse and other equids	Other ungulate	New World Monkey	Old World Monkey	Bird	Fish	Total

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Great Britain 2004									Ź	umber of procedures
Species of animal				Type of t	oxicological test or pro	ocedure				
	Acute lethal toxicity	Acute lethal concentration	Acute limit setting	Acute non - lethal clinical sign	Subacute limit- setting or dose ranging	Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Teratogenicity
Mouse	8,395	1,400	4	80			•		40	
Rat	I	917		504	50	Ø	1	112	991	ı
Other rodent	73	I	ı	I	ı	ı	1	ı	I	
Rabbit	I	I	ı	I	ı	ı	1	ı	I	
Cat	I	I	ı	I	ı	ı	1	ı	I	
Dog	I	I	ı	I	I	ı	ı	I	I	
Other carnivore	I	I	1	I	1	1	1	ı	I	
Horse and other equids	I	I	1	I	1	1	1	ı	I	
Other ungulate	I	I	I	I	I	ı	ı	I	I	
New World monkey	I	I	ı	I	1	1	1	ı	I	
Old World monkey	I	I	I	I	I	I	I	I	I	
Bird	I	I	I	I	I	I	I	I	I	
Reptile / Amphibian	I	I	I	I	I	I	I	ı	I	
Fish	1	I	I	I	1	1	'	1	I	-
Total	8,468	2,317	4	584	50	9	1	112	1,031	

Table 16 Scientific procedures (toxicology) by species of animal and type of toxicological test: other safety or toxicology testing(Continued)

Number of procedures

Species of animal				Type of	toxicological test or pro	ocedure					Total
	Other reproductive toxicity	In eyes	For skin Irritation	For skin sensitisation	Toxicokinetics	Pyrogenicity	Biocompatibility	Enzyme induction for <i>in vitro</i> tests	Immunotoxicology	Other toxicology	
Mouse	40	•		180	1,797		400		399	12,996	25,731
Rat	296			I	860	1	26	65	234	6,542	10,603
Other rodent	1	I		06	1	•		•	1	29	192
Rabbit	I	61	78	I	132	89	104	1	-	149	614
Cat	I	I		I	I	ı	'	1	ı	1	ı
Dog	I	I		I	39	1		1	ı	63	102
Ferret	I	ı		I	I	ı		ı	ı	18	18
Horse and other equids	ı	ı		ı	ı	ı			ı	ı	,
Other ungulate	I	ı		I	ı	ı	35	ı	ı	109	144
New World Monkey		ı		ı	1				ı		
Old World Monkey	I	I		I	ı				ı	602	602
Bird	I	I		I	ı				ı	1	ı
Reptile / Amphibian	I	I	I	I	I	ı	1	I	I	1,294	1,294
Fish	I	Ĩ	ı	I	1	ı		ı	1		I
Total	336	61	78	270	2,828	89	565	65	634	21,802	39,300



Table 18a Tree table – scientific procedures involving cats, 2004

Table 18b Tree table – scientific procedures involving rabbits, 2004

8,018					
	 141	Fundamental biologica	al research		
		32 21 	Respiratory or cardiovascular Nervous or special senses Alimentary and excretory Skin and musculo-skeletal Reproductive Immune system Other system or system not rele	evant 	Non-toxicology Toxicology
	 7,486	Applied studies – hum	an medicine, dentistry, veterinary	medicine	
		951 10 118 16 - 183 6,208	Respiratory or cardiovascular Nervous or special senses Alimentary and excretory Skin and musculo-skeletal Reproductive Immune system Other system or system not rele	evant	
				1,915 5,571	Non-toxicology Toxicology
	 147	Safety – protection of	man, animals or environment (all	toxiocology)	
			Respiratory or cardiovascular Nervous or special senses Alimentary and excretory Skin and musculo-skeletal Reproductive Other system or system not rele	evant	
	 147	Other uses (all direct o	liagnosis)		
			Nervous or special senses Immune system Other system or system not rele	evant	
	L			244	Direct diagnosis (all non-toxicology)
	 	Breeding			
Table 18cTree table – scientific procedures involving horses andother equids, 2004

8,517]				
	356	Fundamental biologic	al research (all non-toxicology)		
			Respiratory or cardiovascular Nervous or special senses		
			Alimentary and excretory Skin and musculo-skeletal		
		121	Reproductive Immune system		
		41	Other system or system not relevant		
	280	Applied studies – all v	veterinary medicine		
		88 20 14 21 137	Respiratory or cardiovascular Nervous or special senses Alimentary and excretory Skin and musculo-skeletal Reproductive Immune system Other system or system not relevant		
		·····		237 43	Non-toxicology Toxicology (all pharmaceutical work)
	5	Safety – protection of	man, animals or environment (all toxicolog	JY)	
			Respiratory or cardiovascular Nervous or special senses Reproductive Other system or system not relevant		
	7,876	Other uses (all non-to	xicology)		
		- - 40 - - 7,836	Respiratory or cardiovascular Nervous or special senses Alimentary and excretory Skin and musculo-skeletal Immune system Other system or system not relevant		
			7	16 40 ,820	Education Forensic Direct diagnosis
		Breeding			

Table 18dTree table – scientific procedures involving New Worldprimates, 2004



Table 18eTree table – scientific procedures involving Old Worldprimates, 2004

3,173	1					
	1					
		76	Fundamental biologica	al research (all non-toxicology)		
	 !		0			
				Respiratory or cardiovascular		
			41	Nervous or special senses		
			-	Alimentary and excretory		
			-	Skin and musculo-skeletal		
			19	Reproductive		
		L	8	Immune system		
			8	Other system or system not rele	evant	
					68	Non-toxicology
		 			8	Toxicology
	; +	2,521	Applied studies – hum	an medicine, dentistry, veterinary	medicine	
			93	Respiratory or cardiovascular		
			178	Nervous or special senses		
			1	Alimentary and excretory		
				Skin and musculo-skeletal		
				Reproductive		
		L	2 134	Other system or system not rele	evant	
		L	2,104		ovant.	
		 			439	Non-toxicology
					2,082	loxicology (nearly
						safety)
						,
		575	Safety – protection of	man, animals or environment (all	toxicoloav)	
		0.0			(o,ee.egj)	
				Despiratory or cordioveceulor		
				Nervous or special senses		
				Alimentary and excretory		
				Skin and musculo-skeletal		
				Reproductive		
		[575	Other system or system not rele	evant	
			Othersee			
			Other uses			
			1	Immune system		
		L		Other system or system not rele	evant	
					1	Direct diagnosis
		_	Breeding			

Table 18f Tree table – scientific procedures involving rabbits, 2004



Table 18gTree table – scientific procedures involving genetically modifiedanimals, 2004



Table 18hTree table – scientific procedures involving animals with a harmfulgenetic defect, 2004



Part B

Table 19 Project licence holders and scientific procedures by type of designated establishment

Great Britain 2004

Type of designated establishment		Numb	er of licen	ce holders	(¹⁾ reporti	ing counta	tble ⁽²⁾ proc	sedures		Licensees	Number of		Proce	dures
			Ň	umber of p	rocedure	S			Total	reporting non-	licence holders ⁽¹⁾	Total	Total	Percentage
	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		countable ⁽²⁾ procedures only	reporting no procedures	licensees)
Public health laboratories	4		ю	Q	-	2	~	2	18	۲	2	26	16,308	0.6
Universities, medical schools	433	233	254	268	134	72	70	302	1,766	10	704	2,480	1,201,982	42.1
NHS hospitals	-	4	ю	4	4	I	N	ω	26	I	თ	35	26,809	0.0
Government departments	40	11	14	10	7	ю	I	17	102	ı	37	139	69,797	2.4
Other public bodies	50	59	30	30	17	12	13	73	254	Ν	64	320	449,920	15.8
Non-profit-making organisations	16	Q	17	18	Ø	-	I	28	93	ı	31	124	138,813	4.9
Commercial organisations	56	24	37	25	12	14	18	142	328	Ю	95	426	951,315	33.3
Total	600	306	358	360	183	104	104	572	2,587	16	947	3,550	2,854,944	100

(1) Some licence-holders hold more than one licence; these figures are compiled by project licence, not by actual licence-holder.

Details of procedures on immature forms (e.g. larvae, embryos, fish fry) are collected but not counted (see introductory notes, paragraph 12) Animals in the wild involved in rodenticide trials are also not counted. Details (if applicable) are given in the commentary. (2) Only procedures on adult or free-living animals (including neonatal and juvenile mammals, and newly-hatched birds) are counted.

Thousands of procedures

Table 20 Scientific procedures by species of animal, 1988-2004

Great Britain																Thousands of	orocedures
Species of animal				Ň	cientific procedui	sə											
	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Mouse	1850.5	1744.9	1,636.3	1,698.9	1,449.0	1,457.3	1,475.0	1,454.9	1,502.1	1,517.9	1,590.8	1,641.9	1,607.0	1,657.7	1,720.3	1,816.9	1,919.1
Rat	860.4	882.3	891.5	881.7	833	819.7	755.9	694.4	688.8	636.7	575.9	567.0	535.0	500.2	509.6	496.4	464.7
Other rodent	184.1	171.8	162.5	152	131.5	138.2	141.1	134.2	125.2	103.3	93.1	81.4	71.5	61.6	60.09	48.1	37.5
Rabbit	131.8	113.4	89.8	81.5	79.5	70.5	68.8	61.2	53.6	45.0	37.5	41.4	39.7	33.7	30.3	25.3	21.7
Carnivore	20.5	21.4	19.3	17.6	17.1	15.3	14.1	15.1	15	12.7	11.9	13.9	11.6	11.6	12.1	10.9	10.7
Ungulate	38.1	34.8	34.8	31.1	34.4	33	32.2	55.3	60.3	60.09	68.0	63.6	63.0	37.4	57.3	75.5	75.1
Primate	6.3	5.3	5.3	4.5	5	5	5.2	4.7	4.4	3.9	3.7	4.0	3.7	4.0	4.0	4.8	4.2
Other mammal	0.4	0.2	0.8	1.3	1.3	2.5	3.2	+	0.8	0.8	0.9	0.5	0.5	0.8	1.3	1.7	2.4
Bird	269.5	252	245.6	226.7	220.3	116.4	189.6	140.4	113.9	120.8	141.2	106.0	124.2	126.9	138.3	121.6	105.3
Reptile/Amphibian	11.3	11.6	13.1	15	19	17.7	17.2	17.2	17.3	15.3	14.4	14.6	15.6	17.5	17.6	16.6	19.5
Fish	107.5	77.5	108	132	138.3	152.1	139.9	131.1	135.2	119.6	122.3	122.4	243.0	171.1	182.0	174.0	194.6
Cephalopod ⁽¹⁾	:	:	:	:	:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total	3,480.3	3,315.1	3,207.1	3,242.4	2,928.3	2,827.7	2,842.4	2,709.6	2,716.6	2,636.0	2,659.7	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9

(1) Octopus vulgaris, from 1 October 1993.

Table 21 Scientific procedures (toxicology) by type of legislation, 1995-2004

Great Britain									Thousand	of procedures
Legislative requirements	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
UK requirements anly	42.3	25.4	21.9	39.2	37.3	26.2	24.5	23.2	19.8	18.0
Requirements of one EU country only (1999 onwards)					5.8	2.9	1.3	1.0	0.7	0.3
EU requirements	69.69	60.5	54.1	49.3	118.7	69.8	73.6	68.2	45.0	43.4
Requirements of non-EU Council of Europe country/ies					25.2	10.6	4.6	3.7	0.6	0.6
Other international requirements	48.0	38.2	24.5	25.7	33.9	29.2	30.6	30.5	22.6	14.0
Joint requirements (any combination of above)	399.9	441.1	415.0	355.5	247.5	242.1	255.1	295.0	284.8	300.1
Non-legislative purposes	117.5	155.0	109.6	94.8	74.7	74.1	65.7	64.2	74.3	59.1
Total	677.2	720.2	625.1	564.4	543.2	454.9	455.5	485.8	447.7	435.5

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Scientific Procedures

Great Britain Level of anaesthesia

	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
No anaesthesia throughout the procedure $^{\left(1\right) }$	2213.1	2094.9	2,205.4	2,223.7	1,960.0	1,792.5	1,796.6	1,751.4	1767.1	1690.8	1723.6	1683.9	1636.3	1551.1	1634.8	1691.9	1710.8
Anaesthesia, with recovery, for part of procedure ⁽²⁾	604.5	568.7	529.8	566.9	579.3	627	632.5	658.2	694.1	698.8	702.1	759.5	873.9	802.4	810.8	833.7	874.9
Terminal Anaesthesia ⁽³⁾	662.7	651.5	472	451.9	388.9	408.2	413.3	300	255.4	246.4	233.9	213.3	204.5	268.9	287.2	266.1	269.3
Total	3480.3	3,315.1	3,207.1	3,242.4	2,928.3	2,827.7	2,842.4	2,709.6	2,716.6	2,636.0	2,659.4	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9

Includes some experiments in which the subject of the study is the anaesthetic agent itself.
 May be local, regional or general anaesthesia.
 At end of procedure or for whole procedure.

Table 23 Scientific procedures by type of designated establishment, 1988-2004

Great Britain

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Great Britain																Thousands of	procedures
Type of designated establishment ⁽¹⁾	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Public health laboratories	56.4	58.4	73.2	60.2	63.1	51.5	49.2	45.1	35.1	20.0	19.7	25.2	18.4	15.7	16.6	16.3	16.3
Unversities, medical schools	7.77	747.6	710.0	727.8	737.0	840.6	832.6	824.1	843.8	882.1	934.8	936.1	1,069.7	1,005.7	1,079.8	1, 130.1	1,202.0
Polytechnics etc ⁽²⁾	36.0	29.0	38.1	26.3	32.8												
NHS hospitals	89.6	92.7	89.6	76.5	80.1	75.8	83.3	94.4	94.3	71.1	75.0	70.1	40.1	28.3	23.1	24.0	26.8
Government departments	62.9	58.7	68.7	72.6	65.1	78.1	62.6	78.6	94.2	81.5	86.2	91.8	100.5	84.6	94.1	72.0	69.8
Other public bodies	231.6	217.5	229.2	244.0	217.8	240.5	259.9	235.5	248.4	259.2	287.9	312.6	338.2	309.2	353.5	407.7	449.9
Non-profit making organisations	115.7	103.8	132.1	124.0	104.7	91.4	85.8	102.6	118.9	117.7	119.4	119.5	115.0	161.4	152.3	136.3	138.8
Commercial organisations	2,107.4	2,007.3	1,866.2	1,910.9	1,627.7	1,449.9	1,469.1	1,329.4	1,281.8	1,204.3	1,136.6	1,101.6	1,032.8	1,017.7	1,013.4	1,005.4	951.3
Total	3,480.3	3,315.1	3,207.1	3,242.4	2,928.3	2,827.7	2,842.4	2,709.6	2,716.6	2,636.0	2,659.4	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9

(1) For 1988, recorded on the basis of the registered or designated place which the licensees regarded as their main place of work at the time the returns were issued.

A licensee may have commenced procedures at more than one registered or designated place during the year. For 1989 onwards, recorded on the basis of the designated place of the project licence holder at the time the returns were issued. (2) Polytechnics all became universities during 1992. From 1993 onwards combined figures are given.

Great Britain								Tho	usands of p	rocedures
Field of research	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Psychology	28.4	31.0	38.8	33.1	33.9	106.9	37.9	39.6	38.2	34.7
Pharmaceutical R&D	567.6	504.2	501.5	470.1	481.9	446.7	408.9	365.7	400.4	393.0
Cancer research	262.6	257.8	300.9	293.3	267.0	258.4	268.8	258.1	277.4	275.2
Ecology	14.5	15.2	11.9	13.7	9.1	12.6	19.8	22.1	32.0	35.8
Tobacco	-(1)	0.0	0.0	0.0	0.0	0.1	-(1)	0.0	0.0	0.0
Alcohol	3.2	2.2	1.9	0.4	1.2	3.1	3.1	2.3	1.5	0.9
Other	1,156.0	1,185.8	1,155.8	1,284.7	1,320.5	1,432.0	1,428.4	1,559.0	1,594.6	1,679.8
Total	2,032.4	1,996.4	2,010.8	2,095.3	2,113.6	2,259.8	2,167.0	2,246.9	2,344.1	2,419.4

Table 24 Scientific procedures (non-toxicology) by field of research, 1995-2004

(1) Fewer than 50 procedures

Table 25 Scientific procedures (toxicology) for safety evaluation, 1992-2004

Great Britain											The	ousands of p	procedures
	1992	1993	1994	1995 ⁽¹⁾	1996	1997	1998	1999	2000	2001	2002	2003	2004
Protection of man, animal or the environment by													
toxicology or other safety evaluation:													
Environmental pollution	59.2	62.9	51.8	35.7	35.7	27.6	34.0	32.3	35.0	38.2	38.2	32.8	29.1
Substances used in agriculture	77	67.3	68.6	65.6	68.8	53.8	55.8	48.1	35.3	41.0	57.8	40.1	28.3
Substances used in industry	91.8	80.2	65.9	85.1	80.4	76.2	58.8	57.6	53.9	52.7	42.3	36.1	33.7
Substances used in the household	2.1	2.2	1.4	1.7	2.6	2.0	1.5	0.3	1.2	0.6	1.0	0.2	0.3
Foodstuffs and food additives	6.1	7.6	8.2	7.4	3.8	7.5	4.0	4.9	6.0	3.5	5.4	8.1	0.9
Cosmetics and toiletries	2.2	3.8	3.5	1.9	2.8	1.3	0.6	0.0	0.0	0.0	0.0	0.0	0.0
Tobacco	0.2	o	0.03	- (2)									
Alcohol research	1.1	7.3	9.1	- (2)									
Other safety evaluation	19	10.6	8.7										
Pharmaceutical - safety, efficacy, ADME and residue				333.2	365.8	311.2	284.4	269.6	203.8	204.8	220.1	202.3	211.8
Pharmaceutical - quality control				83.8	84.3	77.8	74.0	85.6	70.9	72.2	74.5	78.3	92.3
Other purposes				62.7	76	67.7	51.4	44.7	48.8	42.5	46.4	49.8	39.3
Total	258.6	242	217.2	677.2	720.2	625.1	564.4	543.2	454.9	455.5	485.8	447.7	435.5
A													

No comparable figures are available.
(1) Where series have been discontinued or a new series started, it is because there is little or no direct comparability between figures from previous years rand the current year.
(2) In previous years, research on tobacco and alcohol was included, for historical reasons, in the "safety" categories. From 1995 onwards, they are in the non-toxicology tables.

Table 26 Scientific procedures by primary purpose, 1995-2004

Great Britain								Thousands of	of procedures	
Primary purpose of the procedure	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Fundamental biological research	841.2	884.8	829.4	894.9	803.8	872.8	778.7	864.3	832.9	880.9
Applied studies -										
human medicine or dentistry	1,073.3	1,012.2	945.4	847.3	836.2	739.0	689.9	669.9	693.7	671.9
veterinary medicine	199.2	144.1	160.1	181.3	169.6	190.7	182.2	175.0	150.7	156.4
Protection of man, animals or										
the environment	209.2	219.7	201.0	170.4	153.3	161.2	153.6	185.6	151.4	114.1
Education	7.1	6.7	5.9	6.3	5.5	4.7	4.6	4.3	3.7	2.7
Training	1.7	1.7	1.6	1.6	1.4	1.3	1.2	1.0	0.9	0.9
Forensic enquiries	0.1	0.1	0.1	0.1	0.1	- ⁽¹⁾	-(1)	_(1)	_(1)	_(1)
Direct diagnosis	65.0	55.8	55.5	52.0	47.8	45.3	34.5	41.3	55.8	45.3
Breeding	312.7	391.5	437.0	505.8	639.1	699.6	777.8	791.2	902.6	982.6
Total	2,709.6	2,716.6	2,636.0	2,659.7	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9

(1) Fewer than 50 procedures

Table 27 Scientific procedures by primary purpose and genetic status, 1995-2004

Great Britain									Thousands o	of procedures
Primary purpose of procedure	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Normal animal										
Fundamental biological research	713.1	724.8	656.2	664.1	621.5	653.2	560.9	584.7	563.4	560.2
Applied studies	1,219.2	1,101.1	1,043.8	969.4	937.9	857.7	810.5	780.6	779.7	756.4
Safety	208.9	219.0	200.8	170.1	153.3	161.1	153.5	185.4	151.3	114.0
Other uses	73.0	64.2	62.8	59.9	54.7	51.3	40.1	46.7	59.6	48.3
Breeding	53.5	72.2	83.0	89.2	126.7	152.8	179.8	165.5	194.9	194.5
Total	2,267.7	2,181.3	2,046.6	1,952.7	1,894.1	1,876.1	1,744.8	1,762.8	1,748.9	1,673.4
Animal with harmful genetic defect										
Fundamental biological research	53.8	43.9	43.3	57.5	55.1	54.5	46.8	63.8	47.7	68.7
Applied studies	40.7	41.0	50.1	42.7	42.9	50.8	44.6	37.7	40.7	46.6
Safety	0.2	0.7	0.3	-	-	-	(1)	-	0.1	(1)
Other uses	(1)	(1)	0.2	(1)	0.1	0.1	0.1	(1)	0.4	0.1
Breeding	131.9	148.0	142.8	159.1	152.9	151.5	155.3	158.4	190.0	152.2
Total	226.6	233.7	236.6	259.3	251.0	256.9	246.8	259.9	278.8	267.5
Genetically modified animal										
Fundamental biological research	74.3	116.2	129.9	173.2	127.2	165.1	171.0	215.8	221.9	252.0
Applied studies	12.7	14.2	11.7	16.5	24.9	21.2	17.0	26.6	24.0	25.4
Safety	0.1	-	-	0.3	-	0.1	0.1	0.2	0.1	0.1
Other uses	1.0	-	(1)	(1)	(1)	(1)	(1)	(1)	0.4	0.6
Breeding	127.2	171.2	211.1	257.6	359.5	395.4	442.7	467.3	517.7	635.9
Total	215.3	301.6	352.8	447.6	511.6	581.8	630.8	710.0	764.1	914.0
All animals										
Fundamental biological research	841.2	884.8	829.4	894.9	803.8	872.8	778.7	864.3	832.9	880.9
Applied studies	1,272.6	1,156.3	1,105.6	1,028.7	1,005.7	929.7	872.1	844.9	844.4	828.3
Safety	209.2	219.7	201.0	170.1	153.3	161.2	153.6	185.6	151.4	114.1
Other uses	74.0	64.2	63.0	59.9	54.9	51.4	40.3	46.7	60.4	49.0
Breeding	312.6	391.5	437.0	505.8	639.1	699.6	777.8	791.2	902.6	982.6
Total	2,709.6	2,716.6	2,636.0	2,659.7	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9

(1) Fewer than 50 procedures

APPENDIX A

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.

2. Operation of the Act is not a devolved responsibility in Great Britain, the Home Office administering the legislation in England, Scotland and Wales. The Act is separately administered in Northern Ireland.

Scope of the Act

3. 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 one invertebrate species, *Octopus vulgaris.* 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.

4. The definition of a regulated procedure encompasses some 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.

5. 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 Exemption (issued under the Medicines Act 1968).

6. 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.

Personal Licences

7. A personal licence is the Home Secretary'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 Home Office licence need the endorsement of a sponsor (normally someone in a senior position at the applicant's place of work). Satisfactory completion of an accredited training course is also required before a personal licence is issued.

8. During 2004, 2,156 personal licences were granted and 2,392 were revoked. On 31 December 2004 there were 14,113 active licences. Personal licences continue to be in force until revoked, but they must be reviewed at least every five years.

Project Licences

9. A project licence is granted when the Home Secretary 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. In deciding whether and on what terms to authorise the project, the likely adverse effects on the animals used must be weighed against the potential benefits (to humans, other animals or the environment) which are expected 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 before the licence is granted.

10. When making an application for a project licence, the applicant nominates, and the Home Office assigns, an overall severity banding for the project. There are three possible severity bandings: mild, moderate and substantial. A fourth band, unclassified, is used for procedures where the animal is decerebrate or used under terminal anaesthesia – i.e. the animal is anaesthetised before the procedure starts, is kept anaesthetised throughout the course of the procedure and is killed without recovering consciousness.

11. It is not possible to lay down hard and fast rules about how the severity should be assessed. It depends not only upon the amount of suffering caused, but also the duration, the number of animals and what action is taken to reduce suffering, such as the use of anaesthesia or early endpoints. The overall severity is used in weighing the likely adverse effects on the animals against the benefits likely to accrue, as required by section 5(4) of the Act.

12. The following table details the number of project licences which were active on 31 December 2004, the number granted during 2004 and the number revoked during 2004 (normally either at the licence holder's request or because the licence had run the maximum allowed term of five years). The total figures are subdivided into severity bandings.

Project licences							
Severity band	In force on 31 December 2004		Granted duri	ing 2004	Revoked during 2004		
	Number	%	Number	%	Number	%	
Mild	1,116	38	214	37	254	40	
Moderate	1,641	56	334	58	346	54	
Substantial	56	2	12	2	14	2	
Unclassified	86	3	15	3	20	3	
Total	2,899		575		634		

Designation of premises

13. Except where otherwise authorised in a project licence (e.g. for field work at a specified place and time), any place where work is carried out under the Act must be designated as a scientific procedure establishment. Since January 1990, establishments which breed certain types of animal (mouse, rat, guinea-pig, hamster, rabbit, dog, cat and primate) for use in scientific procedures ('breeding establishments'), and establishments which obtain such animals from elsewhere and supply them to laboratories ('supplying establishments') must hold a certificate of designation. Quail *(Coturnix coturnix)* was added to the list of species specified in Schedule 2 of the Act in 1993, and ferrets, gerbils, genetically modified pigs and genetically modified sheep were added to the list in 1999. Designated establishments are required to nominate a person to be responsible for the day-to-day care of animals and a veterinary surgeon to advise on their health and welfare.

14. The following table details the number of certificates of designation which were in force on 31 December 2004, the number granted during 2004 and the number revoked during 2004. The figures are subdivided for different types of establishment.

Establishment type	In force on 31/12/2004	Granted during 2004	Revoked during 2004
Commercial concern	82	0	3
Higher education	84	2	1
Quango	30	0	1
Government	10	0	1
Non-profit	13	0	0
NHS hospital	5	0	0
Public health	3	0	0
Total	227	2	6

Certificates of Designation

15. Of the 227 certificates of designation active on 31 December 2004, 223 were registered as user establishments, 141 as breeding establishments and 68 as supplying establishments. These figures add up to more than the total number of establishments because a single establishment may be represented in more than one of the categories: for example, an establishment may be registered as both a breeder and user of animals.

Guidance and Codes of Practice

16. In addition to these annual statistics, the Act requires the Home Secretary to publish and lay 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. These and other documents have been published and can also be found at the Home Office website http://www.homeoffice.gov.uk/comrace/animals/index.html. These documents include:

- Guidance on the operation of the Animals (Scientific Procedures) Act 1986 (latest version 2000; HC 321);
- Code of practice for the housing and care of animals used in scientific procedures (1989; HC 107);
- Code of practice for the housing and care of animals in designated breeding and supplying establishments (1995; HC 125);
- Code of Practice for the Humane Killing of Animals under Schedule 1 to the Animals (Scientific Procedures) Act 1986 (1997; HC193);
- Guidance on the Conduct of Regulatory Toxicology and Safety Evaluation Studies;
- Code of Practice for the housing and care of animals in designated breeding and supplying establishments; Supplement: Ferrets and Gerbils (laid before Parliament on 7 November 2001);
- Information document on the handling of infringements under the 1986 Act (placed on website in June 2002);
- Supplementary Guidance to applicants for project licences: projects for educational purposes (September 2002);
- "Points to Consider" document entitled "Non-Rodent Selection in Pharmaceutical Toxicology" (produced by the Association of the British Pharmaceutical Industry in conjunction with the Home Office in August 2002);
- Home Office response to the report of the Expert Group on Efficient Regulation (October 2002);
- Home Office response to the Report of the House of Lords Select Committee on Animals in Scientific Procedures (Cm 5729 – January 2003);
- Inter-Departmental group on the 3Rs minutes;
- Inter-departmental concordat on data sharing.

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 (HC 321, The Stationery Office, 2000) as mentioned above. 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 certificates of designation 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. Training programmes for applicants for personal and project licences are described in Appendix F of the Guidance on the operation of the Animals (Scientific Procedures) Act 1986 (2000; HC 321). All training programmes are accredited under a scheme recognised by the Home Office. Accreditation seeks to achieve common and high standards for licensee training which will facilitate free movement of licensees within the UK and Europe as well as ensuring high standards in the use of animals for scientific purposes.

19. Satisfactory completion of an accredited course prior to application for a personal licence has been a requirement under Home Office policy since 1 April 1994. A similar requirement has applied to new applicants for project licences from 1 April 1995.

20. During 1995, mandatory training for Named Veterinary Surgeons was also introduced. Training requirements for Named Animal Care and Welfare Officers were introduced in 2004.

The acquisition and use of primates

21. During 1996, following recommendations made by the Animal Procedures Committee, new measures on the acquisition and use of non-human primates were introduced:

- the use of wild-caught primates was banned except where exceptional and specific justification can be established;
- specific justification must be made for the use of old world (as opposed to new world) primates;
- specific justification must be made for the use of old world primates in toxicological procedures of more than mild severity;
- approval for the acquisition of primates from overseas will only be given if the conditions at the breeding or supplying centre are acceptable to the Home Office; and
- each batch of animals acquired from overseas, or other non-designated, sources must be separately authorised and the transport arrangements approved by the Home Office.

Animals Scientific Procedures Division

22. Towards the end of 2003 the Animals Scientific Procedures Division was formed within the Home Office, to link more closely together under one senior manager the Animal Procedures Licensing, and Policy Development, sections, the Animals (Scientific Procedures) Inspectorate (which retains its independent advisory role) and, for certain management purposes, the Secretariat of the Animal Procedures Committee. The Division therefore deals with all Home Office business relating to the Animals (Scientific Procedures) Act 1986.

23. Administrative staff, operating the licensing system on behalf of the Secretary of State, process applications for new licences and certificates; process amendments to existing authorities; and revoke or vary licences and certificates as necessary. It is these staff in the Animals Scientific Procedures Division (not Inspectors nor the Animal Procedures Committee) who grant, refuse, vary, revoke and suspend licences and certificates for the Secretary of State. The licensing team also administers the collection of annual fees from designated establishments and of annual statistical returns of procedures from project licence holders.

24. On 31 December 2004, the administrative licensing section had a total complement of 23 staff and managers. The licensing work was carried out at five regional offices: Cambridge, Dundee, London, Shrewsbury and Swindon.

25. Policy staff in the Animals Scientific Procedures Division are the primary source of advice to Ministers on issues relating to the Act, including the preparation of responses to Parliamentary Questions and correspondence from MPs and the public about the use of animals in scientific procedures.

The Inspectorate

26. The Act provides for the appointment of Inspectors and describes their duties. Inspectors hold either a medical or veterinary qualification.

27. Inspectors assess all applications for new licences or amendments to existing licences in detail and advise the Home Secretary on how to ensure that only properly justified work is licensed. When assessing research proposals, the Inspector ensures that full consideration is given to alternatives, not only the *replacement* of procedures with others which do not use animals but, where animals have to be used, 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.

28. Inspectors also advise the Home Secretary on policy matters connected with the operation of the Act and they are available to give advice to licensees and other personnel working under the Act.

29. At 31 December 2004, there were 30 inspectors in post. The distribution of inspectors was:

	Chief Inspector	Superintending Inspectors	Inspectors
London	1	1	7
Cambridge		1	4
Dundee		2	5
Shrewsbury			4
Swindon			5
Total	1	4	25

30. In 2004, the Inspectorate carried out 3,888 visits in addition to meeting demands for advice and assessment in connection with the issue and amendment of licences and the formulation of policy. Of these visits, 2,682 were for the purpose of inspection of designated establishments and work in progress. Well over 50 per cent of the visits to designated departments were unannounced. The remaining 1,206 visits were for the purpose of maintaining scientific or professional skills, representing the Home Office or furthering Home Office policy.

Performance against published target

31. Since April 2002, the Licensing Section and the Inspectorate have been committed to process at least 85 per cent of applications for project licences within 35 working days.

32. Data for 2004 indicate that the average processing time for all applications was 22 working days; 81 per cent of completed and signed project licence applications were processed within the 35 working days target, although many applications were actually turned around in significantly less time. It is expected that this performance will improve further once a new IT system currently under development is in place.

The Animal Procedures Committee

33. The 1986 Act established the Animal Procedures Committee (APC), which has the duty of advising the Home Secretary on matters concerned with the Act and his functions under it. The Home Secretary may refer matters to the Committee, but the APC is also free to consider topics of its own choosing. The Committee is required in its consideration of any matter to have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures. Each year, the Committee makes a report to the Home Secretary, which is laid before Parliament and published.

34. The Act requires that, excluding the Chairman, the Committee must have a minimum of 12 members; one must be a lawyer and at least two thirds must be medical practitioners, veterinary surgeons or have qualifications or experience in a biological subject. At least half of the members must not have held a licence under the Act within the last six years. The Home Secretary must also ensure that animal welfare interests are adequately represented.

35. More information about the Committee and its work can be found on its website at http://www.apc.gov.uk/

Recent developments

36. In May 2004, Caroline Flint announced the creation of a new national centre for replacement, refinement and reduction of animals in research with an initial budget of $\pounds 660k$. At the same time, she announced that the Home Office would transfer its research budget ($\pounds 250k$) to the new centre when current commitments have been honoured.

37. In June 2004 the Inter-Departmental Group on the 3Rs reported to Ministers on its review of the Inter-Departmental Concordat on Data Sharing. The Concordat is aimed at minimising requirements for animal tests by ensuring that the regulators concerned encourage and overcome barriers to data sharing between animal users. The review concluded that the concordat is comprehensive in its coverage of the issues relevant to the successful implementation of data sharing and identified a number of areas in which encouraging progress had been made since it was announced in 2000. The review also concluded that the concordat provided a sound framework for further action and that no changes were required to its provisions. A further review of the implementation of the Concordat was agreed in two years time.

38. In July 2004, Caroline Flint announced the outcome of the review of section 24 of the Animals (Scientific Procedures) Act 1986 – the so-called 'confidentiality clause' – which prohibits the disclosure by Home Office Ministers and officials of confidential information relating to the use of animals in scientific procedures other than in the discharge of their functions under the 1986 Act. Caroline Flint reported that the conflicting views expressed about section 24 in the course of the review had shown it to be a complex and contentious issue that did not lend itself to a decision that would satisfy all those with an interest. In particular, those representing the views of many in the scientific research, had expressed significant concern about the potential impact of repealing section 24 and had urged strongly that it be retained. In the circumstances, the review concluded that section 24 should be retained for the time being. However, the future repeal of section 24 was not ruled out and a further review of section 24 would be carried out in two years time.

39. In December 2004 the Home Office began publishing, on the Home Office website, abstracts of project licences granted under the Animals (Scientific Procedures) Act 1986. This implemented a commitment given in the Government's reply to the report of the House of Lords Select Committee on Animals in Scientific Procedures to publish abridged details of project licences. Further abstracts will be published as and when new licences are granted.

40. Work on revising Directive 86/609/EEC, which the Animals (Scientific Procedures) Act 1986 transposes into UK legislation, announced in 2003, continued during 2004. Four technical expert working groups set up by the European Commission provided preliminary advice on what a revised Directive might incorporate, and four technical issues have been referred to the Animal Welfare Committee of the European Food Standards Agency (EFSA) for consideration and advice. The Commission will produce a consultation document in the light of the advice received from EFSA.

Summary of infringements

41. In the published statistics for 2000, details were given of new streamlined procedures for handling infringements. Action on 28 infringements was completed under these procedures in 2004.

Class One infringements

42. These involve minor breaches of licence or certificate conditions, which are not potential criminal offences, have no aggravating circumstances and no disputed facts.

43. Three Class One infringements were dealt with in the reporting period. Two occurred in academic establishments, and one in a Quango. All three were discovered by the inspectorate.

Class Two infringements

44. These may include potential criminal offences, but are cases where it is clear from the circumstances that prosecution, variation of licence/certificate conditions or revocation action would not be appropriate. Formal admonition is generally the action taken against those responsible.

45. Twelve Class Two infringements were dealt with in the reporting period. Academic establishments and Quangos were involved in five each, and commercial establishments in two. Nine were self-reported and three were discovered by the inspectorate.

Class Three infringements

46. These are the more serious cases, where training/re-training, variation, suspension or revocation of licences/certificates, or referral to the police for possible prosecution are considered. Any case where animal welfare may have been compromised must be treated as a Class Three infringement, and all such cases are referred to the Head of the Animal Procedures Licensing Section for consideration.

47. Thirteen infringements in this category had action completed on them in the reporting period.

48. Nine were reported by licensees to the Home Office, and four were discovered and reported by the Inspectorate.

49. A total of twelve establishments had Class Three infringements reported. Academic establishments were involved in seven, commercial establishments in three, and Quangos in the remaining two.

Nature of Class Three infringements

50. As in previous years, the nature of the infringements varied in severity. In four cases a regulated procedure was applied to animals without appropriate project licence authority in breach of section 3(b) of the 1986 Act, and in one case without appropriate personal licence authority and to animals that had previously completed a series of regulated procedures, without the authority for their further use in breach of sections 3(a) and 14(3) of the Act. In one case regulated procedures were applied to animals that had previously completed a series of regulated procedures, without the authority for their further use in breach of section 3(a) and 14(3) of the Act. In one case regulated procedures were applied to animals that had previously completed a series of regulated procedures, without the authority for their further use in breach of section 14(3); in two cases there was inadequate supervision of animals; in one case severity limits were exceeded; in three cases animals were not being maintained to the required standards as set out in the Home Office Code of Practice for the Housing and Care of Animals in Designated Breeding and Supplying Establishments; and in one case animals were not being maintained to the required standards as set out in the Home Office Code of Practice for the Housing and Care of Animals in Designated Breeding and Supplying Establishments; and in one case animals were not being maintained to the required standards as set out in the Home Office Code of Practice for the Housing and Care of Animals used in Scientific Procedures.

Action taken

51. It should be borne in mind when reading the following paragraphs that any infringement case may involve more than one personal or project licence holder.

52. As a result of these infringements, 21 licence holders were admonished; seven were required to attend relevant modules of an accredited training course; three holders of certificates of designation were required to review the systems of control at their establishments in order to prevent recurrence; and 1 non-licensee was sent a letter of censure.

53. Those admonished include personal and project licence holders, and holders of certificates of designation. They also include those who were additionally required to undergo training.

Return of procedures by project for 2004

OFFICIAL USE	ONLY
Serial Number	
Project licence number	
Establishment code	

Dear Project Licence Holder

This form sets out the arrangements for the 2004 annual return of statistics of regulated procedures conducted under the Animals (Scientific Procedures) Act 1986. It should be used to record procedures that were started during 2004. If you are not the project licence holder for the project licence number displayed above, please return the form to the address below with an explanatory note.

If you are the project licence holder please:-

- read and answer question 1 under SECTION 1. If the answer to the question is NO simply sign and date the form, giving a
 contact telephone number and email address, and return it to the address below. However if the answer is YES, please read
 the rest of this letter, accompanying notes, and code lists carefully before completing the form in black ink.
- complete the form with care; this is a computer input document. This should avoid queries at a later date. PLEASE NOTE CAREFULLY THE CODING INSTRUCTIONS. THERE ARE SOME WORKED EXAMPLES ON PAGES 9 & 10.
- discard any old coding instructions, and use only those instructions supplied with this form.
- after satisfying yourself that it has been completed accurately, sign and date the form, giving a contact telephone number and email address, and return it by 31 JANUARY 2005, to:-

Home Office Room 511, Allington Towers 19 Allington Street LONDON SW1E 5EB

It is a requirement of the Animals (Scientific Procedures) Act 1986 that this return is completed, and it should be returned to us by 31 January 2005 at the latest. Failure to comply constitutes a breach of the Act and may be considered as a Class 2 infringement.

retain a copy of this return in case of queries.

Thank you in advance for your care and attention.

Animals Scientific Procedures Division Science and Research Group

SECTION 1 (to be completed by the Project Licence Holder)

- under normal circumstances the form will not be accepted unless you, the project licence holder, sign SECTION 1. If this is
 not possible due, for example, to sickness or other unavoidable leave of absence, a note from the signatory to explain the
 circumstances should be attached.
- 1. Have any procedures under the Animals (Scientific Procedures) Act 1986 under the project shown above been started during 2004?

Enter "Y" for YES or "N" for NO

2. If NO please sign below and return the form. If YES please complete SECTION 2 and check that the form has been completed in accordance with the instructions. Then sign below and return the form.

Declaration: I am satisfied that the information required by the Secretary of State under the conditions of my project licence has been supplied accurately in accordance with the instructions given.

Signature of project licence holder	Date
Name of signatory in BLOCK LETTERS	
Contact telephone number Ema	il address

PPL NO:	F	FORM SE	RIAL NO:			
Section 2	Select the appropriate codes by referring to the enclosed notes.		01	02	03	04
Which animals	Species were used in the procedure?	Row 1				
	Is animal on the CITES list? (see notes)	Row 2				
Stage What was the stage	of Development e of development of the animal?	Row 3				
Ge Were the anin	enetic Status nals genetically abnormal?	Row 4				
From where w	Source vere the animals obtained?	Row 5				
A Were the a	naesthesia animals anaesthetised?	Row 6				
	Was an NMBA administered?	Row 7				
Prir What was the prim	nary Purpose hary purpose of the procedure?	Row 8				
B What was the primary ta	ody System arget body system for the procedure?	Row 9				
TOXICOLOGY Purpose Use List A	ALL WORK OTHER THAN TOXICOLOGY Field of Research Use List B	Row 10				
Type of Test Use List A	Production Use List B	Row 11				
Legislative Requiremen Use List A	nts Techniques Use List B	Row 12				
Number Enter the total numb	er of Procedures er of procedures for each column	Row 13				
Number of anim Enter the total number in reg	Pals used for the first time or of animals used for the first time ulated procedures	Row 14				
Number of animals R Enter the total number of an in regulated If no animals were r	eused for the first time <u>this year</u> nimals <u>reused</u> for the <u>first time this year</u> procedures (see Notes) eused this should be set to zero	Row 15				

PPL NO:				FORM SERIAL NO:						
05	06	07	08	09	10	11	12	13	14	15

PPL NO:			FORM SERIAL NO:							
16	17	18	19	20	21	22	23	24	25	26

GENERAL NOTES

- It is a condition of every project licence that the project licence holder must make a return before 31 January of all regulated procedures on living animals commenced during each year. Only one reminder of this obligation will be sent.
- 2. Information subsequently published by the Home Office will not identify the work of any individual establishment or project licence holder.
- 3. If you hold more than one project licence, you will receive a separate return of procedures form for each licence. The project licence number is shown on the front of the form. Please take care to ensure that the work of personal licensees appears on the return of procedures form carrying the correct number. It is the responsibility of project licence holders to ensure that the work of all personal licensees performing regulated procedures on their project is included in their returns.
- 4. The form SHOULD NOT be used to notify changes in personal details. Such changes should be notified **separately** to your regional office or to:

APLS, Room 511 Home Office Allington Towers 19 Allington Street LONDON SW1E 5EB

NOTES ON COMPLETING SECTION 2

- 5. Before completing SECTION 2 please study the section carefully and read the notes on Code Lists for each ROW. Be sure that you understand what is meant by:
 - CITES listed species, ROW 2
 - Schedule 2 listed species, ROW 5
 - Procedure, ROW 13

You may find it helpful to refer to paragraphs 2.6 to 2.33 of the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (Published in March 2000 by HMSO, reference HC321) before completing this section. This Guidance is also available at www.homeoffice.gov.uk/comrace/animals/legislation.html

- 6. If you have carried out any work using harmful mutant or genetically modified animals, you must read the whole of Annex A of the notes (on Page 8) carefully.
- 7. Complete SECTION 2 column by column in line with the sequence shown by the arrows. For each entry in a column (i.e. each box) select the most appropriate code from the code list for that ROW.
- 8. Do not enter more than one code in any box. Where a different set of codes is needed to describe fully the use of different groups of animals in a particular procedure, complete as many columns as necessary. If a mistake is made and alterations are necessary, strike out the whole column and complete a fresh one.
- 9. Each completed column should contain a unique combination of codes and record all the procedures for any animal or group of animals of the same species which are described by that particular combination of codes.
- 10. If your project requires more than 26 columns to describe it, please photocopy and complete SECTION 2 and attach the additional sheets to your return, making clear that they are additional sheets and that the project licence number appears on them.
- 11. Forms not completed in accordance with the guidance notes may be returned to the licence holder for clarification. Acceptance of the form in compliance with standard condition 10 of the licence will NOT be recorded until a properly completed form is received in the Home Office.
- 12. Please consult your Inspector if you are uncertain how to complete the form correctly.

CODE LISTS

	V 1 : SPECIES	NOW 3. STAGE OF DEVELOPMENT
Sele	ect the appropriate code from the list below.	Select the appropriate code from the list below.
MAN	IMAL	1 Adult animal, free-living (including neonatal and juvenile
R0	Use this code for rodenticide field trials only. There is no need to complete the rest of the column. You must provide a covering letter giving estimates of the numbers of each species which may have under gone pain, suffering, distress or lasting harm during the field trials.	mammals and newly-hatched birds). 2 Larval/embryonic/foetal animal. DO NOT COUNT THESE ANIMALS – ENTER "0" IN ROWS 13, 14 AND 15.
R1 R2 R3 R4 R5 R9 L1 C1 C2 C3 C4 C5 C9 U1 U2 U3 U4	Mouse Rat Guinea pig Hamster Gerbil Other rodent (<i>please append a note indicating species used</i>) Rabbit Cat Dog - beagle - greyhound - other including cross-bred dogs Ferret Other carnivore (<i>please append a note indicating species used</i>) Horse, donkey and cross-bred equids Pig Goat Sheep	ROW 4 : GENETIC STATUS Select the most appropriate code from the list below 1 Normal animal 2 Animal with harmful genetic defect (e.g. harmful mutants) 3 Genetically modified animal (e.g. transgenic, knock-out). Important guidance on coding and counting of harmful mutants or genetically modified animals is given in Annex A. ROW 5 : SOURCE OF ANIMALS Schedule 2 of the Act lists the following species: mouse, rat, guinear pig, hamster, gerbil, rabbit, dog, cat, ferret, primate and quail
U5	Cattle	(<i>Coturnix coturnix</i>). Also: pigs, if genetically modified
U7	Camelid	sheep, if genetically modified
U9	Other ungulate (please append a note indicating species used)	Enter:
	Primate	0 If the species is NOT listed in schedule 2
P1	- prosimian	For schedule 2 species enter:-
P2 P3	 new world monkey marmoset, tamarin squirrel, owl or spider monkey 	1 If the animals were acquired from within own designated establishment.
P5	- old world monkey - macague	2 If the animals were acquired from another designated estab- lishment in the UK (e.g. a university; commercial breeder).
P6 P7	 baboon other old world monkey 	3 If the animals were acquired from non-designated sources in the UK.
P8 P9	- ape - gibbon - great ape	4 If the animals were acquired from other countries within the EU other than the UK (See list at LIST A, ROW 12 below).
J9 BIRI T1	Other Mammal (<i>please append a note indicating species used</i>) D Domestic fowl (<i>Gallus domesticus</i>)	5 If the animals were acquired from member countries of the Council of Europe which are parties to convention ETS 123 (excluding EU member states). (See list below).
T3	Quail (<i>Coturnix coturnix</i>)	6 If the animals were acquired from other sources.
T4	Quail (spp. other than C. coturnix)	Non-EU ETS 123 countries (code 5 above) as at 1 January 2004
T9	Other bird (please append a note indicating species used)	Cyprus Switzerland
D1	TILE Any reptilian species (<i>please indicate species used</i>)	Norway Turkey
AMF	PHIBIAN Any amphibian species (please indicate species used)	
FISH	-	
F1	Any fish species (please indicate species used)	Select the most appropriate numeric code from the list below.
CEP	HALOPOD	0 No anaesthesia throughout the procedure.
F 5	Octopus vulgaris	Include procedures without anaesthesia which end by a
-		Schedule 1 method of killing even if this consisted of an
ROV	V 2 : SPECIES	potential anaesthetic agents.
Anin	nals of endangered species listed in Appendix 1 of the	1 General anaesthesia with recovery.

Convention on International Trade in Endangered Species of Flora and Fauna (CITES) or in Annex C.1 to the Council Regulation (EEC) 3626/82(a) are subject to special controls and information is required on their use. Most species and strains of animals used in the laboratories are not included in the CITES lists. Please consult your Inspector for further information.

Select the appropriate code from the list below.

 the specifies used in this procedure is listed in Appendix 1 or Annex C.1. *(please give both common and Latin name for species)* the species is not so listed.

Some examples of CITES codes:

- Common marmosets; macaca spp except *M. silenus*Cotton top tamarins (*Saguinus oedipus*);
- some birds of prey such as Peregrine falcon (*Falco peregrinus*)

General anaesthesia without recovery. Used at the end of a procedure which did not otherwise involve anaesthesia. (See note below).

Used at any stage of the procedure irrespective of other uses

General anaesthesia without recovery.

Local or regional anaesthesia.

Used at any stage of the procedure.

Used throughout the procedure.

of anaesthesia.

NOTE

2

3

4

If the animal was killed by a method listed in Schedule 1 of the Act using an overdose of an anaesthetic agent, this was not part of the regulated procedure and should not be recorded as such.

ROW 7 : NEUROMUSCULAR BLOCKING AGENTS

Select the appropriate code from the list below.

- 0 No use of neuromuscular blocking agents (NMBA).
- 1 NMBA used during the procedure at some stage. (Associated codes for row 6 will usually be 1, 3 or 4.)

ROW 8 : PRIMARY PURPOSE OF THE PROCEDURE

Select the appropriate code from the list below.

- 1 **Fundamental biological research:** studies of normal or abnormal structure or function of living organisms, organs, tissues, cells or other systems (including fundamental studies in toxicology).
- 2 Applied studies human medicine or dentistry: research, development or quality control of products or appliances including toxicological evaluation and safety or efficacy testing.
- 3 Applied studies veterinary medicine: research, development or quality control of products or appli
 - ances including toxicological evaluation and safety or efficacy testing.
- 4 Protection of man, animals or environment by toxicological or other safety or environmental evaluation (excluding medical or veterinary products or appliances). This category is intended to cater for toxicological work which is not related either to fundamental research or to the solution of medical or veterinary problems as such. Ecological studies may be included here with the appropriate codes in Rows 10-12: A codes for toxicological testing or B codes for other investigative studies.

5 Education

- 6 Training:
 - use of animals in acquisition of manual skills is permitted in microsurgery training only.
- 7 Forensic enquiries:
- human or veterinary.
- 8 Direct diagnosis:
- procedures for specific detection of human or veterinary pathogens or production of diagnostic reagents.

9 Breeding

of harmful mutants or genetically modified animals. Before selecting this code please read the guidance in Annex A. If using this code row 11 must be B61, B62, or B64.

ROW 9 : BODY SYSTEM

Select the code from the list below which most closely describes the primary target body system for the procedure.

- 01 Respiratory
- 02 Cardiovascular
- 03 Nervous (work directed towards central or peripheral nervous systems other than the special senses)
- 04 Special Senses (sight, hearing, smell, taste)
- 05 Alimentary (including liver) and Excretory
- 06 Skin
- 07 Musculo-skeletal
- 08 Reproductive
- 09 Immune and reticulo-endothelial
- 10 Other system (where the target was a single system not listed)
- 11 Multiple systems (where more than one system was of primary interest)
- 12 System not relevant (where the system or systems affected were not predictable or not relevant)

ROW 10, 11 & 12

Codes from <u>EITHER</u> list A <u>OR</u> LIST B should be used to complete these rows within a column. A mixture of A and B codes within a column is <u>not permitted</u>.

Use **list A** if the primary purpose of the procedure described in the column was a toxicological or other regulatory or safety purpose (including efficacy, quality control, ADME).

Use list B for any other primary purpose.

LIST A, ROW 10

TOXICOLOGY OR OTHER SAFETY OR EFFICACY EVALUATION

If the procedure was carried out for a toxicological or other safetyrelated purpose (including efficacy, quality control, or other regulatory purpose), select the most appropriate code from the list below.

- A01 Environmental pollution
- A02 Substances used in agriculture
- A03 Substances used in industry
- A04 Substances used in the household (see example (col. 2) on page 9)
- A05 Food additives other than those administered in food for health purposes
- A06 Foodstuffs other than additives
- A07 Cosmetics and toiletries finished products
- A08 Cosmetics and toiletries ingredients

Pharmaceutical safety/efficacy evaluation

- A11 Safety testing
- A12 Efficacy testing
- A13 Quality control
- A14 Absorption, Distribution, Metabolism and Excretion (ADME) and residue studies

Other purpose

- A21 Fundamental research in toxicology
- A22 Tobacco safety testing (inducing alternatives)
- A23 Safety/Efficacy testing of medical appliances or devices
- A24 Method development or validation
- A25 Other toxicological purpose

LIST A, ROW 11

TYPE OF TEST OR PROCEDURE

If the procedure was carried out for a toxicological or other safety-related purpose (i.e. you have used a code from A01– A25 in Row 10), select the code from the list below which describes the procedure most accurately. <u>The OECD test references are examples</u> and are given only for guidance.

- A30 Acute quantitative lethal toxicity test (LD50) (OECD 401). Please append a note if the test was conducted as an LD50 test according to OECD 401.
- A31 Acute quantitative lethal concentration tests (LC50) (OECD 403 or 203).
- A32 Acute limit-setting (e.g. OECD 401), or dose-ranging lethal toxicity tests.
- A33 Acute oral toxicity test (e.g. OECD 420, OECD 423, OECD 425). Includes such tests as Fixed Dose Procedure, Acute Toxic Class method, Up and Down method, Maximum Non-Lethal Dose or Maximum Tolerated Dose.
- A34 Subacute limit-setting (e.g. OECD 407) or dose-ranging toxicity test (usually 14 to 28 days duration)
- A35 Subacute quantitative toxicity test (e.g. OECD 407, 410). (usually 14 to 28 days duration).
- A36 Subchronic and chronic toxicity tests (e.g. OECD 408, 409, 411, 413, 452) (tests for 90 days or more)
- A37 Carcinogenicity tests (e.g. OECD 451)
- A38 Genetic toxicology tests (e.g. OECD 474, 475) includes mutagenicity tests and the Micronucleus test.
- A39 Teratogenicity tests
- A40 Other reproductive toxicity tests, including multigeneration studies
- A41 Tests for clinical signs in eyes (e.g. OECD 405)
- A42 Tests for skin irritation (e.g. OECD 404)
- A43 Tests for skin sensitisation (e.g. OECD 406). Please indicate if you have used either the Guinea pig Maximisation Test or the Buehler Assay (OECD406).
- A44 Toxicokinetics (e.g. OECD 417)
- A45 Pyrogenicity tests
- A46 Biocompatibility tests
- A47 Enzyme induction for *in vitro* tests
- A48 Immunotoxicology tests
- A50 Other toxicology tests these other tests may include collection of normal tissues such as blood for *in vitro* work, and investigative procedures not compatible with other codes.

LIST A, ROW 12

LEGISLATIVE REQUIREMENTS

If the procedure was carried out for a toxicological or other safetyrelated purpose (i.e. you have used a code from A01 – A25 in row 10), select the code from the list below which most closely describes the legislative requirements for which the procedure was performed. Note that "legislative requirement" includes a requirement imposed by a product or manufacturing licence of the country concerned.

Where a test was intended to satisfy both UK and other requirements and involved more animals than the UK minimum requirements two columns should be used to describe the tests. The first column should record the number of animals used to satisfy UK requirements using Code A91 in Row 12 and the second column should show the remainder using the most appropriate Code (A92 or A93) in Row 12.

A91 Procedures performed to meet UK legislative requirements only

A92 Procedures performed to meet national legislation specific to only one EU member state, excluding the UK (see list below).

- A93 Procedures performed to meet EU legislative requirements including European Pharmacopoeia
- A94 Procedures performed to meet member country of Council of Europe (excluding EU) legislation (see list below)
- A95 Procedures performed to meet legislative requirements of other countries e.g. USA, Japan
- A96 Any combination of A91-A95 requirements
- A97 Toxicity tests carried out for purposes other than meeting legislative requirements

Safety testing to satisfy HSE regulations or similar legislation in other countries should be classified as a legislative requirement choosing from codes A91-A96 as appropriate.

COUNTRY LIST FOR CODE A92 ABOVE AND CODE 4 IN ROW 5 (EU countries other than the UK) as at 1 January 2004

Austria	Germany	Netherlands
Belgium	Greece	Portugal
Denmark	Irish Republic	Spain
Finland	Italy	Sweden
France	Luxembourg	

COUNTRY LIST FOR CODE A94 ABOVE

(Council of Europe nations other than EU) as at 1 January 2004

Albania	Hungary	Russian Federation
Andorra	Iceland	San Marino
Armenia	Latvia	Slovakia
Azerbaijan	Liechtenstein	Slovenia
Bulgaria	Lithuania	Switzerland
Croatia	Malta	Former Yugoslav
Cyprus	Moldova	Rep.of Macedonia
Czech Republic	Norway	Turkey
Estonia	Poland	Ukraine
Georgia	Romania	

<u>REMEMBER</u>: Do not mix codes from lists A and B in a column.

LIST B, ROW 10

FUNDAMENTAL AND APPLIED STUDIES OTHER THAN TOXICOLOGY

If the procedure was carried out for a purpose other than toxicology or safety evaluation, select the code from the list below which best describes the **primary field of research**.

Any of these studies (e.g. clinical medicine, clinical surgery, pharmaceutical R and D, cancer research) may apply to either veterinary or medical science – the appropriate code for the primary purpose of the animal use would have been given in Row 8.

- B01 Anatomy and developmental biology
- B02 Physiology
- B03 Biochemistry
- B04 Psychology/Behaviour
- B05 Pathology
- B06 Immunology
- B07 Microbiology
- B08 Parasitology B09 Pharmacology
 - 09 Pharmacology 10 Pharmaceutical Research and De
- B10 Pharmaceutical Research and Development except anti-cancer agents (code B17)
- B11 Therapeutics
- B12 Clinical medicine
- B13 Clinical surgery including technique development
- B14 Dentistry
- B15 Genetics
- B16 Molecular biology
- B17 Cancer Research including therapy
- B18 Nutrition B19 Zoology
- B19 Zoology B20 Botany and pla
- B20 Botany and plant pathologyB21 Agricultural animal science not included in codes above
- B22 Ecology and environmental studies other than toxicology or other safety evaluation
- B23 Animal welfare studies not included in the codes above
 B24 Other purpose if you use this code you must provide a separate note describing the procedure
- B31 Tobacco research] Use these codes for research on
- B32 Alcohol research **J** tobacco or alcohol or their constituents. **Do not** use these codes for use of these substances as pharmacological tools or standards

LIST B, ROW 11

PRODUCTION AND BREEDING

If you used a code from B01 to B32 in Row 10, select a code from the list below which applies to the procedure described in this column.

Production of biological materials

Ascites model for production of monoclonal antibodies B50

- B51 Production and maintenance of infectious agents
- Production and maintenance of vectors (e.g. insects) B52
- B53 Production and maintenance of neoplasms
- B54 Initial immunisation for subsequent in vitro or in vivo production of monoclonal antibodies
- Production of polyclonal antibodies B55
- Production of other biological material (e.g. plasma, tissues) B56

Breeding

You should read Annex A on pages 8 and 9, as well as the example on page 10 to ensure correct use of the following codes.

- Animals used to generate founder genetically modified **B61** animals for novel transgenic lines, chimeras or clones - this includes normal animals used in such programmes, e.g. superovulation, vasectomy, pseudopregnant recipients, as well as those animals culled as not being of the appropriate genetic status, but which have undergone regulated biopsy procedures.
- Genetically modified animals generated by recognised **B62** husbandry methods for the maintenance of a breeding colony. This may include normal animals (which have undergone regulated biopsy procedures) produced by using heterozygote parents, as well as animals with a fate as set out in Annex A, paragraph 2, attached.
- B63 Genetically modified animals used in research programmes. where they underwent regulated procedures other than those required for a breeding programme, i.e. where the primary purpose was NOT breeding, i.e. Row 8 = 1-8. Normal or wildtype animals used as controls in such research and also subject to regulated procedures should be coded as 1 in Row 4 and codes B50-B56, or B79 as appropriate, in this list.
- B64 Harmful mutant animals generated by recognised husbandry methods for maintenance of breeding colonies. This may include animals with a fate set out in Annex A, paragraph 2, attached. Normal animals, which have not undergone any other regulated procedures, do not need to be accounted for see Annex A, 1(i). Where harmful mutant animals have been crossbred with a GM line, the offspring should be reported as GM
- **B65** Harmful mutant animals used in research programmes, where they underwent regulated procedures other than those required for a breeding programme, i.e. where the primary purpose was NOT breeding, i.e. Row 8 = 1-8. Normal or wildtype animals used as controls in such research and also subject to regulated procedures should be coded as 1 in Row 4 and codes B50-B56, or B79 as appropriate, in this list.

Other

B79 None of the above

LIST B, ROW 12

TECHNIQUES OF PARTICULAR INTEREST

If you used a code from B01 to B32 in Row 10, select a code from the list below which applies to the procedure described in this column.

- Direct interference with any part of the organs of special B91 sense including the brain centres
- B92 Direct injection of micro-organisms or material suspected of containing micro-organisms into the brain
- **B93** Other direct physical interference with the brain
- **B**94 Induction of psychological stress integral to the procedure
- Use of aversive training stimuli **B95**
- Exposure to ionising radiation at doses intended to produce a B96 potentially adverse effect on the animal
- **B**97 Inhalation – DO NOT USE FOR FISH
- } where the study of such injury or trauma was the purpose of the procedure **B98** Thermal injury
- B99 Physical trauma
- B00 None of the above

IMPORTANT NOTES ON RE-USE

ROWS 13 and 14

If your records show that the number of procedures carried out (Row 13) exceeds the number of animals used for the first time (Row 14), then animals have been re-used, as defined by Section 14 of the Act. Standard condition 5 of the project licence requires that there is express authority for the re-use of animals. Re-use will be authorised in your project licence either in sub-section (iv) or (vii) of a protocol in Section 19(b), OR as an additional condition to your project licence.

BOW 15

This row is needed to assess re-use as required by the Council of Europe. Report the number of animals re-used for the FIRST time during the reporting year. This will include animals used for the first time in the reporting year which have been re-used, as well as those animals used for the first time in previous years, and re-used for the first time during the reporting year.

For example: an animal is bled three times per year for the collection of normal blood.

In the first year the animal is used, it would be counted once in Row 14, three procedures would be recorded in Row 13, and one procedure in Row 15 for the first re-use.

In subsequent years, the figures would be Row 13=3, Row 14=0 and Row 15=1. See also the worked example in column 3 on page 9.

ROW 13 : NUMBER OF PROCEDURES CARRIED OUT ON ANIMALS

Each separate use of one animal counts as one procedure. Only procedures started during the year should be included. Procedures which have been reported in returns for previous years and have continued into the current reporting year should not be included.

Do not include foetal, larval or embryonic animals: enter '0' in row 13 for these animals. Also enter '0' in Row 13 if you have entered 'R0' in Row 1.

ROW 14 : NUMBER OF ANIMALS USED FOR THE FIRST TIME

Where animals are used in more than one separate procedure (i.e. reuse; see below) only the first use counts towards the total which you should enter in row 14. This is true whether or not the second and/or subsequent procedures are described in the same column or any other columns of the return or on another return.

If there is no re-use, the number of animals entered here will be the same as in row 13. See worked examples on pages 9 and 10.

If you have entered '0' in row 13, enter '0' in row 14.

Re-use. In general, if the same animal is being used as a matter of necessity, as in a series of regulated procedures for a particular purpose, this is not regarded as re-use. For example, where it is necessary to know how an animal responds to drugs A, B and C before interpreting its response to drug D, there is no choice and the successive use of the animal constitutes a single series of procedures without re-use. By contrast, if the procedures are unrelated or a different animal could equally well have been chosen for the second or subsequent procedures, use of the same animal is regarded as reuse. For example, if, by choice, repeated samples of normal blood were taken from a rabbit, but each sample could equally as well have come from a fresh rabbit, this would count as re-use and should be entered as such.

ROW 15 : NUMBER OF ANIMALS RE-USED FOR THE FIRST TIME IN THE CURRENT YEAR

Please read the guidance on re-use in the instructions above.

Please record here animals re-used for the first time this year, regardless of whether the first use of the animal was this year or any previous year.

If there is no re-use the number recorded here must be 0.

If you have entered 0 in Row 13, then this row must also be 0. The sum of the values in Rows 14 and 15 must not exceed the value in Row 13.

ANNEX A

Coding and counting of animals with abnormal genetic constitution

To avoid the risk of double counting, the encoding of animals with harmful genetic defects (harmful mutants) and genetically modified animals (e.g. transgenic animals, knock-outs, chimeras and clones) (Row 4, codes 2 or 3) differs, depending on whether their use was limited to breeding procedures or whether they were subsequently used in other regulated procedures under project licence authority.

Mating is a regulated procedure under the terms of the Act if it may result in the creation of either harmful mutant or genetically modified animals which are protected by the Act. However the parents do not themselves suffer potential harm during mating. **Consequently, it is only the offspring which should be counted for the return of procedures in accordance with these notes.**

The harmful mutant or genetically modified parents (used only for breeding) should be reported once only, when they are originally created (see Section 3 below for imported animals). Genetically normal parents which have undergone no other regulated procedures should not be counted for the purposes of the annual statistics.

- (i) For animals with harmful genetic defects (harmful mutants), only those animals in which the defect actually manifests itself (as denoted by genetic testing, coat colour or marking, or by direct observation) should be reported, using code 2 in Row 4. Normal animals which have been produced from the breeding programme and have NOT been subjected to any other regulated procedure (such as blood sampling), should not be reported. Where harmful mutant animals have been crossbred with a genetically modified line, the offspring should be reported as genetically modified.
- (ii) For genetically modified animals:
 - all animals used in procedures (e.g. vasectomy, superovulation, implantation) for the development of genetically modified animals should be recorded in Row 4 as code 1 (normal) or 3 (genetically modified), as appropriate: in Row 8 as code 9; in Row 11 as code B61. Note: Animals coded as B61 in Row 11 should always be coded 9 in Row 8.
 - subsequently, during breeding of the established genetically modified line, only those animals identified as genetically modified should be recorded as such using code 3 in Row 4. Normal animals from the breeding programme should be recorded as code 1 in Row 4 only if further regulated procedures were carried out on those animals, e.g. biopsy procedures.

1. Animals which are used under project licence authority, for a purpose other than breeding.

These should be encoded and enumerated later when the necessary information is available on their primary use in a procedure other than breeding using the appropriate code from Row 8. This may mean that these animals are not reported in the year in which they are born.

Coding in **all rows** should reflect the further use in a regulated procedure, rather than the initial breeding:

- when their use for a scientific purpose consisted of what would otherwise have been non-regulated procedures (i.e. noninvasive observations, killing by a Schedule 1 method for dissection or *in vitro* study), then codes B62 or B64 should be used as appropriate in Row 11, and codes 1-8 in row 8.
- (ii) if the use was a regulated procedure within the same project as that under which the animal was bred, the coding should reflect the particular purpose and use for that animal. For example, use of nude mice for maintenance of a neoplasm would be coded 2 in Row 4, code 1 – 8 in Row 8, and B53 in List B, Row 11. If there is no other suitable code in Row 11, use codes B63 or B65 as appropriate.
- (iii) likewise, if an animal was transferred to a project other than the one under which it was bred, it should be reported there and the coding should reflect the purpose for which the animal was used in the project to which it was transferred. It should NOT be entered in the return of the project under which it was bred. In these circumstances it may be that animals are born under the *breeding licence* at the end of one calendar year, but not moved to the *using* project licence until the following year such that they will only be returned in the year in which they are used.

The assumption underlying these arrangements is that the objectives of procedures in (i), (ii) and (iii) above require the use of the animals with harmful genetic defects or genetic modifications; consequently they have not been re-used in procedures, as defined by Section 14 of the Act, and the recording and returning arrangements should reflect this. However any further use in regulated procedures beyond that described above may constitute re-use and would require appropriate coding and counting to reflect this (such re-use, of course, requires appropriate project licence authority – see "Important notes on re-use" at top right of Page 7).

2. Animals bred under project licence authority, but not used in further regulated procedures

The fact that such animals have been produced should be included in the returns using code 9 in Row 8 and appropriate codes from the B list in Rows 10 to 12. In Row 11, codes B62 and B64 should be used. In addition to the animals described at 1(i) above, B62 and B64 codes will include those animals which, for the reasons set out below, were not used for any specific scientific purpose beyond being bred:

- (i) they died or were humanely killed as a result of the harmful genetic defect or the genetic manipulation;
- (ii) they died or were humanely killed as a result of other causes, e.g. disease;
- (iii) they were humanely killed as surplus to requirements;
- (iv) they were retained for breeding;
- (v) they were exported live to a place outside the jurisdiction of the Act (for which special permission must have been obtained from the Home Office).

3. Live animals from non-designated sources, usually imported, for use in breeding programmes authorised by project licence

Specific authority must have been obtained from the Home Office for such acquisition.

- (i) If these animals were used only in non-harmful breeding procedures (as parents only) to procedure a new colony, they should be recorded once in the year in which they were obtained using code 9 for Row 8, and codes B62 or B64, as appropriate, in List B, Row 11.
- (ii) Animals which go on to be used in other regulated procedures should be coded for that use as noted in Section 1 of Annex A above.

N.B. HARMFUL MUTANT AND GENETICALLY MODIFIED ANIMALS SHOULD BE REPORTED ONLY ONCE IN THEIR LIFETIME.

Examples (counting; re-use; and use of certain toxicology codes):

Column	1	2	3
Row 1	R2	R1	C1
Row 2	0	0	0
Row 3	1	1	1
Row 4	1	1	1
Row 5	2	2	2
Row 6	1	0	0
Row 7	0	0	0
Row 8	2	4	3
Row 9	11	12	05
Row 10	A14	A03	B18
Row 11	A50	A35	B79
Row 12	A96	A93	B00
Row 13	15	40	90
Row 14	15	40	50
Row 15	0	0	40

Column 1

Fifteen 8-week-old rats of normal genetic status were purchased from a commercial breeder in the UK for the following experiment. This required surgical implantation of vascular cannulae with recovery from general anaesthesia, without the use of neuromuscular blocking agents. Subsequently the animals were dosed with a potential drug for cancer therapy and three timed blood samples are taken from the cannulae for a pharmacokinetic study. Finally the animals were killed by perfusion of fixative under general anaesthesia. The whole series of six interventional techniques were carried out for a particular purpose and were covered by the description in a single 19(b) protocol sheet of the project licence.

Column 2

40 genetically normal, six week old mice were purchased from a commercial breeder in the UK for use in a sub-acute quantitative toxicity test (28 days study) to provide data on a household product for a client of a contract toxicology company. The 28 day study was needed to fulfil the requirements for safety evaluation of the product during the manufacturing process when material needs to be moved in bulk, i.e. the testing is required under the regulations relating to the safety of substances used in industry for production within the EU, and consequently row 10 should be coded A03 (industry) and not A04 (household).

Column 3

A Company uses cats for the study of feline nutrition. The regulated procedures do not involve general anaesthesia and the project licence authorises re-use of the animals. Last year 40 new cats were purchased and used. This year 50 more cats were purchased from the same UK designated source and used. In the experiment recorded in Column 3 all 90 cats were used for a feeding study with subsequent blood sampling. The 50 cats purchased this year were used for the first time. The 40 cats used last year were re-used in this experiment for the first time during this new calendar year.

Further examples - breeding procedures

Columns 4 - 10

At the beginning of the calendar year, there are 10 pairs of genetically modified mice in a breeding colony for fundamental immunological research. The colony is maintained using heterozygote parents as homozygous offspring must be killed at five weeks of age due to an adverse phenotype. The breeding pairs had been included in the previous year's return for use in breeding procedures. During the course of the year 300 offspring are produced. All of these animals undergo local anaesthesia to remove the tip of the tail for genotyping.

Assuming a perfect Mendelian distribution, 75 animals are found to be homozygous and are killed by 5 weeks of age using a Schedule 1 method of killing. However, the tissues from 50 of the animals were used for in vitro cell culture and further relevant research (Column 4). The remaining 25 animals are returned for use in the breeding programme only (Column 5). Seventy five animals are found not to express the genotype of interest and were culled by a Schedule 1 method of killing (Column 6). Of the remaining 150 heterozygote animals, 30 are retained as the future breeding nucleus (Column 7). Fifty are used in further procedures involving general anaesthesia with recovery but without neuromuscular blockade for dosing and sampling under procedures in the project licence under which they were bred (Column 8). Another 50 are killed by perfusion under terminal general anaesthesia in accordance with the project licence (Column 9). Ten animals are moved to the project licence of a collaborator in the UK in order to set up their own breeding colony. Ten animals are exported, with appropriate Home Office authority, to a collaborator in another country (Column 10).

Note: the 20 animals of the original 10 pairs are not counted for the current calendar year. Also the 10 animals which were moved to the UK collaborator are not counted, as they should be returned under the project licence to which they have moved.

Column	4	5	6	7	8	9	10
Row 1	R1						
Row 2	0	0	0	0	0	0	0
Row 3	1	1	1	1	1	1	1
Row 4	3	3	1	3	3	3	3
Row 5	1	1	1	1	1	1	1
Row 6	2	2	2	2	1	2	2
Row 7	0	0	0	0	0	0	0
Row 8	1	9	9	9	1	1	9
Row 9	09	09	09	09	09	09	09
Row 10	B06						
Row 11	B62	B62	B62	B62	B63	B62	B62
Row 12	B00						
Row 13	50	25	75	30	50	50	10
Row 14	50	25	75	30	50	50	10
Row 15	0	0	0	0	0	0	0

APPENDIX C

ERRATA IN 2003 PUBLISHED TABLES

Since the publication of the annual statistics for the year 2003, a number of errors have come to light. The corrected tables in their entirety will be found on the website for the 2003 publication:

http://www.official-documents.co.uk/document/cm62/6291/6291.htm

Table 8

The penultimate column of table 8, which describes procedures not related to production, showed incorrect values. The correct values are shown, *in italics*, in the excerpt below. The "Other" column in this table includes all procedures related to breeding, together with any other procedures not specifically related to production.

Species of animal	Other	Total
Mouse	1,495,306	1,627,459
Rat	323,514	353,233
Other rodent	32,182	34,999
Rabbit	3,007	7,788
Cat	1,217	1,234
Dog	1,409	2,068
Ferret	663	1,078
Other carnivore	1,476	1,476
Horse and other equids	3,161	8,795
Other ungulate	42,432	63,355
New World monkey	737	817
Old World monkey	423	441
Other mammal	1,737	1,737
Bird	38,695	103,254
Reptile/Amphibian	8,727	15,106
Fish	117,719	121,222
Total	2,072,405	2,344,062

Table 8: non-toxicological procedures for production, 2003 (excerpt)

Table 12 Toxicology procedures by species and type of toxicological test

In the 2003 publication, the row for rabbits was missing from the **first** page of the table only. The column totals for the **first** page were also incorrect. However the second page and the total column and the grand total all appeared correctly.

A revised, corrected, table appears on the site for the 2003 publication, as mentioned above.

Table 13 Toxicology procedures by species and type of test, for safety testing of substances other than pharmaceuticals

The row for "horse and other equids" did not appear in this table. However, no procedures were reported for these species for these kinds of tests in 2003 and the row, had it appeared, would have been entirely zero.

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PREVIOUS RETURNS

Annual publications giving detailed figures for scientific procedures under the Animals (Scientific Procedures) Act 1986 were published (by HMSO) as "Statistics of scientific procedures on living animals" as follows:

Year	Command
	Paper
2003	Cm 6291
2002	Cm 5886
2001	Cm 5581
2000	Cm 5244
1999	Cm 4841
1998	Cm 4418
1997	Cm 4025
1996	Cm 3722
1995	Cm 3516
1994	Cm 3012
1993	Cm 2746
1992	Cm 2356
1991	Cm 2023
1990	Cm 1574
1989	Cm 1152
1988	Cm 743
1987	Cm 515

Detailed figures for experiments on living animals under the Cruelty to Animals Act 1876 were published (by HMSO) as "Statistics of experiments on living animals" as follows:

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

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

Feedback

The Home Office would welcome comments from users on how well this publication meets their needs, and will consider any suggestions for improving it in future years. Comments and suggestions must be sent to the address below by 31 March 2006 if they are to be taken into account in time for the next publication (covering procedures started in 2005).

Comments should be sent to: Science and Research Group, 1st Floor, Seacole Block, Home Office, 2 Marsham Street, LONDON SW1P 4DF or email: publications.rds@homeoffice.gsi.gov.uk



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