

**Statistics of Scientific Procedures  
on Living Animals  
Great Britain  
2003**

*Speaking of Research*

**© Crown Copyright 2004**

The text in this document (excluding the Royal Arms and departmental logos) may be reproduced free of charge in any format or medium providing that it is reproduced accurately and not used in a misleading context. The material must be acknowledged as Crown copyright and the title of the document specified.

Any enquiries relating to the copyright in this document should be addressed to The Licensing Division, HMSO, St Clements House, 2–16 Colegate, Norwich NR3 1BQ. Fax: 01603 723000 or e-mail: [licensing@cabinet-office.x.gsi.gov.uk](mailto:licensing@cabinet-office.x.gsi.gov.uk)



HOME OFFICE

# Statistics of Scientific Procedures on Living Animals

GREAT BRITAIN  
2003

Presented to Parliament by the Secretary of State for the  
Home Department  
by Command of Her Majesty  
September 2004

*LONDON*

HMSO

Cm 6291

£14.75

## CONTENTS

	<i>Page</i>	
<b>INTRODUCTORY NOTES</b>	4	
<b>MAIN POINTS</b>	12	
<b>COMMENTARY</b>	13	
<b>TABLES</b>		
Explanatory flow chart	23	
<b>Part A</b>	<b>Scientific Procedures: 2003</b>	
All procedures:		
1	Scientific procedures by species of animal and primary purpose of the procedure	24
1a	Animals by species of animal and primary purpose of the procedure	26
2	Scientific procedures by schedule 2 listed species and source of animals	28
2.1	As for table 2 but animals with harmful genetic defect only	29
2.2	As for table 2 but genetically modified animals only	30
3	Scientific procedures by species of animal, primary purpose and genetic status	31
3.1	Scientific procedures using genetically normal animals for production and breeding of genetically modified or harmful mutant animal	35
3.2	Scientific procedures using harmful mutant animals in breeding procedures or research	36
3.3	Scientific procedures using genetically modified animals in breeding procedures or research	37
4a	Scientific procedures by species of animal and target body system	38
4b	Scientific procedures by species of animal and level of anaesthesia	39
Non-toxicology:		
5	Scientific procedures (non-toxicology) by species of animal and field of research	40
5a	Animals (non-toxicology) by species of animal and field of research	44
5.1	As for table 5 but animals with harmful genetic defect only	48
5.2	As for table 5 but genetically modified animals only	49
6	<i>Discontinued</i>	
7	<i>Discontinued</i>	
8	Scientific procedures (non-toxicology) by species of animal and production and breeding	50
9	Scientific procedures (non-toxicology) by species of animal and techniques of particular interest	51
Toxicology:		
10	Scientific procedures (toxicology) by species of animal and toxicological purpose	52
10a	Animals (toxicology) by species of animal and toxicological purpose	56
11	Scientific procedures (toxicology) by species of animal, type of legislation and toxicological purpose	60
12-16	Scientific procedures (toxicology) by species of animal and type of toxicological test:	
12	- all purposes	64
13	- safety testing of non-pharmaceuticals other than cosmetics	66
14	<i>- this table discontinued because no procedures for cosmetics or ingredients in 2003</i>	
15	- pharmaceutical safety	67
16	- other safety/toxicology	68
17	<i>Discontinued</i>	

Tree tables:

18a	Procedures involving cats	69
18b	Procedures involving dogs	70
18c	Procedures involving horses and other equids	71
18d	Procedures involving new-world primates	72
18e	Procedures involving old-world primates	73
18f	Procedures involving rabbits	74
18g	Procedures involving genetically modified animals	75
18h	Procedures involving animals with a harmful genetic defect	76
<b>Part B</b>	<b>Procedures, project licence holders and designated places: 2003</b>	
19	Project licence holders and scientific procedures by type of designated establishment	77
<b>Part C</b>	<b>Historical</b>	
20	Scientific procedures by species of animal, 1988-2003	78
21	Scientific procedures (toxicology) by type of legislation, 1995-2003	78
22	Scientific procedures by use of anaesthesia, 1988-2003	79
23	Scientific procedures by type of designated establishment, 1988-2003	79
24	Scientific procedures (non-toxicology) by field of research, 1995-2003	80
25	Scientific procedures (toxicology) for safety evaluation, 1992-2003	80
26	Scientific procedures by primary purpose, 1995-2003	81
27	Scientific procedures by primary purpose and genetic status, 1995-2003	81
<b>APPENDIX A</b>	<b>General System of control and the Inspectorate</b>	82
<b>APPENDIX B</b>	<b>Return form - return of procedures by project for 2003, associated notes and code lists</b>	89

Details of previous years' publications

*inside back cover*

Feedback guidance

*inside back cover*

# STATISTICS OF SCIENTIFIC PROCEDURES ON LIVING ANIMALS GREAT BRITAIN 2003

## 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 2003. 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 by the licensing staff at the end of the year just 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 Research Development and Statistics Directorate (RDS) of the Home Office.

7. To complete the return, project licence holders were asked to classify their procedures. 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 special reports and tables, which are provided by RDS to ASPI. During this period Inspectors may contact licensees to discuss and confirm coding, and inform RDS of any amendments which may be necessary.

### **Description of statistical tables**

9. Project licence holders were 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 2003**

*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 will be retained for the time being to preserve continuity from previous years. The sequence of tables published in this year's report is the same as that published in 2001 and 2002.*

### **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 2003 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 2003 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, supplies of Schedule 2-listed species from non-designated sources in the UK, or from Europe or elsewhere, are subject to prior approval by the Home Office. Such supply 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 were 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.

<u>Abbreviated title</u>	<u>Description: studies in which interest centres on:</u>
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

- The number of scientific procedures started in 2003 was just over 2.79 million, a rise of about 59,000 (2.2 per cent) on 2002. Although 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, and currently numbers fluctuate year by year.
- 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 (6 per cent), and birds (4 per cent).
- 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 decreased from 9,900 in 2002 to 9,100 – an 8 per cent decrease; and since 1995 there has been a 27 per cent decrease in such use.
- The number of procedures using non-human primates was 4,799, up 822 from 2002; with pharmaceutical research, development and safety evaluation accounting for 3,428 (71 per cent) of these procedures. Since 1995 there has been a 24 per cent fall in the numbers of primates used for the first time.
- 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.
- Genetically normal animals were used in 1,749,000 regulated procedures representing 63 per cent of all procedures for 2003 (compared with 65 per cent in 2002 and 84 per cent in 1995).
- Species with harmful, but naturally-occurring, genetic mutations were used in 279,000 regulated procedures, representing 10 per cent of all procedures for 2003. Rodents were used in 92 per cent of the procedures using animals with harmful genetic mutations.
- Genetically modified animals were used in 764,000 regulated procedures representing 27 per cent of all procedures for 2003 (compared with 26 per cent in 2002 and 8 per cent in 1995). Rodents were used in 98 per cent of the procedures using animals which were genetically modified.
- Just under one third (32 per cent) of the genetically modified animals were used in scientific procedures other than the maintenance of breeding colonies.
- About 41 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 animal welfare cost of the procedure.
- Non-toxicological procedures accounted for about 84 per cent of the procedures carried out in 2003, with the main areas of use being for immunological studies, pharmaceutical research and development, and cancer research. This contrasts with 75 per cent of procedures being for a non-toxicological purpose in 1995.
- Procedures for toxicological purposes accounted for 16 per cent of all procedures started in 2003; this contrasts with 25 per cent of procedures being for a non-toxicological purpose in 1995.
- About 63 per cent of toxicological procedures were for pharmacological safety and efficacy evaluation in 2003.
- Five out of every six toxicological procedures were performed to conform to legal or regulatory requirements.

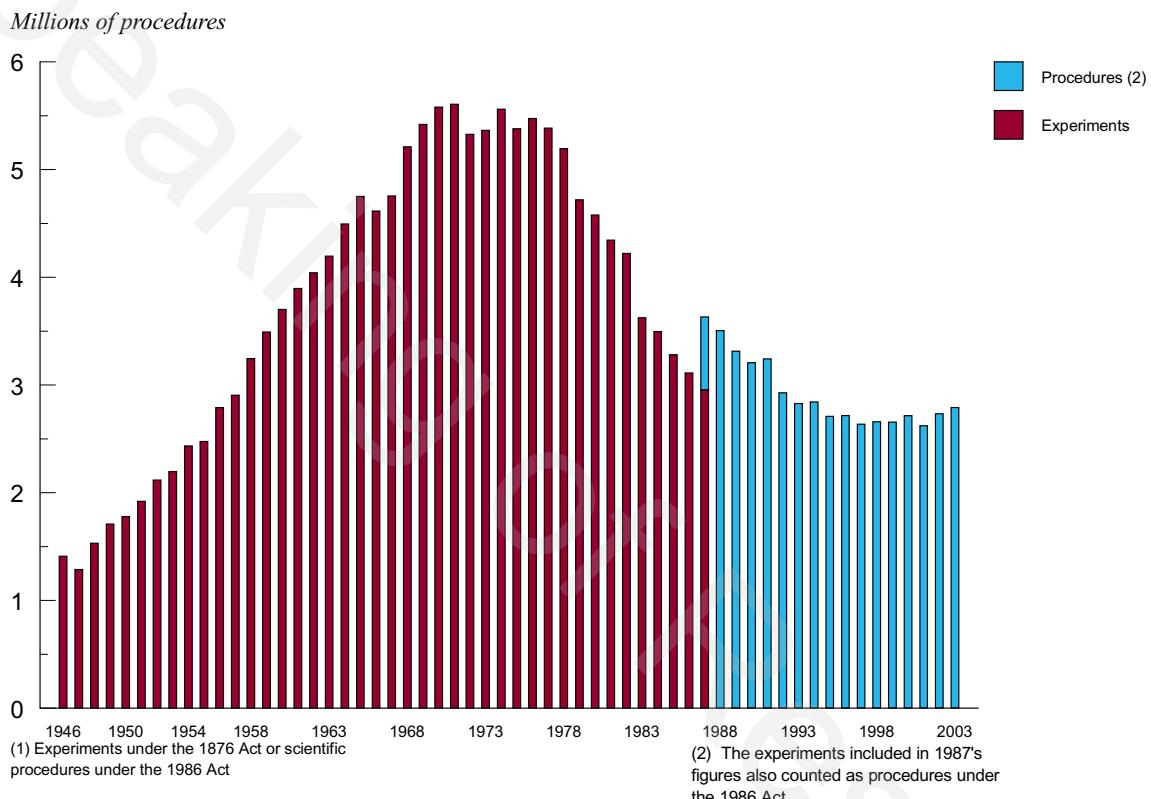
## COMMENTARY

### OVERALL PICTURE

#### Procedures started in 2003

The number of scientific procedures started in 2003 was just over 2.79 million (Table 1), a rise of about 59,000 (2.2 per cent) compared to 2002. Although 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 and currently numbers fluctuate year by year. The overall level of scientific procedures is determined by a number of factors, including the economic climate and global trends in scientific endeavour.

Some 2.72 million animals were used for the first time in procedures started in 2003 (Table 1a). This was about 66,000 (2.5 per cent) more than in 2002, broadly reflecting the number of procedures started.



**Figure 1: Experiments or procedures commenced each year, 1946-2003<sup>(1)</sup>**

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

The species of animals involved in the largest numbers of procedures in 2003 were mice (65 per cent of procedures), rats (18 per cent), fish (6 per cent), and birds (4 per cent). Domestic fowl accounted for five-sixths of all birds used. These proportions are all broadly similar to those in recent years.

Dogs (0.25 per cent of all procedures in 2003), cats (0.04 per cent) and non-human primates (0.17 per cent) were involved in relatively small numbers of procedures (a combined total of 13,135 in 2003), and the total use of these three groups fell by 201 procedures from 2002.

Despite the overall rise in the number of procedures in 2003, there were falls in procedures using many species (see below), but the principal increase in 2003 was in procedures involving mice (up 97,000), mainly due to their increased use in breeding procedures. Other species showing increases on the 2002 figures were gerbils (up 2,600), pigs (up 3,000), sheep (up 4,800), cattle (up 9,400), new world primates (up 270), old world primates (up 550), and quail (up 6,500). The general increase in the use of farm animals over the last two years is probably due to the outbreak of foot and mouth disease in 2001, which curtailed research in that year by limiting the movement of animals.

The increase in use of pigs, sheep, and cattle in 2003 was mainly associated with procedures for the purpose of direct diagnosis of disease and applied studies into veterinary medicine. The large increase of some 6,500 procedures using quail (not *C. coturnix*) was accounted for predominantly by testing of agrochemicals relating to ecotoxicology.

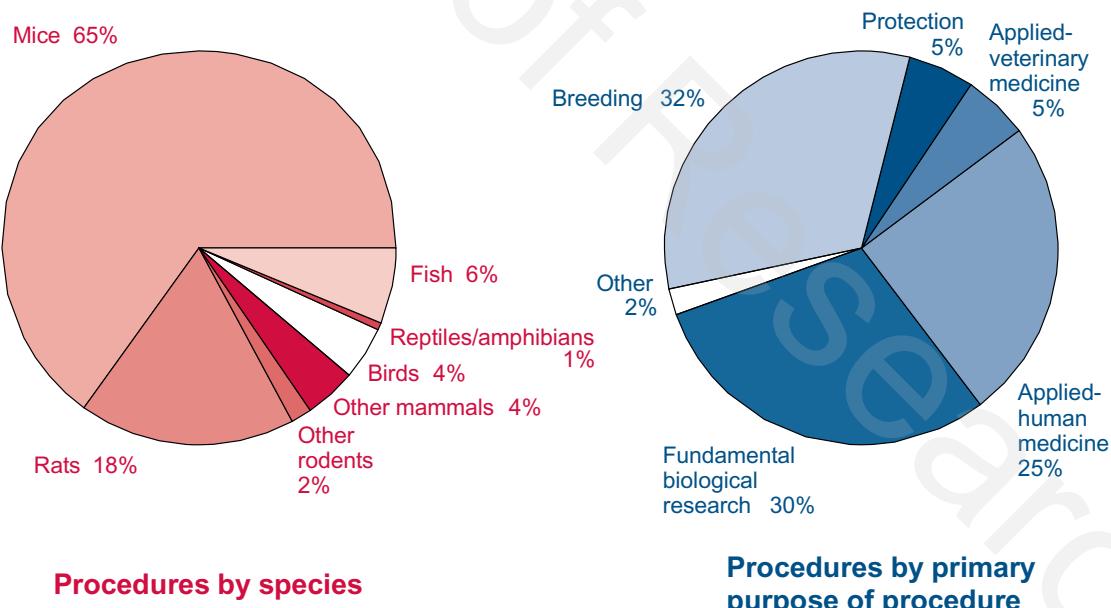
There was an increase in use of new world primates by about 29 per cent, but the numbers of procedures are not dissimilar to levels obtaining in recent years before 2002. Although the numbers of procedures involving non-human primates increased in 2003, the actual number of animals (used for the first time) fell by 100 from the 2002 figure. This is in line with a declining trend; since 1995 there has been a 24 per cent fall in the number of such animals. Many primates are re-used since 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 2003 the 'other carnivore' category included badgers, weasels, foxes and seals, all used for research relevant to those species. The 'other mammals' included species such as bats, voles and various types of shrew.

There were decreases in procedures using most species, but notably guinea pigs (down 12,100 procedures on 2002), rabbits (down 5,000), in both cases part of a long term trend; rats (down 13,200), fowl (down 22,300), fish (down 8,000), dogs (down 870) and cats (down 153).

No procedures were performed in 2003 on greyhound dogs, camelids, non-specific ungulate species, 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.

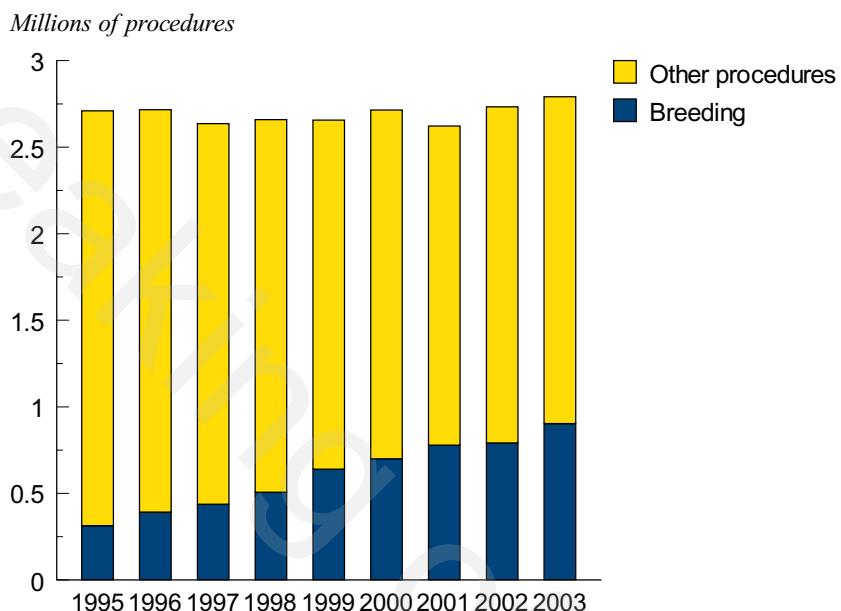


**Figure 2: Procedures by species of animal and primary purpose of procedure, 2003**

#### Primary purpose (Tables 1 and 1a, Tables 26 and 27, Figure 2)

In 2003, the main purposes for performing scientific procedures were for fundamental biological research, breeding, and applied studies into human medicine or dentistry. These accounted for 833,000 (30 per cent), 903,000 (32 per cent), and 694,000, (25 per cent) of the total number of procedures respectively.

Breeding procedures accounted for much of the overall rise in procedures in 2003; see figure 2A. There were rises in applied studies for human medicine and dentistry (up 24,000), breeding (up 111,000), and procedures undertaken for the direct diagnosis of disease, which rose by 14,500 or 35 per cent, continuing an increase from the low point in 2001 for that category. Procedures for fundamental biological research were down 31,000 or 4 per cent on 2002; there were also decreases in procedures directed towards veterinary medicine (down 24,000) and protection of man, animals or the environment (down 34,000). Numbers of procedures for fundamental biological research and applied studies in veterinary medicine have been fluctuating over the last seven years. Downward trends continued for procedures directed towards education and training.



**Figure 2A: Breeding, and other procedures, 1995-2003**

**Source** (Tables 2, 2.1 and 2.2)

In 2003, 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 (2.31 million) of procedures carried out on animals listed in Schedule 2 used animals acquired from designated establishments in the United Kingdom, 58 per cent from the user's own establishment, and 41 per cent from another designated establishment. The number of procedures involving Schedule 2 listed animals obtained from sources outside the EU in 2003 rose by 2,630 to 15,850 and of these, almost all (15,200) were performed on animals obtained from outside Europe (67 per cent of which were mice). Thirty eight 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 about a third 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. Eighty five per cent of harmful mutant and 93 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, ferrets and rabbits 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 included all categories of dog except greyhound. 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 fall in 2003 of 340 procedures using imported dogs from the previous year.

Some 393,000 procedures, down 7,600 (2 per cent) on 2002, were performed on species not listed in Schedule 2. This number has shown fluctuations in recent years.

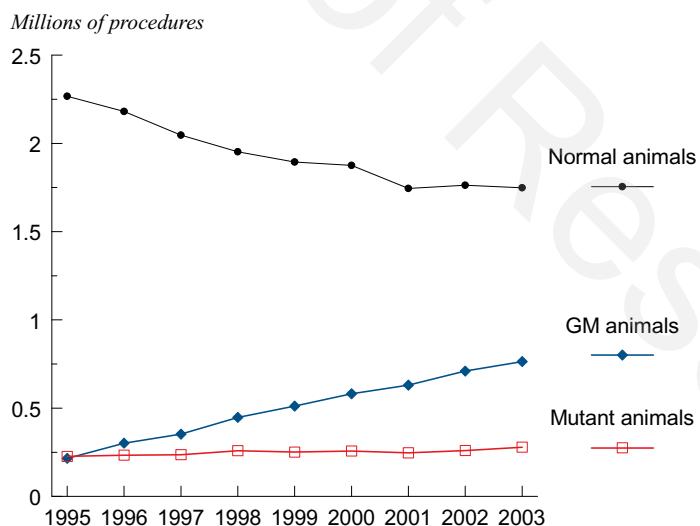
#### **Genetic status (Tables 3, 3.1, 3.2, 3.3, Table 27, figure 2B)**

##### **Genetically normal animals (Tables 3, 3.1)**

Just over five out of every eight procedures started in 2003 involved normal animals; these were down 14,000 on 2002. In the longer term, the use of genetically normal animals has decreased from 2.27 million in 1995 to 1.75 million, a drop of 23 per cent over this period. Table 3.1 shows normal animals used only in breeding programmes. Nearly all these animals were mice (98 per cent), the remainder being rats, other rodents, pigs, sheep, fish, birds, and amphibians. Comparison with 2002 shows similar use to that year.

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

Some 279,000 procedures (10 per cent of all procedures) started in 2003 involved animals with a naturally occurring harmful genetic defect, 19,000 more than in 2002. Use of such animals has risen from 8 per cent of all procedures in 1995 to just under 10 per cent now. The animals used in 2003 were mostly mice (82 per cent), rats (11 per cent), and fish (7 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. The fish and amphibia were bred and/or used mainly for fundamental research. The procedures involving cats and 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 2002. About 32 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, 1995-2003**

##### **Genetically modified animals (Tables 3, 3.3)**

The use of genetically modified (GM) animals was identified as a separate category for the first time in 1990; this category accounted for some 764,000 procedures in 2003, 54,000 (7 per cent) more than in 2002. More than a quarter of all procedures in 2003 involved genetically modified animals, and 97 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 in 2003. There was an increase in GM mouse use across almost all areas, while GM rat use conversely declined across all areas. No GM pigs

were used in 2003, and GM sheep use declined by about half. There were rises in the number of procedures using GM birds (fowl), amphibians and fish. The regulated use of GM animals has more than trebled since 1995 and in percentage terms now represents about 27 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. Table 3.3 shows that the pattern of species and use of GM animals is broadly similar to last year, with increases in all areas except the use of rats, ungulates and rabbits, which has fallen (there was no GM rabbit use at all in 2003). About 65 per cent of GM animals (500,000) were used to maintain the breeding colony only, and 32 per cent (246,000) used for further scientific purposes. Fewer than one half of one per cent were used in toxicology procedures.

#### **Target body system (Table 4a)**

In 2003, just over three fifths of all procedures were directed towards a particular body system. The largest single category was the immune system, accounting for 18 per cent, or 489,000 procedures. The next largest was the nervous system (15 per cent, 408,000 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 roughly equally. The main trends are that procedures directed towards the cardiovascular, respiratory and alimentary systems have tended to fall in recent years; those directed towards the immune system and the senses (in the latter case, from a low base) have tended to rise; while numbers of procedures directed towards other body systems have fluctuated. About 18 per cent of all procedures in 2003 were directed towards more than one body system, and nearly 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 over 60 per cent of procedures did not use anaesthesia. Local anaesthesia was used in 311,000 procedures (up 54,000 from the year 2002, and about 11 per cent of the total), mainly in mice (296,000—usually for tissue collection for genetic analysis). Anaesthesia without recovery was used in 266,000 procedures, about 9.5 per cent of the total (down 21,000 from the year 2002).

Neuromuscular blocking agents (NMBA) were reported in 3,400 procedures, less than one sixth of one per cent of procedures, all of these in conjunction with general anaesthesia. Seven out of every eight of these procedures were carried out under general anaesthesia without recovery. Just over half 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 2.34 million procedures, in which 2.29 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 2003. There was a rise of 97,000 in the number of such procedures and of 103,000 in the number of animals used, compared with 2002, reflecting the rise in the overall number of procedures. About one third of this increase was due to a rise in the use of ungulates other than equids after a dip to 26,000 in 2001. Of the procedures started in 2003, 1.62 million (69 per cent) were performed on mice and 353,000 (15 per cent) on rats; 103,000 (4 per cent) on birds (mainly domestic fowl) and 121,000 (5 per cent) on fish. A total of 2,100 procedures used dogs, 1,200 used cats and 1,260 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 422,000 procedures (18 per cent of all non-toxicology procedures), mainly on rodents, though a wide range of species was used. Pharmaceutical research and development (400,000) and cancer research

(277,000) represented around 17 and 12 per cent of this total respectively; a range of species was used in pharmaceutical research, but mice and rats accounted for all but one per cent of the procedures carried out for cancer research. Anatomy, 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 2002 were: anatomy (up 12,000, a 6 per cent rise, following a rising trend); physiology (up 24,000 or 13 per cent, also a rising trend), biochemistry (up 15,000), pharmaceutical research and development (up 35,000), genetics (up 19,000, a rising trend), cancer research (up 19,000), animal science (up 11,000), and ecology (up 10,000, a rising trend). In the latter three cases, numbers of procedures have fluctuated in recent years. Decreases were reported in procedures for parasitology (down 30,000, a drop of 22 per cent, reversing the rise in 2002), pharmacology (down 5,000), therapeutics (down 4,000) and non-specific research (down 15,500), the last two categories declining from recent peaks.

Animals with harmful genetic defects (Table 5.1) were used across a wide range of disciplines, but none were used for clinical surgery, dentistry, zoology, botany, animal science, ecology, animal welfare and research related to the use of tobacco or alcohol. The principal disciplines for which such animals were used were: cancer research (82,000 or 30 per cent of all procedures involving animals with harmful mutations); physiology (38,000, or 14 per cent); anatomy (35,100 or 13 per cent); genetics (31,000, 11 per cent), and 'other' use (i.e. disciplines not otherwise specified), 36,500 or 13 per cent.

There was a broadly similar spread of disciplines involving genetically modified animals (Table 5.2). The greatest use was for immunology (230,000 or 30 per cent of procedures using GM animals), cancer research (104,000 or 14 per cent) and anatomy, which includes developmental biology (105,000 or 14 per cent). Procedures for all disciplines showed increases from 2002 except for therapeutics, clinical surgery and non-specified work. No procedures using GM animals were performed for the disciplines of dentistry, clinical surgery, zoology, botany, ecology, animal welfare, or tobacco research.

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

In 2003 some 272,000 procedures, 43,000 fewer than in 2002, were for the purposes of production of biological materials. Of these, about 36 per cent were for the production of infectious agents and, of this particular group, 62 per cent used birds and a further 31 per cent used mice. Vectors, neoplasms and polyclonal antibodies accounted for a further 14 per cent; here, rodents were the main animals used except for polyclonal antibody production, where a wider range of species was used. The remaining 48 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 modest rise of 46 to 4,370. No procedures were performed during 2003 using the ascites model.

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

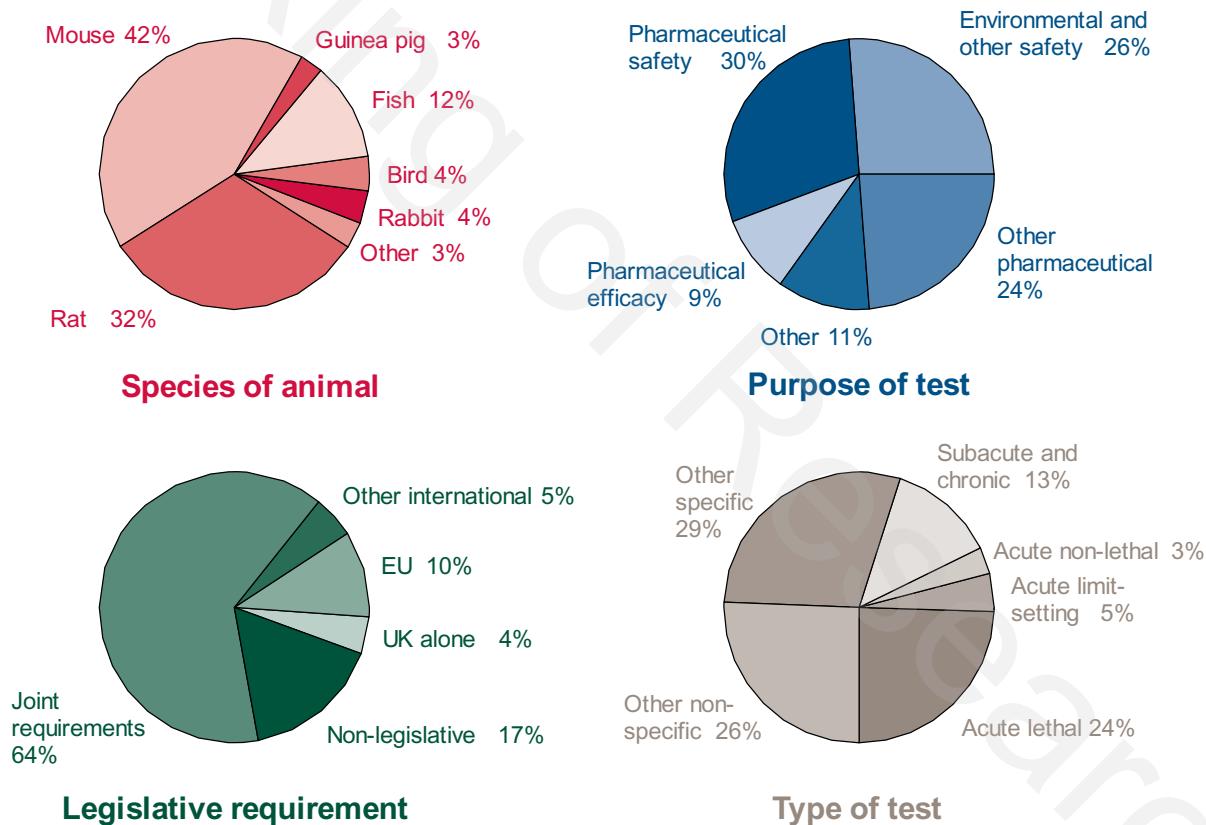
Among non-toxicological work, certain procedures have been identified as being of particular interest. These have been described above in paragraph 15A(iii) of the introductory notes. About 164,000 procedures, representing 7 per cent of non-toxicological procedures, fell into this category in 2003, about 5,600 more than the number reported in 2002. The number of these procedures has fluctuated from year to year since this category of procedure was separately identified in 1995. There were some increases, principally in procedures involving physical trauma (up 7,000), psychological stress (up 6,800 on 2002) and aversive training (up 3,600); but there were also decreases, including procedures involving injection into the brain (down 10,400) and those involving interference with the brain (down 3,600). Physical trauma procedures used mainly rodents, but procedures involving psychological stress also used fish. Aversive training mainly involved mice, rats and birds. The physical trauma category included studies on conditions such as stroke and atherosclerosis.

## TOXICOLOGY OR OTHER SAFETY OR EFFICACY EVALUATION

### Purpose (Tables 10, 10a, Table 25 and Figure 3)

Procedures for the purpose of toxicology or safety and efficacy evaluation accounted for 448,000, or just over 16 per cent, of the total number of procedures carried out in 2003. This was about 38,000 fewer than in 2002. This decrease was almost exactly reflected in a similar fall (37,000) in the number of animals used for the first time, to 436,000.

Of those procedures started in 2003, 189,000 (42 per cent) used mice; a further 143,000 (32 per cent) used rats, and other rodents were used in 13,100 procedures (3 per cent). Some 53,000 (12 per cent of the total) used fish; 17,500 used rabbits; birds were used in 18,000 procedures, and dogs (beagles) in 5,000. Other species accounted for just under two per cent of all toxicology procedures; 3,500 used non-human primates but only 8 used cats. Species for which there was a fall in the number of toxicological procedures in 2003 included: rats (down 25,000, or 15 per cent); guinea pigs (down 10,000), rabbits (down 2,200), beagle dogs (down 840) and fish (down 14,000). There were some species with an increase in use: procedures on mice rose 8,200, or 5 per cent; pigs (up 720), new world monkeys (up 180), old world monkeys (up 490) and birds (up 7,100). There was actually an overall decrease of 70 in the number of non-human primates (used for the first time), a decrease of 224 in old world monkeys being offset by an increase of 154 in new world monkeys. The non-human primates were used mainly for pharmaceutical safety.



**Figure 3: Procedures (toxicology) by species of animal, purpose of test, legislative requirement and type of test, 2003**

Only about one in every 280 procedures involving genetically modified animals was carried out for toxicology, and nearly all of the animals so used were mice, with a few rats (see Table 3.3). A broadly similar picture emerged in the case of animals with harmful genetic defects (Table 3.2).

Pharmaceutical safety and efficacy evaluation accounted for 63 per cent of toxicology procedures in 2003. The next most common purposes were safety evaluation of substances used in agriculture (40,000) and in industry (36,000), and evaluation of environmental pollution (33,000).

There were decreases in most types of procedures, but particularly those concerned with the safety of substances used in agriculture (down 18,000), and pharmaceutical efficacy testing (down 15,000) and, to a lesser extent, pharmaceutical safety testing (down 4,700), substances used in industry (down 6,200), and environmental pollution (down 5,400). A few categories showed a rise in the number of procedures; those for pharmaceutical quality control were up 3,700 (18 per cent); method development (up 5,600), pharmaceutical ADME and residue testing, up 2,300, and safety of food additives, up 2,800.

In November 1997 the Government announced that no further licences would be issued for cosmetic finished-product 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 2003. 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)**

Of the total of 448,000 toxicology or safety procedures in 2003, 83 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; about 46,000 (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 23,000 (5 per cent) for other international legislation. The majority of procedures performed to fulfil legislative requirements (285,000, or 64 per cent) were used to satisfy a combination of the above requirements. The remaining 74,000 procedures, 17 per cent of toxicology and safety work (and a rise of 10,000 procedures from 2002), were performed for purposes other than direct legislative or regulatory requirements.

#### **Type of test (Tables 12, 13, 15, 16)**

*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 2003 acute quantitative lethal toxicity tests accounted for 89,000 procedures or 20 per cent of all toxicology work. Tests were reported in this category for the following purposes: pharmaceutical safety, efficacy, and 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 tests was carried out according to OECD Guideline 401. The acute lethal toxicity tests included testing of biopharmaceuticals and food safety tests. Acute lethal concentration tests accounted for 20,700 procedures (5 per cent of all toxicology), and acute limit-setting lethal toxicity tests another 20,400 procedures (5 per cent). There was an overall decrease in the use of procedures for acute safety testing from 158,000 in 2002 to 144,000 in 2003.

A further 38,000 (8.5 per cent) were carried out for subacute limit-setting or subacute toxicity tests. This was 12,900 less than in 2002. Of the remainder, other, non-specified, toxicological tests (mainly using mice and rats) accounted for the greatest single proportion with 115,000 procedures (26 per cent of the total), a rise of about 1,100 on 2002. 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 9,600 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 non-crystalloid substances for intravenous injection into humans; a further 1,110 procedures carried out on rabbits to test for clinical signs in the eye (160 fewer than in 2002); 53,000 procedures, of which 73 per cent were on rats, to test for reproductive toxicity; and 11,000 procedures on rodents to test for skin sensitisation, mainly on mice and guinea pigs used for the safety testing of products used in agriculture and industry.

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 38,400 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 a 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 2002: environmental and industrial safety down 27,400, pharmaceutical safety down 14,100, but other safety was up 3,400.

#### Rodenticide trials

It is impractical to collect accurate figures on the number of animals affected in field trials of rodenticidal substances. In 2003, a single project licence holder made a positive return, estimating that a total of 25 wild rodents were involved. This figure is not included in the tables.

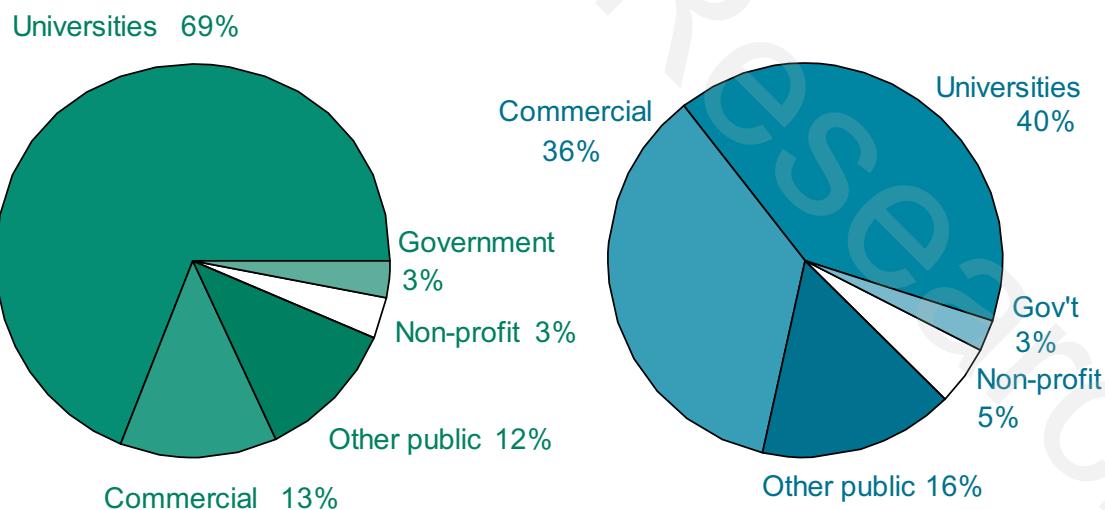
#### Use of animals in CITES list

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). The only procedures performed in 2003 on animals in this category were 168 procedures on wildfowl, directed towards the conservation of those species.

#### 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

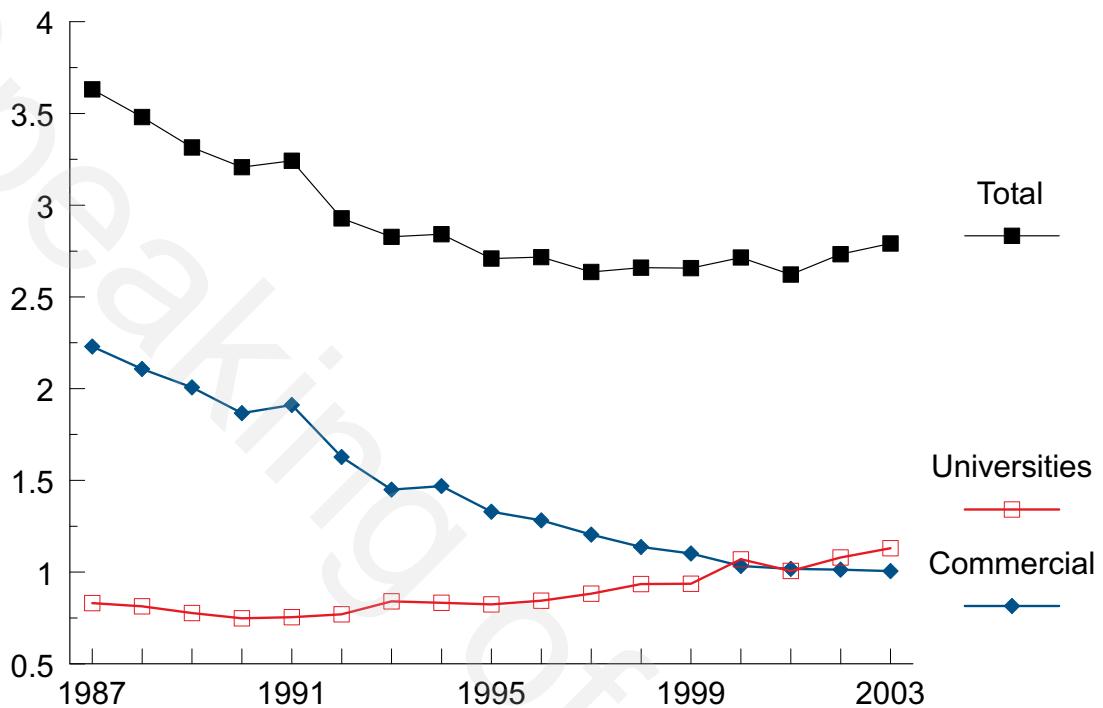


**Figure 4: Project licence holders and procedures started in 2003, by type of designated place** (note: only those project licence holders reporting procedures in 2003 are included)

## Returns (Table 19)

Returns were received in respect of 3,940 project licences in 2003. Returns were received from every licensee. Just over 2,800 licensees reported starting procedures in 2003, some 10 more than in 2002. Of these, about 2,100 (75 per cent, similar to the proportion in 2002), reported starting more than 50 procedures. The holders of about 1,100 project licences (28 per cent of all licensees) reported starting no procedures in 2003 (Table 19). This was very similar to the position in 2002.

### *Millions of procedures*



**Figure 5: Procedures by type of establishment, 1987-2003.** 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).

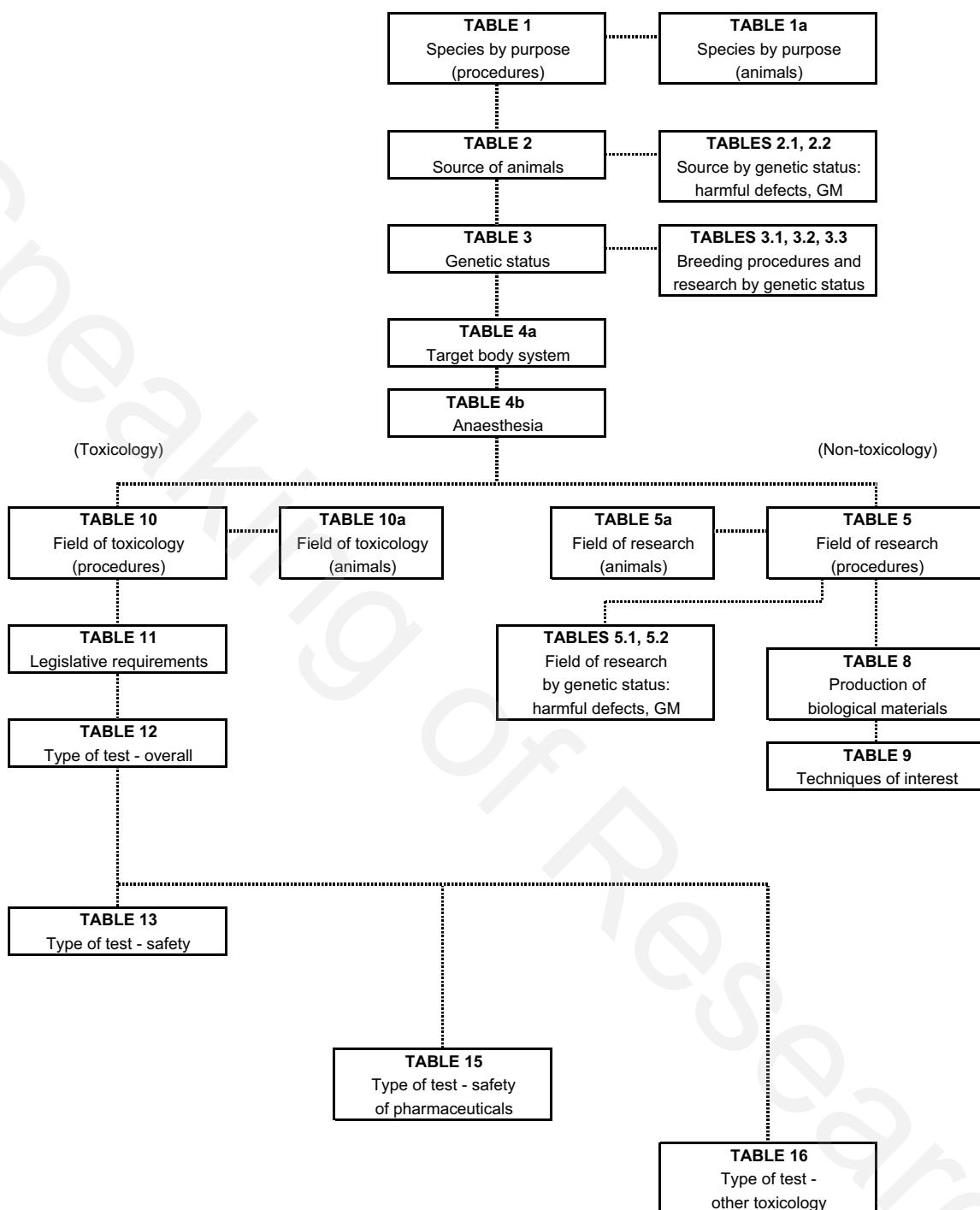
## Project licensees and designated places (Table 19, Table 23, Figures 4 and 5)

Sixty nine per cent of the projects on which procedures were started were based at universities or other academic establishments (including medical schools) but they accounted for only just over 40 per cent of the number of procedures. Projects at commercial organisations reported 36 per cent of the procedures started in 2003, and accounted for 13 per cent of all projects reporting procedures (Table 19 and Figure 4). 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 40 per cent. The proportion of procedures carried out by commercial licensees has fallen from 60 per cent in 1987 to 36 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 although it fell to just below the level reported by commercial firms in 2001, overtook it once again in 2002 (see Figure 5). The fall in the number of procedures carried out by commercial licensees has been largely responsible for the overall fall in the total number of procedures over recent years, but the rise in the number of procedures conducted in universities and non-governmental public bodies has contributed to the overall rise in the number of procedures in 2003 (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 the not-for-profit sector appears to have peaked in 2001.

## Historical tables

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

## Organisation Chart: Relationship between the tables in part A, 2003



### 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 table

**Table 1 Scientific procedures by species of animal and primary purpose of the procedure**

Species of animal	Fundamental biological research	Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Primary purpose of the procedure				Total
				Protection of man, animals or environment	Education	Training	Forensic enquiries	
Mammal								
Mouse	553,039	354,089	23,211	28,871	1,195	-	-	7,567
Rat	127,700	277,002	1,701	64,766	740	-	-	107
Guinea pig	2,803	25,640	1,583	2,832	466	-	-	128
Hamster	2,350	948	799	-	-	-	-	11
Gerbil	1,829	5,609	6	-	-	-	-	299
Other rodent	1,838	-	-	-	-	-	-	-
Rabbit	2,539	15,736	1,394	2,934	78	-	-	923
Cat	147	17	1,077	-	-	-	-	2,212
Dog	42	5,695	140	667	-	-	-	433
Beagle	-	-	-	-	-	-	-	1
Greyhound	-	-	-	-	-	-	-	1,242
Other including cross-bred dogs	7	-	219	-	-	-	-	-
Ferret	119	923	3	113	-	-	-	323
Other carnivore	1,112	-	251	-	-	-	-	-
Horse, donkey and cross-bred equids	205	-	716	-	-	-	-	-
Pig	5,126	864	1,181	316	-	-	-	42
Goat	366	18	26	9	-	-	-	42
Sheep	9,574	426	6,810	129	9	-	-	9
Cattle	4,499	-	2,882	62	-	-	-	3
Deer	135	-	-	-	-	-	-	21,136
Camelid	-	-	-	-	-	-	-	8,735
Other ungulate	-	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-
New World monkey	336	-	-	-	-	-	-	-
marmoset, tamarin	-	795	-	-	-	-	-	17
Squirrel, owl, spider monkey	-	67	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-
								1,148
								67
								-

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

Species of animal	Number of procedures						Total
	Fundamental biological research	Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Protection of man, animals or environment	Education	Training	
Old World monkey	119	2,725	-	740	-	-	-
Macaque	-	-	-	-	-	-	3,584
Baboon	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-
Other mammal	1,242	80	-	353	-	-	1,737
Bird	25,487	140	74,024	263	242	-	-
Domestic fowl ( <i>Gallus domesticus</i> )	802	50	1,134	-	-	-	-
Turkey	140	-	-	-	-	-	-
Quail ( <i>Coturnix coturnix</i> )	141	-	-	6,959	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i> )	8,043	-	855	379	-	-	-
Other bird	-	-	-	-	-	-	-
Reptile	121	1,467	-	-	-	-	-
Any reptilian species	12,308	-	-	-	-	-	1,588
Amphibian	-	-	-	-	-	-	-
Any amphibian species	-	-	-	-	-	-	14,985
Fish	70,757	1,452	32,667	42,025	-	-	-
Any fish species	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-
Total	832,926	693,743	150,679	151,448	3,671	883	45
							55,816
							902,570
							2,791,781

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

Species of animal	Fundamental biological research	Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Primary purpose of the procedure Protection of man, animals or environment	Education	Training	Forensic enquiries	Direct diagnosis	Number of animals	
									Total	Breeding
Mammal										
Mouse	548,387	353,493	23,211	28,853	1,195	-	-	7,491	847,165	1,809,795
Rat	125,532	269,125	1,701	64,766	728	883	-	107	23,520	486,362
Guinea pig	2,803	25,442	1,583	2,832	133	-	-	101	-	32,894
Hamster	1,942	948	799	-	-	-	-	11	299	3,999
Gerbil	1,112	5,391	6	-	-	-	-	-	-	6,509
Other rodent	1,838	-	-	30	-	-	-	923	-	2,791
Rabbit	2,401	8,088	977	2,910	52	-	-	2,149	433	17,010
Cat	134	17	395	-	-	-	-	-	1	547
Dog	39	4,106	115	583	-	-	-	141	-	4,984
Beagle	-	-	-	-	-	-	-	-	-	-
Greyhound	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	7	-	96	-	-	-	-	1	-	104
Ferret	119	921	3	251	105	-	11	-	29	-
Other carnivore	1,112	-	-	-	-	-	-	-	1,083	1,468
Horse, donkey and cross-bred equids	37	-	260	-	-	11	-	-	-	-
Pig	5,114	798	1,177	316	-	-	-	97	-	405
Goat	307	18	26	9	-	-	-	3,979	14	11,398
Sheep	9,448	292	6,719	129	9	-	-	9	-	369
Cattle	4,146	-	2,879	62	-	-	-	3	1,022	17,906
Deer	135	-	-	-	-	-	-	8,735	-	15,822
Camelid	-	-	-	-	-	-	-	-	-	135
Other ungulate	-	-	-	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-	-	-	-
marmoset, tamarin	-	-	-	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-	-	-
	280	456	-	-	-	-	-	-	17	-
									753	-

**Table 1a Animals by species of animal and primary purpose of the procedure (Continued)**

Species of animal	Number of animals				
	Fundamental biological research	Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Protection of man, animals or environment	Total
Old World monkey	85	1,735	-	500	-
Macaque	-	-	-	-	2,320
Baboon	-	-	-	-	-
Other Old World monkey	-	-	-	-	-
Apes	-	-	-	-	-
Gibbon	-	-	-	-	-
Great ape	-	-	-	-	-
Other mammal	1,242	80	-	353	1,737
Bird	-	-	-	-	-
Domestic fowl ( <i>Gallus domesticus</i> )	24,638	140	74,024	242	454
Turkey	802	6	1,134	-	24
Quail ( <i>Coturnix coturnix</i> )	140	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i> )	141	-	6,959	-	-
Other bird	8,043	-	704	-	446
Reptile	-	-	-	-	-
Any reptilian species	105	11	-	-	116
Amphibian	-	-	-	-	-
Any amphibian species	6,621	-	-	-	9,288
Fish	-	-	-	-	-
Any fish species	70,667	1,452	32,319	42,025	174
Cephalopod	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-
Total	817,377	672,519	148,379	151,064	3,300
					883
					3
					27,243
					900,831
					2,721,599

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

Species of animal	Animals acquired from within own designated establishment	Source				Total
		Animals acquired from another designated breeding or supplying establishment in the UK	Animals acquired from non-designated sources in the UK	Animals within the EU (outside the UK)	Animals acquired from other sources who are signatories to ETS123	
Mouse	1,264,555	536,271	197	5,358	275	1,816,866
Rat	106,248	387,381	713	500	397	496,419
Guinea pig	612	31,845	-	965	-	33,452
Hamster	1,499	2,328	-	580	-	4,407
Gerbil	1,778	4,882	-	733	-	7,444
Rabbit	5,229	19,897	102	98	-	25,326
Cat	713	120	-	409	-	1,242
Dog	2,421	3,810	110	50	-	7,094
Ferret	77	995	-	-	13	1,085
Pig (genetically modified)	-	-	-	-	-	-
Sheep (genetically modified)	254	-	-	-	-	254
Primate	805	1,026	-	-	-	4,799
Quail ( <i>Coturnix coturnix</i> )	-	140	-	-	-	140
Animals not listed	-	-	-	-	-	393,253
Total	1,384,191	988,695	1,122	8,693	672	393,253
						2,791,781

**Table 2.1 Scientific procedures by Schedule 2 listed species and source of animals  
(animals with a harmful genetic defect)**

Great Britain 2003

Species of animal	Animals acquired from within own designated establishment	Animals acquired from another designated breeding or supplying establishment in the UK	Source			Animals not listed in schedule 2 <sup>(1)</sup>	Total
			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		
Mouse	207,973	18,047	-	225	-	1,812	-
Rat	27,429	1,402	-	188	-	403	228,057
Guinea pig	-	-	-	-	-	-	29,422
Hamster	-	-	-	-	-	-	-
Gerbil	-	-	-	-	-	-	-
Rabbit	433	116	-	-	-	-	549
Cat	1	-	-	-	-	-	-
Dog	9	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-
Quail ( <i>Coturnix coturnix</i> )	-	-	-	-	-	-	-
Animals not listed	-	-	-	-	-	-	-
Total	235,845	19,565	-	413	-	2,215	20,764
							278,802

(1) The "animals not listed in Schedule 2" here were 172 domestic fowl, 1,017 amphibians and 19,575 fish.

**Table 2.2 Scientific procedures by Schedule 2 listed species and source of animals (genetically modified animals)**

Great Britain 2003

Species of animal	Animals acquired from within own designated establishment	Animals acquired from another designated breeding or supplying establishment in the UK	Source			Animals not listed in schedule 2 (1)	Total
			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		
Mouse	710,105	25,994		2,712	39	5,046	-
Rat	1,981	343		16	-	-	2,340
Guinea pig	-	-		-	-	-	-
Hamster	-	-		-	-	-	-
Gerbil	-	-		-	-	-	-
Rabbit	-	-		-	-	-	-
Cat	-	-		-	-	-	-
Dog	-	-		-	-	-	-
Ferret	-	-		-	-	-	-
Pig (genetically modified)	-	-		-	-	-	-
Sheep (genetically modified)	254	-		-	-	-	254
Primate	-	-		-	-	-	-
Quail ( <i>Coturnix coturnix</i> )	-	-		-	-	-	-
Animals not listed	-	-		-	-	-	-
Total	712,340	26,337		2,728	39	5,046	17,605
							764,095

(1) The "animals not listed in Schedule 2" here were 246 domestic fowl, 1,371 amphibians and 15,988 fish.

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

Great Britain 2003		Number of procedures			
Species of animal	Primary purpose of procedure	Genetic status			Total
		Normal animal	Animal with harmful genetic defect	Genetically modified animal	
Mouse	Fundamental biological research	298,322	37,591	217,126	553,039
	Applied studies	318,749	35,241	23,310	377,300
	Safety	28,737	90	44	28,871
	Other uses	7,959	369	434	8,762
	Breeding	191,146	154,766	502,982	848,894
	Total	844,913	228,057	743,896	1,816,866
Rat	Fundamental biological research	123,744	2,925	1,031	127,700
	Applied studies	273,136	5,299	268	278,703
	Safety	64,760	-	6	64,766
	Other uses	1,730	-	-	1,730
	Breeding	1,287	21,198	1,035	23,520
	Total	464,657	29,422	2,340	496,419
Guinea pig	Fundamental biological research	2,803	-	-	2,803
	Applied studies	27,223	-	-	27,223
	Safety	2,832	-	-	2,832
	Other uses	594	-	-	594
	Breeding	-	-	-	-
	Total	33,452	-	-	33,452
Hamster	Fundamental biological research	2,350	-	-	2,350
	Applied studies	1,747	-	-	1,747
	Safety	-	-	-	-
	Other uses	11	-	-	11
	Breeding	299	-	-	299
	Total	4,407	-	-	4,407
Gerbil	Fundamental biological research	1,829	-	-	1,829
	Applied studies	5,615	-	-	5,615
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	7,444	-	-	7,444
Other rodent	Fundamental biological research	1,838	-	-	1,838
	Applied studies	-	-	-	-
	Safety	30	-	-	30
	Other uses	923	-	-	923
	Breeding	-	-	-	-
	Total	2,791	-	-	2,791
Rabbit	Fundamental biological research	2,539	-	-	2,539
	Applied studies	17,014	116	-	17,130
	Safety	2,934	-	-	2,934
	Other uses	2,290	-	-	2,290
	Breeding	-	433	-	433
	Total	24,777	549	-	25,326
Cat	Fundamental biological research	147	-	-	147
	Applied studies	1,094	-	-	1,094
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	1	-	1
	Total	1,241	1	-	1,242
Dog - Beagle	Fundamental biological research	42	-	-	42
	Applied studies	5,835	-	-	5,835
	Safety	667	-	-	667
	Other uses	323	-	-	323
	Breeding	-	-	-	-
	Total	6,867	-	-	6,867
Dog - Other	Fundamental biological research	7	-	-	7
	Applied studies	211	8	-	219
	Safety	-	-	-	-
	Other uses	-	1	-	1
	Breeding	-	-	-	-
	Total	218	9	-	227
Ferret	Fundamental biological research	119	-	-	119
	Applied studies	926	-	-	926
	Safety	-	-	-	-
	Other uses	40	-	-	40
	Breeding	-	-	-	-
	Total	1,085	-	-	1,085

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

Great Britain 2003					Number of procedures
Species of animal	Primary purpose of procedure	Genetic status			Total
		Normal animal	Animal with harmful genetic defect	Genetically modified animal	
Other carnivore	Fundamental biological research	1,112	-	-	1,112
	Applied studies	251	-	-	251
	Safety	113	-	-	113
	Other uses	-	-	-	-
	Breeding	-	-	-	-
Total		1,476	-	-	1,476
Horse, Donkey etc	Fundamental biological research	205	-	-	205
	Applied studies	716	-	-	716
	Safety	-	-	-	-
	Other uses	7,958	-	-	7,958
	Breeding	-	-	-	-
Total		8,879	-	-	8,879
Pig	Fundamental biological research	5,126	-	-	5,126
	Applied studies	2,045	-	-	2,045
	Safety	316	-	-	316
	Other uses	3,979	-	-	3,979
	Breeding	14	-	-	14
Total		11,480	-	-	11,480
Goat	Fundamental biological research	366	-	-	366
	Applied studies	44	-	-	44
	Safety	9	-	-	9
	Other uses	9	-	-	9
	Breeding	-	-	-	-
Total		428	-	-	428
Sheep	Fundamental biological research	9,574	-	-	9,574
	Applied studies	7,220	-	16	7,236
	Safety	129	-	-	129
	Other uses	21,148	-	-	21,148
	Breeding	46	-	238	284
Total		38,117	-	254	38,371
Cattle	Fundamental biological research	4,499	-	-	4,499
	Applied studies	2,882	-	-	2,882
	Safety	62	-	-	62
	Other uses	8,735	-	-	8,735
	Breeding	-	-	-	-
Total		16,178	-	-	16,178
Deer	Fundamental biological research	135	-	-	135
	Applied studies	-	-	-	-
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
Total		135	-	-	135
Other ungulate	Fundamental biological research	-	-	-	-
	Applied studies	-	-	-	-
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
Total		-	-	-	-
Marmoset, Tamarin	Fundamental biological research	336	-	-	336
	Applied studies	795	-	-	795
	Safety	-	-	-	-
	Other uses	17	-	-	17
	Breeding	-	-	-	-
Total		1,148	-	-	1,148
Squirrel, Owl or Spider monkey	Fundamental biological research	-	-	-	-
	Applied studies	67	-	-	67
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
Total		67	-	-	67
Macaque	Fundamental biological research	119	-	-	119
	Applied studies	2,725	-	-	2,725
	Safety	740	-	-	740
	Other uses	-	-	-	-
	Breeding	-	-	-	-
Total		3,584	-	-	3,584

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

Great Britain 2003					Number of procedures
Species of animal	Primary purpose of procedure	Genetic status			Total
		Normal animal	Animal with harmful genetic defect	Genetically modified animal	
Other mammal	Fundamental biological research	1,242	-	-	1,242
	Applied studies	80	-	-	80
	Safety	353	-	-	353
	Other uses	62	-	-	62
	Breeding	-	-	-	-
	Total	1,737	-	-	1,737
Domestic fowl	Fundamental biological research	25,463	24	-	25,487
	Applied studies	74,164	-	-	74,164
	Safety	263	-	-	263
	Other uses	1,973	-	-	1,973
	Breeding	60	148	246	454
	Total	101,923	172	246	102,341
Turkey	Fundamental biological research	802	-	-	802
	Applied studies	1,184	-	-	1,184
	Safety	-	-	-	-
	Other uses	134	-	-	134
	Breeding	-	-	-	-
	Total	2,120	-	-	2,120
Quail ( <i>Coturnix coturnix</i> )	Fundamental biological research	140	-	-	140
	Applied studies	-	-	-	-
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	140	-	-	140
Quail (spp. other than <i>Coturnix coturnix</i> )	Fundamental biological research	141	-	-	141
	Applied studies	-	-	-	-
	Safety	6,959	-	-	6,959
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	7,100	-	-	7,100
Other bird	Fundamental biological research	8,043	-	-	8,043
	Applied studies	855	-	-	855
	Safety	379	-	-	379
	Other uses	633	-	-	633
	Breeding	-	-	-	-
	Total	9,910	-	-	9,910
Reptile	Fundamental biological research	121	-	-	121
	Applied studies	1,467	-	-	1,467
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	1,588	-	-	1,588
Amphibian	Fundamental biological research	11,641	-	667	12,308
	Applied studies	-	-	-	-
	Safety	-	-	-	-
	Other uses	919	-	-	919
	Breeding	37	1,017	704	1,758
	Total	12,597	1,017	1,371	14,985
Fish	Fundamental biological research	60,577	7,124	3,056	70,757
	Applied studies	33,668	-	451	34,119
	Safety	42,025	-	-	42,025
	Other uses	174	-	-	174
	Breeding	1,981	12,451	12,481	26,913
	Total	138,425	19,575	15,988	173,988
All species	Fundamental biological research	563,382	47,664	221,880	832,926
	Applied studies	779,713	40,664	24,045	844,422
	Safety	151,308	90	50	151,448
	Other uses	59,611	370	434	60,415
	Breeding	194,870	190,014	517,686	902,570
<b>TOTAL</b>		<b>1,748,884</b>	<b>278,802</b>	<b>764,095</b>	<b>2,791,781</b>

Species not listed had no procedures

# Speaking of Research

**Table 3.1 Procedures using genetically normal animals for the production and breeding of genetically modified or harmful mutant animals**

Species of animal	Generation of founder genetically modified animals	Normal animals within genetically modified breeding colonies	Normal animals within harmful mutant breeding colonies	Number of procedures Totals
Mouse	100,663	87,032	3,451	191,146
Rat	229	1,020	38	1,287
Other rodent	299	-	-	299
Rabbit	-	-	-	-
Cat	-	-	-	-
Dog	-	-	-	-
Ferret	-	-	-	-
Other carnivore	-	-	-	-
Horse and other equids	-	-	-	-
Pig	14	-	-	14
Sheep	46	-	-	46
Other ungulate	-	-	-	-
New World monkey	-	-	-	-
Old World monkey	-	-	-	-
Other mammal	-	-	-	-
Bird	60	-	-	60
Reptile / Amphibian	37	-	-	37
Fish	1,981	-	-	1,981
Total	103,329	88,052	3,489	194,870

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

Species of animal	Maintenance of breeding colony	Used for further non-regulated scientific purpose <sup>(1)</sup>	Used in further regulated procedures	Used in production and other procedures <sup>(2)</sup>	Used in safety evaluation studies <sup>(3)</sup>	Number of procedures Totals
Mouse	154,766	2,254	44,515	25,148	1,374	228,057
Rat	21,198	979	5,316	1,922	7	29,422
Other rodent	-	-	-	-	-	-
Rabbit	433	-	116	-	-	549
Cat	1	-	-	-	-	1
Dog	-	1	8	-	-	9
Ferret	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-
Old World monkey	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-
Bird	148	24	-	-	-	172
Reptile / Amphibian	1,017	-	-	-	-	1,017
Fish	12,451	61	7,063	-	-	19,575
Total	190,014	3,319	57,018	27,070	1,381	278,802

(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)

**Table 3.3 Procedures using genetically modified animals in breeding procedures or research**

Species of animal	Generation of founder animals	Maintenance of breeding colony	Used for further non-regulated scientific purpose <sup>(1)</sup>	Used in further regulated procedures	Used in production and other procedures <sup>(2)</sup>	Used in safety evaluation studies <sup>(3)</sup>	Total
Mouse	15,934	487,048	99,123	82,155	56,914	2,722	743,896
Rat	-	1,035	406	359	527	13	2,340
Other rodent	-	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-
Cat	-	-	-	-	-	-	-
Dog	-	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-
Pig	-	238	15	-	1	-	254
Sheep	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-
Old World monkey	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-
Bird	40	206	-	-	-	-	246
Reptile / Amphibian	128	576	-	36	631	-	1,371
Fish	1,252	11,229	2,997	-	510	-	15,988
<b>Total</b>	<b>17,354</b>	<b>500,332</b>	<b>102,541</b>	<b>82,550</b>	<b>58,583</b>	<b>2,735</b>	<b>764,095</b>

(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)

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

Species of animal		Number of procedures							
		Respiratory	Cardiovascular	Nervous	Senses	Alimentary	Skin	Musculo-skeletal	Body systems
<b>Great Britain 2003</b>									
Mammal									
Mouse	33,355	45,231	186,379	8,712	31,901	43,429	39,006	145,411	425,220
Rat	20,228	24,807	195,413	3,749	14,635	2,776	5,940	40,400	13,589
Other rodent	11,023	1,116	12,276	401	1,092	874	259	973	21,631
Rabbit	201	1,439	443	207	1,821	1,821	528	2,507	9,495
Cat	-	-	116	36	178	13	-	-	4,032
Dog	409	659	7	9	232	16	-	-	1,368
Ferret	696	127	85	53	14	-	-	-	2,507
Other carnivore	-	1	-	36	-	-	-	-	38
Horse, donkey and cross-bred equids	42	54	-	72	20	-	-	-	-
Other ungulate	1,025	3,046	1,680	-	3,011	331	529	2,109	-
Primate	-	258	289	12	1	-	-	-	-
New World monkey	33	99	301	4	72	-	-	-	-
Old World monkey	-	102	80	28	40	761	-	-	-
Other mammal	399	3,169	6,749	146	12,331	719	949	6,945	102
Bird	-	402	427	103	24	-	970	8,658	64,902
Reptile, amphibian	-	4,409	5	3,812	44	500	8,040	5,827	17,605
Fish	-	-	-	-	-	-	-	-	28,342
Total	71,790	80,515	408,057	13,540	64,395	58,800	54,008	224,932	488,663
									156,527
									494,467
									676,087
									2,791,781

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

Species of animal	No anaesthesia	General anaesthesia, with recovery	Local anaesthesia	Type of anaesthesia at end of procedure, without recovery	Number of procedures	
					General anaesthesia throughout, without recovery	Total
Mouse	1,102,908	317,873	296,100	73,718	26,267	1,816,866
Rat	290,220	119,684	3,473	43,581	39,461	496,419
Other rodent	28,809	12,218	256	4,361	2,450	48,094
Rabbit	17,771	1,589	807	3,598	1,561	25,326
Cat	1,053	30	-	38	121	1,242
Dog	4,787	513	429	331	1,034	7,094
Ferret	423	480	-	63	119	1,085
Other carnivore	629	839	-	8	-	1,476
Horse and other equids	451	4	8,413	-	11	8,879
Other ungulates	61,599	3,099	634	295	965	66,592
New World monkey	949	165	1	53	47	1,215
Old World monkey	2,609	927	32	8	8	3,584
Other mammal	968	87	627	45	10	1,737
Bird	60,268	500	-	60,659	184	121,611
Reptile / Amphibian	13,173	2,084	-	148	1,168	16,573
Fish	105,280	62,877	-	5,701	130	173,988
Total	1,691,897	522,969	310,772	192,607	73,536	2,791,781

Neuromuscular blocking agents (NMBA) were used in 3,409 procedures in 2003. All of these procedures involved the use of general anaesthesia.

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

Great Britain 2003		Number of procedures									
Species of animal		Field of research					Field of research				
		Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D
Mammal											
Mouse	163,985	131,902	31,200	16,479	33,153	387,350	41,368	33,736	32,941	174,192	10,510
Rat	15,619	46,314	12,164	11,156	4,067	9,317	1,539	2,914	24,529	197,538	2,570
Guinea pig	7	699	-	-	35	864	960	391	2,066	15,738	12
Hamster	326	254	187	6	148	733	77	1,094	52	143	11
Gerbil	-	-	-	983	-	201	310	245	-	5,609	-
Other rodent	-	1	-	14	-	-	18	14	-	-	-
Rabbit	15	1,004	315	-	203	3,271	745	155	117	790	281
Cat	11	72	-	-	14	38	106	13	43	274	11
Dog	-	-	13	-	-	-	64	-	-	-	-
Beagle	-	-	-	-	-	-	-	-	-	-	-
Greyhound	-	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	-	-	-	-	-	-
Ferret	9	93	-	17	-	104	311	-	61	483	-
Other carnivore	-	-	-	36	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids	11	115	-	-	-	419	7,920	-	169	88	-
Pig	49	356	66	889	164	523	498	-	-	240	52
Goat	-	75	-	-	-	19	26	164	-	2	294
Sheep	268	1,430	388	166	1,619	700	20,908	825	14	439	14
Cattle	60	882	-	14	24	1,922	388	1,190	9	117	40
Deer	11	-	-	10	27	-	-	-	-	-	170
Camelid	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-	-	-	-	-
marmoset, tamain	7	78	-	-	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-	-	-	-

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

Species of animal	Number of procedures												
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Old World monkey	1	38	-	7	-	88	72	-	-	-	234	-	-
Macaque	-	-	-	-	-	-	-	-	-	-	-	-	1
Baboon	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-	-	-	-
Other mammal	-	196	-	-	-	-	-	-	-	-	80	-	-
Bird	897	1,292	547	6,138	575	5,198	9,162	63,954	-	-	169	-	6
Domestic fowl ( <i>Gallus domesticus</i> )	37	-	-	-	-	15	232	2	-	-	717	-	-
Turkey	140	-	95	-	-	-	-	-	-	-	-	-	-
Quail ( <i>Coturnix coturnix</i> )	-	371	-	144	-	1,339	317	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i> )	-	-	-	-	-	-	-	-	-	-	-	-	-
Other bird	-	-	-	-	-	-	-	-	-	-	-	-	-
Reptile	86	6	-	-	-	-	-	-	-	-	-	-	-
Any reptilian species	-	-	-	-	-	-	-	-	-	-	-	-	-
Amphibian	10,058	1,555	752	-	-	-	-	-	-	-	332	32	-
Any amphibian species	-	-	-	-	-	-	-	-	-	-	-	-	-
Fish	36,317	13,586	620	2,009	14,269	10,312	10,140	1,905	-	-	1,522	-	-
Any fish species	-	-	-	-	-	-	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	227,914	200,427	46,239	38,189	54,298	422,482	95,097	106,602	60,546	400,392	13,773	11,400	2,196

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

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

Species of animal	Number of procedures												
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Other	Tobacco	Alcohol	Total
Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	441
Macaque	-	-	-	-	-	-	-	-	-	-	-	-	-
Baboon	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-	-	-	1,737
Other mammal	-	-	-	376	-	-	62	-	-	-	-	-	-
Bird	-	-	-	-	-	1,897	-	-	-	-	-	-	-
Domestic fowl ( <i>Gallus domesticus</i> )	-	-	-	-	-	88	-	-	-	-	-	-	-
Turkey	-	-	-	-	-	-	-	-	-	-	-	-	-
Quail ( <i>Coturnix coturnix</i> )	-	-	-	-	-	-	46	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i> )	-	-	-	-	-	8	5,181	-	-	-	-	-	-
Other bird	-	-	-	-	-	-	-	-	-	-	-	-	-
Reptile	-	-	-	-	-	-	-	-	-	-	-	-	-
Any reptilian species	-	-	-	-	-	-	18	-	-	-	-	-	121
Amphibian	-	-	-	-	-	-	-	-	-	-	-	-	-
Any amphibian species	-	-	-	458	628	-	20	-	-	-	-	-	14,985
Fish	-	-	-	-	-	-	-	-	-	-	-	-	-
Any fish species	-	-	514	138	-	1,881	956	-	-	-	-	-	121,222
Cephalopod	-	-	-	-	-	-	-	-	-	-	-	-	-
Octopus vulgaris	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	27	124,416	93,579	277,420	12,392	7,990	95	33,878	32,018	3,723	77,451	-	1,518
													2,344,062

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

Species of animal		Field of research										Number of animals															
		Anatomy		Physiology		Biochemistry		Psychology		Pathology		Immunology		Microbiology		Parasitology		Pharmacology		Pharmaceutical R&D		Therapeutics		Clinical medicine		Clinical surgery	
Mammal																											
Mouse	163,971	131,252	30,781	16,464	10,574	32,577	385,567	41,368	31,648	32,899	173,893	10,369	6,329	2,570	185,775	24,105	15,540	12	75	3,405	297	1,536					
Rat	15,615	46,155	699	-	-	4,067	9,317	1,539	2,374	58	2,066	15,540	11	50	-	-	-	-	-	-	-	-	-	-	-	-	
Guinea pig	7	254	187	6	148	35	864	933	77	823	52	143	11	50	-	-	-	-	-	-	-	-	-	-	-	-	
Hamster	326	-	-	266	-	201	-	310	245	-	5,391	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Gerbil	-	-	-	14	-	-	-	18	14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Other rodent	-	1	226	-	203	3,270	682	117	117	117	727	281	25	25	132	-	-	-	-	-	-	-	-	-	-	-	
Rabbit	15	998	-	-	14	38	90	-	43	43	259	11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Cat	11	72	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Dog	-	-	13	-	-	-	-	64	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Beagle	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Greyhound	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Other including cross-bred dogs	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Ferret	9	93	-	17	-	104	-	311	-	-	-	61	481	-	-	-	-	-	-	-	-	-	-	-	-	-	
Other carnivore	-	-	-	36	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Horse, donkey and cross-bred equids	11	32	-	-	-	27	111	-	-	-	-	25	88	-	-	-	-	-	-	-	-	-	-	-	-	-	
Pig	49	356	66	883	164	523	498	-	-	-	-	222	52	294	14	-	-	-	-	-	-	-	-	-	-	-	
Goat	-	16	-	-	19	26	164	-	26	-	2	-	6	8	-	-	-	-	-	-	-	-	-	-	-	-	
Sheep	268	1,335	388	166	1,819	567	1,241	803	14	295	167	125	-	-	-	-	-	-	-	-	-	-	-	-	-		
Cattle	60	830	-	14	24	1,920	388	1,190	9	117	40	170	-	-	-	-	-	-	-	-	-	-	-	-	-		
Deer	11	-	-	10	27	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Camelid	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Other ungulate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Primate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Prosimian	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
New World monkey	7	64	-	106	-	-	-	3	-	-	-	102	100	-	-	-	-	-	-	-	-	-	-	-	-		
marmoset, tamarin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Other New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		

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

Species of animal	Number of animals												
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Old World monkey	1	12	-	7	-	87	67	-	-	25	-	-	1
Macaque	-	-	-	-	-	-	-	-	-	-	-	-	-
Baboon	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-	-	-	-
Other mammal	-	196	-	-	-	-	-	-	-	80	-	-	-
Bird	757	1,292	547	6,138	574	4,654	9,156	63,954	-	169	-	-	6
Domestic fowl ( <i>Gallus domesticus</i> )	37	-	-	-	-	15	79	2	-	716	-	-	-
Turkey	140	-	-	-	-	-	-	-	-	-	-	-	-
Quail ( <i>Coturnix coturnix</i> )	-	95	-	-	-	-	-	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i> )	-	371	-	144	-	1,001	317	-	-	-	-	-	-
Other bird	-	-	-	-	-	-	-	-	-	-	-	-	-
Reptile	86	6	-	-	-	-	-	-	-	-	-	-	-
Any reptilian species	5,660	1,283	219	-	-	-	-	-	-	257	31	-	-
Amphibian	-	-	-	-	-	-	-	-	-	-	-	-	-
Any amphibian species	36,317	13,586	620	2,009	14,269	10,312	10,140	1,905	-	1,522	-	-	-
Fish	-	-	-	-	-	-	-	-	-	-	-	-	-
Any fish species	-	-	-	-	-	-	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	223,358	199,011	45,198	36,854	53,721	419,285	67,351	103,297	59,837	390,358	13,632	10,513	2,191

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

Species of animal	Field of research										Number of animals		
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol
Mammal	-	-	-	-	-	-	-	-	-	-	-	-	-
Mouse	-	119,342	90,279	267,334	1,063	330	51	16,186	138	54	67,130	-	1,084
Rat	27	1,926	1,481	8,836	2,874	10	12	-	-	13	4,476	-	434
Guinea pig	-	-	-	34	73	-	-	-	-	91	-	-	343,285
Hamster	-	-	230	-	243	28	-	-	-	-	-	-	20,518
Gerbil	-	-	-	96	-	-	-	-	-	-	-	-	3,310
Other rodent	-	-	-	-	138	923	-	-	-	-	-	-	6,509
Rabbit	7	13	48	-	73	15	-	-	-	-	-	-	2,761
Cat	-	-	-	-	4	-	-	-	-	-	-	-	7,517
Dog	-	-	-	-	9	-	-	-	-	-	-	-	543
Beagle	-	-	-	-	-	-	-	-	-	-	-	-	-
Greyhound	-	-	-	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	74	-	-	14	-	-	-	-	-	-	-	-
Ferret	-	516	-	-	-	207	-	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids	-	-	-	147	-	2,205	-	-	-	-	-	-	-
Pig	-	-	-	-	-	127	-	-	-	-	-	-	-
Goat	-	-	-	-	-	755	-	-	-	-	-	-	-
Sheep	445	10	-	-	-	101	-	-	-	-	-	-	-
Cattle	-	-	-	-	-	-	-	-	-	-	-	-	-
Deer	87	-	-	-	-	-	-	-	-	-	-	-	-
Camelid	-	-	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-	-	-	1	-	-	392
marmoset, tamarin	-	-	-	-	-	-	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Species of animal	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Field of research Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	Number of animals		
														Total	Total	
Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-	200	-
Macaque	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Baboon	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Apes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other mammal	-	-	376	-	-	-	62	-	-	-	-	-	-	-	-	1,737
Bird	-	-	684	2	-	1,733	-	-	-	-	-	-	-	-	-	90,762
Domestic fowl ( <i>Gallus domesticus</i> )	-	-	-	-	88	-	-	-	-	-	-	-	-	-	-	-
Turkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1,612
Quail ( <i>Coturnix coturnix</i> )	-	-	-	-	-	46	-	-	-	-	-	-	-	-	-	140
Quail (spp.other than <i>Coturnix coturnix</i> )	-	-	-	-	-	8	5,181	-	-	-	-	-	-	-	-	141
Other bird	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	9,252
Reptile	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	105
Any reptilian species	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-
Amphibian	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	9,288
Any amphibian species	-	-	410	-	262	-	20	-	-	-	-	-	-	-	-	-
Fish	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Any fish species	-	-	424	138	-	1,533	956	-	-	-	-	-	-	-	-	120,784
Cephalopod	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	27	124,196	93,086	276,628	10,959	7,838	91	33,848	32,010	3,479	77,370	-	-	-	1,518	2,285,656

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

Table 5.1 (Continued)

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

Great Britain 2003		Number of procedures																									
Species of animal		Anatomy		Physiology		Biochemistry		Psychiatry		Pathology		Immunology		Microbiology		Parasitology		Pharmacology		Pharmaceutical R&D		Therapeutics		Clinical medicine		Clinical surgery	
Mammal		88,405	70,146	21,021	9,547	14,997	229,613	7,910	1,182	15,276	35,523	1,764	38	268	38	1,301	27	-	-	-	-	-	-				
Mouse	599	779	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Rat	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Other rodent	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Rabbit	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Pig	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Sheep	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Bird	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Domestic fowl ( <i>Gallus domesticus</i> )	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Amphibian	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Any amphibian species	1,360	11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Fish	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Any fish species	14,583	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Total	104,947	70,936	21,021	9,547	15,070	229,613	7,910	1,182	15,276	36,622	1,802	1,328	-	-	-	-	-	-	-	-	-	-	-				

**Table 5.2 (Continued)**

Great Britain 2003		Number of procedures															
Species of animal		Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	Total	Number of procedures	
Mammal																	
Mouse	-	-	38,051	56,438	104,419	254	-	-	14,493	-	-	30,708	-	126	741,174		
Rat	-	-	32	487	24	-	-	-	-	-	-	-	-	-	2,327		
Other rodent	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Rabbit	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Pig	-	-	-	-	-	-	-	-	-	-	-	-	-	-	254		
Sheep	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Bird	-	-	-	-	-	-	-	-	-	-	-	-	-	-	246		
Domestic fowl ( <i>Gallus domesticus</i> )	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Amphibian	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1,371		
Any amphibian species	-	-	-	-	-	-	-	-	-	-	-	-	-	-	15,988		
Fish	-	-	-	98	-	-	-	-	730	-	-	-	-	-	-		
Any fish species	-	-	-	-	-	-	-	-	15,223	-	-	30,708	-	126	761,360		
Total	-	38,329	57,023	104,443	254	-	-	-	-	-	-	-	-	-			

**Table 8 Scientific procedures (non-toxicology) by species of animal and production of biological materials**

Species of animal	Number of procedures					
	Infectious agents	Vectors	Neoplasms	Production (ascites model)	Monoclonal antibodies (initial immunisation)	Other (1)
						Total
Mouse	31,138	4,457	14,836	-	3,939	67,819
Rat	2,833	651	774	-	347	24,959
Other rodent	1,098	608	-	-	7	262
Rabbit	9	134	-	-	63	4,200
Cat	-	13	-	-	-	4
Dog	-	-	-	-	-	4
Ferret	-	-	-	-	-	82
Other carnivore	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	2
Other ungulate	532	2	5	-	10	643
New World monkey	-	-	-	-	-	19,731
Old World monkey	-	-	-	-	-	42,372
Other mammal	-	-	-	-	-	-
Bird	61,427	30	-	-	417	2,685
Reptile / Amphibian	-	-	-	-	-	6,379
Fish	-	1,844	-	-	-	8,562
<b>Total</b>	<b>98,881</b>	<b>5,895</b>	<b>15,615</b>	<b>-</b>	<b>4,366</b>	<b>17,210</b>
						<b>129,690</b>
						<b>1,951,722</b>
						<b>2,344,062</b>

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

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

Species of animal	Techniques of particular interest							All other techniques	Number of procedures
	Interference with organs of special sense	Injection into brain	Interference with brain	Psychological stress	Aversive training	Radiation	Inhalation		
Mouse	7,810	15,082	4,385	2,377	3,131	9,498	20,913	20	2,760
Rat	9,789	318	19,667	7,713	1,885	832	13,627	93	14,973
Other rodent	506	268	1,005	929	-	-	11,310	-	813
Rabbit	-	-	35	-	-	58	-	29	-
Cat	90	-	41	-	-	-	-	-	-
Dog	8	-	-	-	-	46	-	-	-
Ferret	39	-	-	-	-	378	-	-	-
Other carnivore	-	-	-	-	-	39	-	-	8
Horse and other equids	-	-	-	-	-	24	-	-	8,771
Other ungulate	47	-	188	433	-	10	83	5	94
New World monkey	7	-	135	-	24	1	-	-	-
Old World monkey	7	-	14	-	-	19	-	-	-
Other mammal	28	-	-	-	-	-	-	-	-
Bird	12	340	-	360	6,206	-	136	-	-
Reptile / Amphibian	61	-	-	-	-	-	-	95	14,950
Fish	27	-	-	4,784	-	-	39	-	116,372
<b>Total</b>	<b>18,431</b>	<b>16,008</b>	<b>25,470</b>	<b>16,596</b>	<b>11,246</b>	<b>10,341</b>	<b>46,633</b>	<b>157</b>	<b>18,772</b>
									<b>2,180,408</b>
									<b>2,344,062</b>

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

Species of animal	Toxicology or other safety/efficacy evaluation						Number of procedures
	Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	
Mammal							
Mouse	85	2,644	7,119	98	159	-	-
Rat	378	24,025	21,017	83	7,760	100	-
Guinea pig	-	2,123	422	41	30	-	-
Hamster	-	-	-	-	-	-	-
Gerbil	-	-	-	-	-	-	-
Other rodent	30	-	-	-	-	-	-
Rabbit	-	881	1,862	12	9	6	-
Cat	-	-	-	-	-	-	-
Dog	-	-	192	150	-	-	-
Beagle	-	-	-	-	-	-	-
Greyhound	-	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids	-	-	-	-	-	-	-
Pig	-	-	-	-	258	-	-
Goat	-	-	-	-	1	-	-
Sheep	-	-	-	-	-	-	-
Cattle	-	-	-	-	93	-	-
Deer	-	-	-	-	-	-	-
Camelid	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-
marmoset, tamarin	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-

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

Species of animal	Toxicology or other safety/efficacy evaluation					Number of procedures
	Pollution	Agriculture	Industry	Household	Food additives	
Old World monkey	-	-	-	-	-	-
Macaque	-	-	-	-	-	-
Baboon	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-
Ape	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-
Great Ape	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-
Bird	-	-	-	-	-	-
Domestic fowl ( <i>Gallus domesticus</i> )	-	-	-	-	-	-
Turkey	-	-	-	-	-	-
Quail ( <i>Coturnix coturnix</i> )	-	-	-	-	-	-
Quail (spp,other than <i>Coturnix coturnix</i> )	-	-	-	-	-	-
Other bird	-	-	-	-	-	-
Reptile	-	-	-	-	-	-
Any reptilian species	-	-	-	-	-	-
Amphibian	-	-	-	-	-	-
Any amphibian species	-	-	-	-	-	-
Fish	-	-	-	-	-	-
Any fish species	32,338	3,040	5,495	-	-	-
Cephalopod	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-
Total	32,831	40,104	36,065	234	8,007	118

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

Species of animal	Toxicology or other safety/efficacy evaluation						Number of procedures			
	Safety testing	Pharmaceutical safety/efficacy evaluation	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other
Mammal										
Mouse	48,090	19,747	67,708	10,485	15,050	-	-	583	6,348	11,291
Rat	61,781	258	1,297	15,795	5,527	-	-	174	2,702	2,289
Guinea pig	1,829	1,733	5,258	54	292	-	-	432	162	189,407
Hamster	542	60	-	-	30	-	-	-	57	143,186
Gerbil	-	-	-	-	-	-	-	-	-	12,376
Other rodent	-	-	-	-	-	-	-	-	-	689
Rabbit	9,368	927	3,833	88	54	-	-	-	-	-
Cat	-	-	-	8	-	-	-	-	-	-
Dog	3,775	16	-	820	3	-	-	-	62	8
Beagle	-	-	-	-	-	-	-	-	-	5,026
Greyhound	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	7	-	-	-	-	-
Ferret	-	-	-	-	-	-	-	-	-	7
Other carnivore	-	-	-	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids	30	48	4	-	-	-	-	-	-	-
Pig	682	495	181	20	-	-	-	-	57	2
Goat	-	-	-	-	-	-	-	-	-	84
Sheep	176	76	52	-	-	-	-	-	-	1,693
Cattle	366	428	129	-	-	-	-	-	-	1
Deer	-	-	-	-	-	-	-	-	-	424
Camelid	-	-	-	-	-	-	-	-	-	1,119
Other ungulate	-	-	-	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-
New World monkey	293	1	-	102	-	-	-	-	-	2
marmoset, tamarin	-	-	-	-	-	-	-	-	-	398
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-	-	-

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

Species of animal	Toxicology or other safety/efficacy evaluation						Number of procedures Total			
	Safety testing	Pharmaceutical safety/efficacy evaluation	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other	
Old World monkey	2,141	-	-	190	2	-	-	786	24	3,143
Macaque	-	-	-	-	-	-	-	-	-	-
Baboon	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-	-
Great Ape	-	-	-	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-	-	-	-
Bird	2,033	8,220	-	136	-	-	-	45	-	10,724
Domestic fowl ( <i>Gallus domesticus</i> )	40	210	-	104	-	-	-	-	-	354
Turkey	-	-	-	-	-	-	-	-	-	-
Quail ( <i>Colurnix colurnix</i> )	-	-	-	-	-	-	-	-	-	-
Quail (spp, other than <i>Colurnix colurnix</i> )	-	-	-	-	-	-	-	-	-	-
Other bird	-	-	-	-	-	-	-	-	-	722
Reptile	-	-	-	-	-	-	-	-	-	-
Any reptilian species	-	-	-	-	-	-	-	-	-	1,467
Amphibian	-	-	-	-	-	-	-	-	-	-
Any amphibian species	-	-	-	-	-	-	-	-	-	-
Fish	935	9,798	-	56	1,013	-	-	30	-	52,766
Any fish species	-	-	-	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-	-
<b>Total</b>	<b>132,081</b>	<b>42,017</b>	<b>78,276</b>	<b>28,211</b>	<b>23,458</b>	<b>-</b>	<b>1,570</b>	<b>11,133</b>	<b>13,614</b>	<b>447,719</b>

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

Species of animal	Toxicology or other safety/efficacy evaluation						Number of animals
	Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	
Mammal							
Mouse	85	2,644	7,119	98	159	-	
Rat	378	24,025	21,017	83	7,760	100	
Guinea pig	-	2,123	422	41	30	-	
Hamster	-	-	-	-	-	-	
Gerbil	-	-	-	-	-	-	
Other rodent	30	-	-	-	-	-	
Rabbit	-	881	1,844	12	9	6	
Cat	-	-	-	-	-	-	
Dog	-	-	192	124	-	-	
Beagle	-	-	-	-	-	-	
Greyhound	-	-	-	-	-	-	
Other including cross-bred dogs	-	-	-	-	-	-	
Ferret	-	-	-	-	-	-	
Other carnivore	-	-	-	-	-	-	
Horse, donkey and cross-bred equids	-	-	-	-	-	-	
Pig	-	-	-	-	-	-	
Goat	-	-	-	-	-	-	
Sheep	-	-	-	-	-	-	
Cattle	-	-	-	-	-	-	
Deer	-	-	-	-	-	-	
Camelid	-	-	-	-	-	-	
Other ungulate	-	-	-	-	-	-	
Primate	-	-	-	-	-	-	
Prosimian	-	-	-	-	-	-	
New World monkey	-	-	-	-	-	-	
marmoset, tamarin	-	-	-	-	-	-	
Squirrel, owl, spider monkey	-	-	-	-	-	-	
Other New World monkey	-	-	-	-	-	-	

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

Species of animal	Toxicology or other safety/efficacy evaluation						Number of animals
	Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	
Old World monkey	-	-	-	-	-	-	-
Macaque	-	-	-	-	-	-	-
Baboon	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-
Great Ape	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-
Bird	-	-	-	-	-	-	-
Domestic fowl ( <i>Gallus domesticus</i> )	-	-	-	-	-	-	-
Turkey	-	-	-	-	-	-	-
Quail ( <i>Coturnix coturnix</i> )	-	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i> )	-	-	-	-	-	-	-
Other bird	-	-	-	-	-	-	-
Reptile	-	-	-	-	-	-	-
Any reptilian species	-	-	-	-	-	-	-
Amphibian	-	-	-	-	-	-	-
Any amphibian species	-	-	-	-	-	-	-
Fish	-	-	-	-	-	-	-
Any fish species	32,338	3,040	5,495	-	49	12	-
Cephalopod	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-
Total	32,831	40,104	36,021	234	8,007	118	-

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

Species of animal	Number of animals								
	Toxicology or other safety/efficacy evaluation			Other purposes					
	Safety testing	Pharmaceutical safety/efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other
Mammal									
Mouse	48,072	19,747	67,708	10,485	15,050	-	583	6,348	11,291
Rat	61,770	258	1,297	15,787	5,527	-	174	2,614	2,287
Guinea pig	1,829	1,733	5,258	54	292	-	432	162	143,077
Hamster	542	60	-	-	30	-	-	57	12,376
Gerbil	-	-	-	-	-	-	-	-	689
Other rodent	-	-	-	-	-	-	-	-	-
Rabbit	4,991	855	460	83	54	-	171	127	30
Cat	-	-	-	4	-	-	-	-	9,493
Dog	3,358	5	-	306	-	-	-	-	4
Beagle	-	-	-	-	-	-	-	-	4,005
Greyhound	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	-	-	-	-
Ferret	-	-	-	7	-	-	-	-	7
Other carnivore	-	-	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids	30	48	4	-	-	-	-	-	-
Pig	645	495	181	20	-	-	-	-	-
Goat	-	-	-	-	-	-	-	-	-
Sheep	176	76	104	52	-	-	-	-	-
Cattle	366	428	76	128	-	-	-	-	-
Deer	-	-	-	-	-	-	-	-	-
Cameid	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-
New World monkey	291	1	-	-	-	-	-	-	-
marmoset, tamarin	-	-	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-	-
								2	361

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

Species of animal	Toxicology or other safety/efficacy evaluation						Number of animals	
	Safety testing	Pharmaceutical safety/efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Other purposes	Total
Old World monkey	1,510	-	-	90	-	-	-	504
Macaque	-	-	-	-	-	-	-	16
Baboon	-	-	-	-	-	-	-	2,120
Other Old World monkey	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-
Great Ape	-	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-	-
Bird	2,033	8,220	-	136	-	-	-	35
Domestic fowl ( <i>Gallus domesticus</i> )	40	210	-	104	-	-	-	10,714
Turkey	-	-	-	-	-	-	-	354
Quail ( <i>Coturnix coturnix</i> )	-	-	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i> )	-	-	-	-	-	-	-	6,959
Other bird	-	-	-	-	-	-	-	320
Reptile	-	-	-	-	-	-	-	-
Any reptilian species	-	-	-	-	-	-	-	11
Amphibian	-	-	-	-	-	-	-	-
Any amphibian species	-	-	-	-	-	-	-	-
Fish	935	9,798	-	56	1,013	-	-	52,766
Any fish species	-	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-
Total	126,588	41,934	74,903	27,544	21,997	-	1,376	10,690
						-	-	13,596
						-	-	435,943

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

Species	Legislative requirements	Number of procedures			
		Safety testing other than cosmetics	Pharmaceutical safety	Toxicological purpose	Total
Mouse	UK requirements only	512	3,260	875	4,647
	One EU country only (not UK)	16	38	-	54
	EU requirements, incl. European Pharmacopoeia	891	9,501	9,362	19,754
	Requirements of (non-EU) Council of Europe	32	-	65	97
	Requirements of other countries	1,615	535	1,493	3,643
	Any combination of above	5,724	114,401	1,375	121,500
	Non-legislative purposes	1,315	18,295	20,102	39,712
	Total	10,105	146,030	33,272	189,407
Rat	UK requirements only	1,079	638	166	1,883
	One EU country only (not UK)	199	157	-	356
	EU requirements, incl. European Pharmacopoeia	2,472	-	-	2,472
	Requirements of (non-EU) Council of Europe	28	-	488	516
	Requirements of other countries	11,923	500	280	12,703
	Any combination of above	36,023	68,237	2,483	106,743
	Non-legislative purposes	1,639	9,599	7,275	18,513
	Total	53,363	79,131	10,692	143,186
Other rodent	UK requirements only	79	4,593	103	4,775
	One EU country only (not UK)	149	-	36	185
	EU requirements, incl. European Pharmacopoeia	267	1,694	207	2,168
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	1,094	367	30	1,491
	Any combination of above	1,009	2,642	275	3,926
	Non-legislative purposes	48	180	322	550
	Total	2,646	9,476	973	13,095
Rabbit	UK requirements only	66	1,864	57	1,987
	One EU country only (not UK)	28	-	6	34
	EU requirements, incl. European Pharmacopoeia	343	5,877	12	6,232
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	952	31	35	1,018
	Any combination of above	1,371	6,197	358	7,926
	Non-legislative purposes	10	247	84	341
	Total	2,770	14,216	552	17,538
Cat	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	-	-	-	-
	Non-legislative purposes	-	8	-	8
	Total	-	8	-	8

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

Species	Legislative requirements	Number of procedures			
		Safety testing other than cosmetics	Pharmaceutical safety	Toxicological purpose	Total
Dog	UK requirements only	-	-	-	-
	One EU country only (not UK)	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	16	15	-	31
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	-	-	-	-
	Any combination of above	310	4,123	37	4,470
Ferret	Non-legislative purposes	16	473	36	525
	Total	342	4,611	73	5,026
	UK requirements only	-	-	-	-
	One EU country only (not UK)	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	-	-	-
	Requirements of (non-EU) Council of Europe	-	-	-	-
Other carnivore	Requirements of other countries	-	-	-	-
	Any combination of above	-	-	-	-
	Non-legislative purposes	-	-	-	-
	Total	-	-	-	-
	UK requirements only	-	-	-	-
	One EU country only (not UK)	-	-	-	-
Horse and other equids	EU requirements, incl. European Pharmacopoeia	-	-	-	-
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	-	-	-	-
	Any combination of above	-	-	-	-
	Non-legislative purposes	-	-	-	-
	Total	-	-	-	-
Other ungulate	UK requirements only	-	-	-	-
	One EU country only (not UK)	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	180	502	-	682
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	25	38	6	69
	Any combination of above	147	1,926	29	2,102
	Non-legislative purposes	-	-	-	-
	Total	352	2,765	120	3,237
	UK requirements only	-	-	-	-
	One EU country only (not UK)	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	-	-	-
	Requirements of (non-EU) Council of Europe	-	-	-	-

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

Species	Legislative requirements	Number of procedures			
		Safety testing other than cosmetics	Toxicological purpose Pharmaceutical safety	Other safety / Toxicology	Total
New World monkey	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	-	395	2	397
	Non-legislative purposes	-	1	-	1
	Total	-	396	2	398
Old World monkey	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	2	2,319	795	2,314
	Non-legislative purposes	10	10	17	27
	Total	-	2,331	812	3,143
Other mammal	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	-	-	-	-
	Non-legislative purposes	-	-	-	-
	Total	-	-	-	-
Bird	UK requirements only	18	100	-	118
	One EU country only (not UK)	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	156	3,342	-	3,498
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	106	-	-	106
	Any combination of above	6,507	7,301	45	13,853
	Non-legislative purposes	60	-	722	782
	Total	6,847	10,743	767	18,357
Reptile / Amphibian	UK requirements only	-	-	1,467	1,467
	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	-	-	-	-
	Non-legislative purposes	-	-	-	-
	Total	-	-	1,467	1,467

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

Great Britain 2003		Legislative requirements	Number of procedures		
Species			Safety testing other than cosmetics	Toxicological purpose	Total
			Pharmaceutical safety	Other safety / Toxicology	
Fish	UK requirements only	4,640	200	-	4,840
	One EU country only (not UK)	41	-	-	41
	EU requirements, incl. European Pharmacopoeia	6,225	3,860	-	10,085
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	3,512	-	30	3,542
	Any combination of above	13,981	6,729	-	20,710
	Non-legislative purposes	12,535	-	1,013	13,548
	Total	40,934	10,789	1,043	52,786
Cephalopod	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	-	-	-	-
	Non-legislative purposes	-	-	-	-
	Total	-	-	-	-
All species	UK requirements only	6,394	10,783	2,668	19,845
	One EU country only (not UK)	433	195	42	670
	EU requirements, incl. European Pharmacopoeia	10,550	24,839	9,583	44,972
	Requirements of (non-EU) Council of Europe	60	-	553	613
	Requirements of other countries	19,227	1,473	1,874	22,574
	Any combination of above	65,072	214,304	5,399	284,775
	Non-legislative purposes	15,623	28,991	29,656	74,270
	<b>TOTAL</b>	<b>117,359</b>	<b>280,585</b>	<b>49,775</b>	<b>447,719</b>

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

Species of animal		Type of toxicological test or procedure						Number of procedures			
		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	88,413	1,581	5,887	6,284	4,834	3,527	4,038	7,367	3,235	623	2,917
Rat	67	2,281	3,849	7,390	6,581	14,956	11,552	7,122	4,778	-	-
Other rodent	272	-	720	328	-	95	-	-	-	-	-
Cat	-	-	-	-	-	-	-	-	-	-	-
Dog	-	-	-	-	-	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-	-	-	-	-
Old World monkey	-	-	-	-	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-	-	-	-	-
Bird	180	240	70	-	-	36	410	-	-	-	-
Reptile / Amphibian	-	-	16,645	9,872	-	-	-	-	-	-	-
Fish	-	-	-	-	821	3,565	1,080	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-	-	-	-
Total	88,932	20,747	20,399	14,149	13,019	24,902	19,004	14,489	8,013	3,588	

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

Species of animal	Type of toxicological test or procedure						Number of procedures
	Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	Toxicokinetics	Pyrogenicity	
Mouse	1,939	-	12	7,785	9,375	-	43,340
Rat	38,444	-	118	12,276	-	214	189,407
Other rodent	-	30	3,253	198	-	366	30,317
Rabbit	216	1,107	1,700	-	113	-	143,186
Cat	-	-	-	-	9,597	162	8,045
Dog	-	-	-	-	400	-	13,095
Ferret	-	-	-	-	-	122	17,538
Other carnivore	-	-	-	-	-	-	-
Horse and other Equids	-	-	-	-	4	-	-
Other ungulate	-	-	-	-	6	22	8
New World Monkey	-	-	-	-	305	-	5,026
Old World Monkey	-	-	-	-	63	-	-
Other mammal	-	-	-	-	105	-	-
Bird	6,542	-	-	-	136	-	-
Reptile / Amphibian	-	-	-	-	256	-	-
Fish	5,754	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-
<b>Total</b>	<b>52,895</b>	<b>52,895</b>	<b>1,107</b>	<b>1,866</b>	<b>23,231</b>	<b>9,597</b>	<b>447,719</b>
				<b>11,060</b>	<b>804</b>	<b>580</b>	<b>114,746</b>
						<b>1,354</b>	
							<b>447,719</b>

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

Great Britain 2003		Number of procedures									
Species of animal		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	-	67	-	38	331	18	-	120	901	904	-
Rat	-	701	3,618	5,260	1,408	3,536	2,277	-	545	545	408
Other rodent	-	-	-	10	18	-	-	-	-	-	-
Rabbit	-	-	-	-	18	12	-	-	-	-	220
Dog	-	-	-	-	-	26	41	224	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	-	-	-
Bird	180	240	70	-	-	36	50	-	-	-	-
Reptile / Amphibian	-	-	-	-	-	-	-	-	-	-	-
Fish	-	16,645	9,577	-	-	2,615	1,080	-	-	-	-
Total	247	17,586	13,313	5,617	1,500	6,242	3,701	2,317	1,449	628	628

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

Great Britain 2003		Number of procedures									
Species of animal		Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	Type of toxicological test or procedure	Pyrogenicity	Biocompatibility	Enzyme induction for <i>in vitro</i> tests	Immunotoxicology	Other toxicology
Mouse	-	25,911	-	-	6,939	-	-	120	-	734	10,105
Rat	-	-	112	-	982	-	216	-	-	6,916	53,363
Other rodent	-	-	-	2,598	-	-	-	-	-	30	2,646
Rabbit	-	940	1,578	-	-	-	-	-	-	10	2,770
Dog	-	-	-	-	6	-	-	-	-	27	342
Horse and other equids	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	12	-	-	-	-	340	352
Bird	5,820	-	-	-	56	-	-	-	-	395	6,847
Reptile / Amphibian	-	5,754	-	-	200	-	-	-	-	-	-
Fish	-	37,485	940	1,690	9,537	1,256	-	336	-	5,063	40,934
Total										13,515	117,359

**Table 15: Scientific procedures (toxicology) by species of animal and type of toxicological test: safety testing of pharmaceuticals**

Species of animal	Type of toxicological test or procedure						Number of procedures
	Acute lethal toxicity	Acute lethal concentration	Acute limit setting	Acute non - lethal clinical sign	Subacute limit-setting or dose ranging	Subacute toxicity	
Mouse	74,260	-	5,824	4,520	4,459	3,519	6,466
Rat	-	-	171	2,140	5,083	9,250	2,331
Other rodent	-	-	690	310	-	95	4,233
Rabbit	-	-	-	140	137	100	-
Cat	-	-	-	-	97	407	-
Dog	-	-	-	-	-	1,164	-
Ferret	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-
New World monkey	-	-	1	18	76	88	-
Old World monkey	-	-	-	6	179	930	-
Bird	-	-	-	-	-	360	-
Fish	-	-	265	-	821	-	-
Total	74,260	-	6,951	7,239	11,221	17,598	12,172
							6,564
							5,420

**Table 15: Scientific procedures (toxicology) by species of animal and type of toxicological test: safety testing of pharmaceuticals (continued)**

Species of animal	Type of toxicological test or procedure						Number of procedures
	Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	Toxicokinetics	Pyrogenicity	
Mouse	1,816	-	12	471	9,113	-	-
Rat	12,393	-	6	11,206	-	-	15
Other rodent	-	30	61	198	-	-	-
Rabbit	208	134	44	62	9,403	32	-
Cat	-	-	-	-	-	-	-
Dog	-	-	-	391	-	-	-
Ferret	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-
New World Monkey	-	-	22	293	-	-	-
Old World Monkey	-	-	-	4	-	-	-
Bird	-	-	-	105	-	-	-
Fish	-	-	-	80	-	-	-
Total	14,417	134	92	554	21,571	9,403	32
							15
							1,313
							76,156
							280,585

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

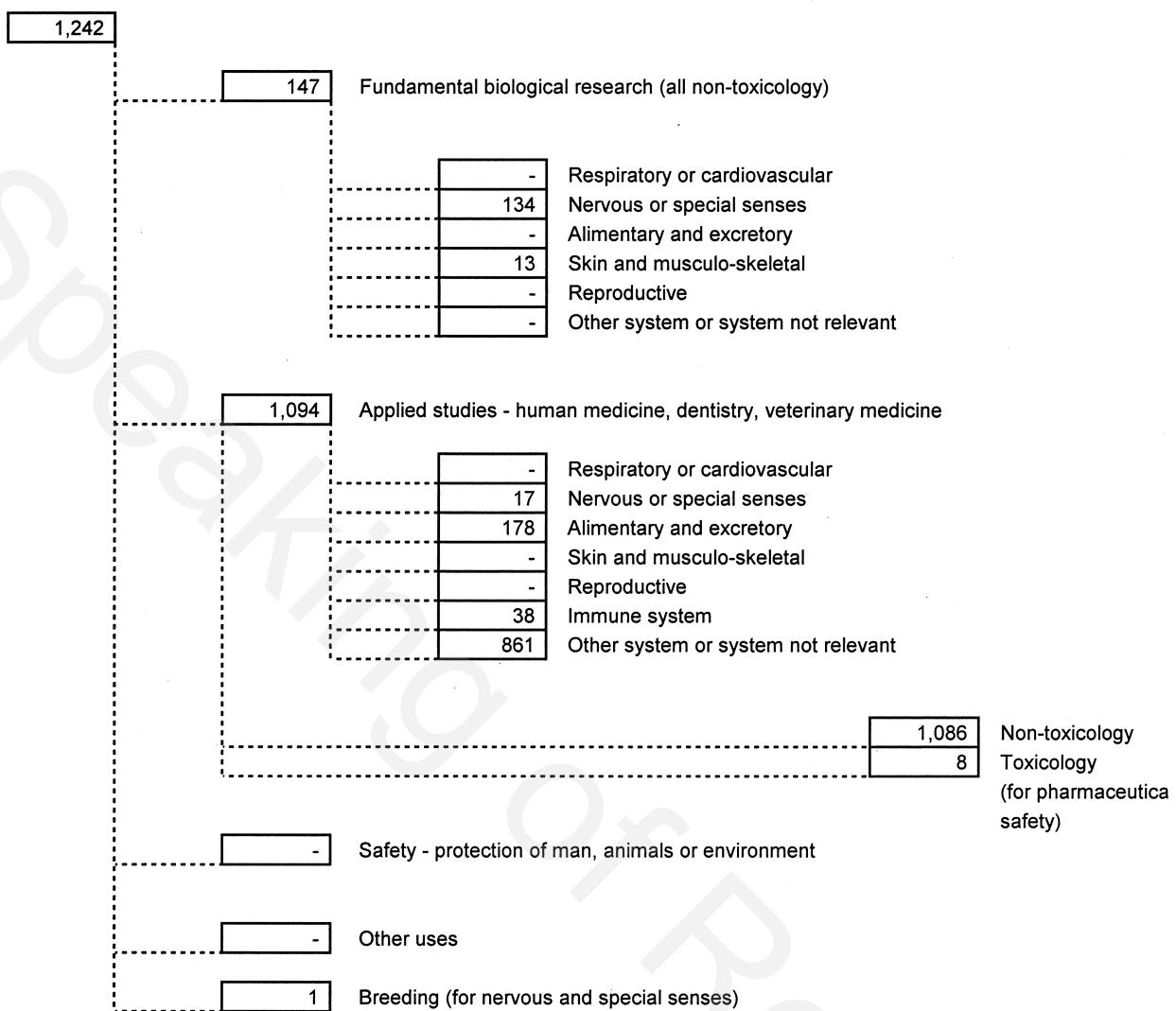
Great Britain 2003

Species of animal	Type of toxicological test or procedure						Number of procedures
	Acute lethal toxicity	Acute lethal concentration	Acute limit setting	Acute non - lethal clinical sign	Subacute toxicity	Subchronic and chronic	
Mouse	14,153	1,581	25	1,433	357	8	-
Rat	-	1,580	60	-	90	204	-
Other rodent	272	-	30	-	-	8	-
Rabbit	-	-	-	-	-	-	-
Cat	-	-	-	-	-	-	-
Dog	-	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-
Old World monkey	-	-	-	-	-	-	-
Bird	-	-	-	-	-	-	-
Reptile / Amphibian	-	-	-	-	-	-	-
Fish	-	-	-	-	-	-	-
Total	14,425	3,161	145	1,433	447	1,170	25
							175

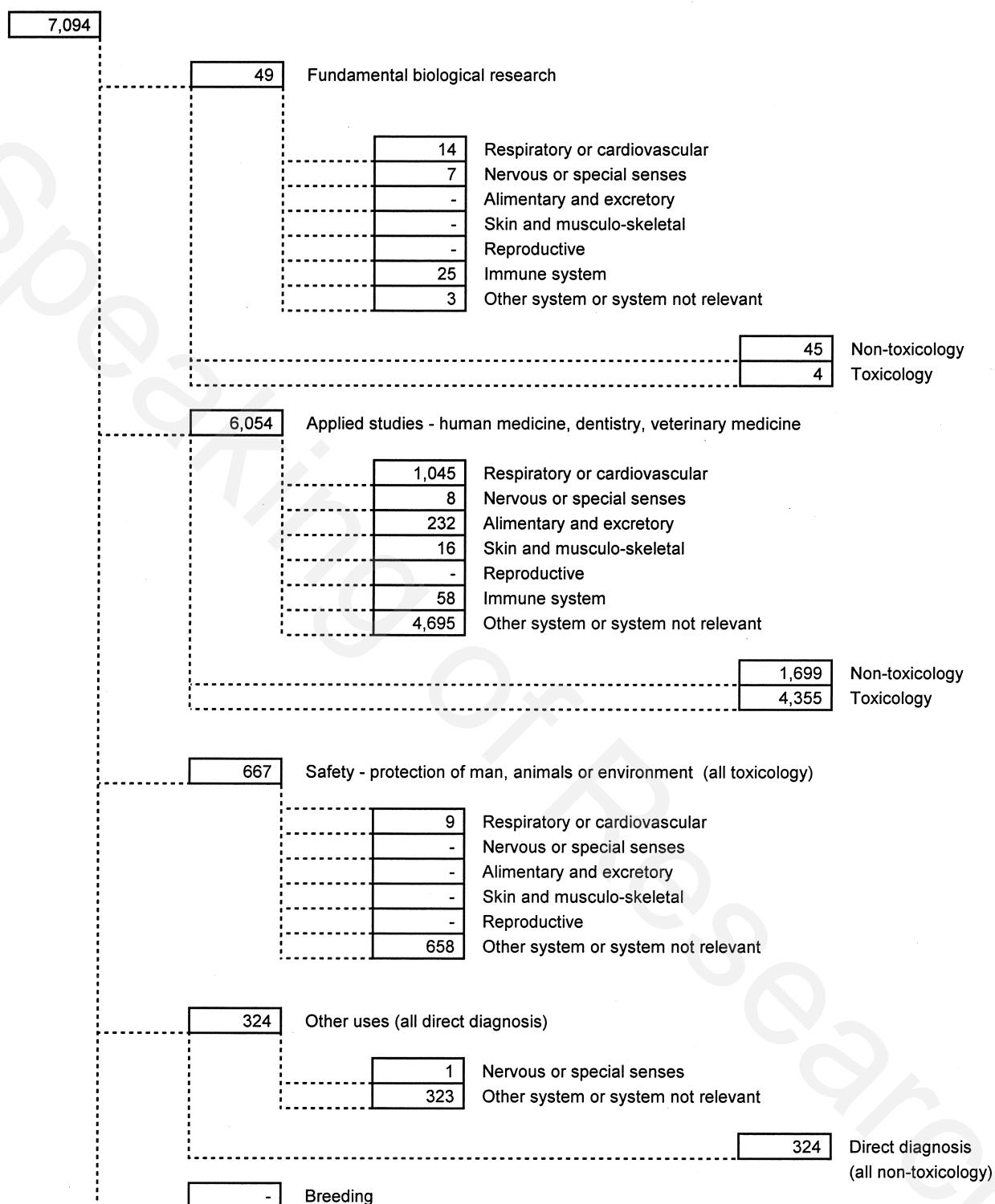
**Table 16 Scientific procedures (toxicology) by species of animal and type of toxicological test: other safety or toxicology testing (Continued)**

Species of animal	Type of toxicological test or procedure						Number of procedures
	Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	Toxicokinetics	Pyrogenicity	
Mouse	123	-	-	-	375	262	-
Rat	140	-	-	-	-	88	162
Other rodent	-	-	-	-	594	-	135
Rabbit	8	33	78	-	-	51	-
Cat	-	-	-	-	-	194	90
Dog	-	-	-	-	-	3	-
Other carnivore	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-
New World Monkey	-	-	-	-	-	-	-
Old World Monkey	-	-	-	-	-	-	-
Bird	722	-	-	-	-	-	-
Reptile / Amphibian	-	-	-	-	-	-	-
Fish	-	-	-	-	-	-	-
Total	993	33	84	969	404	194	772
							229
							41
							25,075
							49,775
							Total

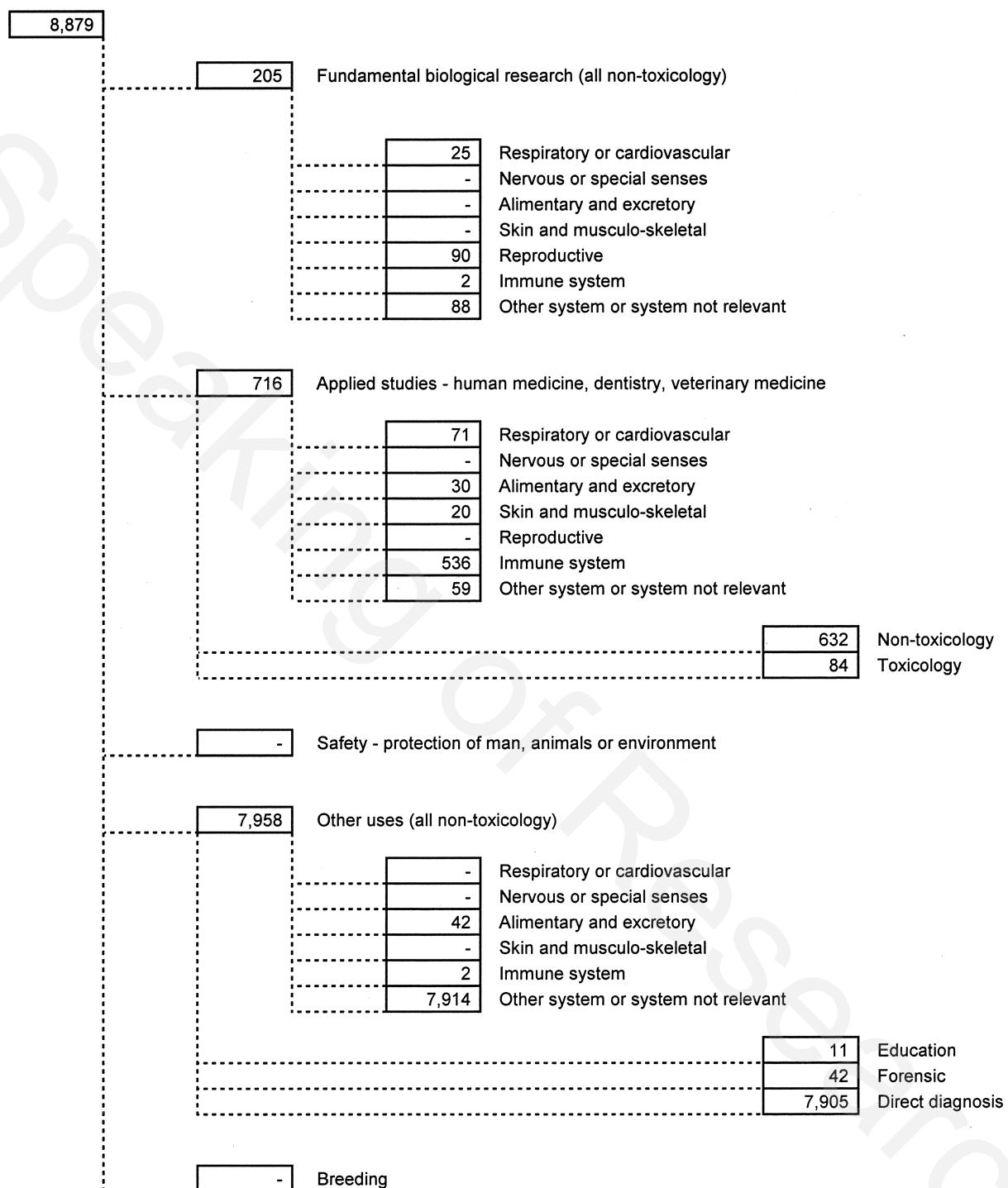
**Table 18a Tree table - scientific procedures involving cats, 2003**



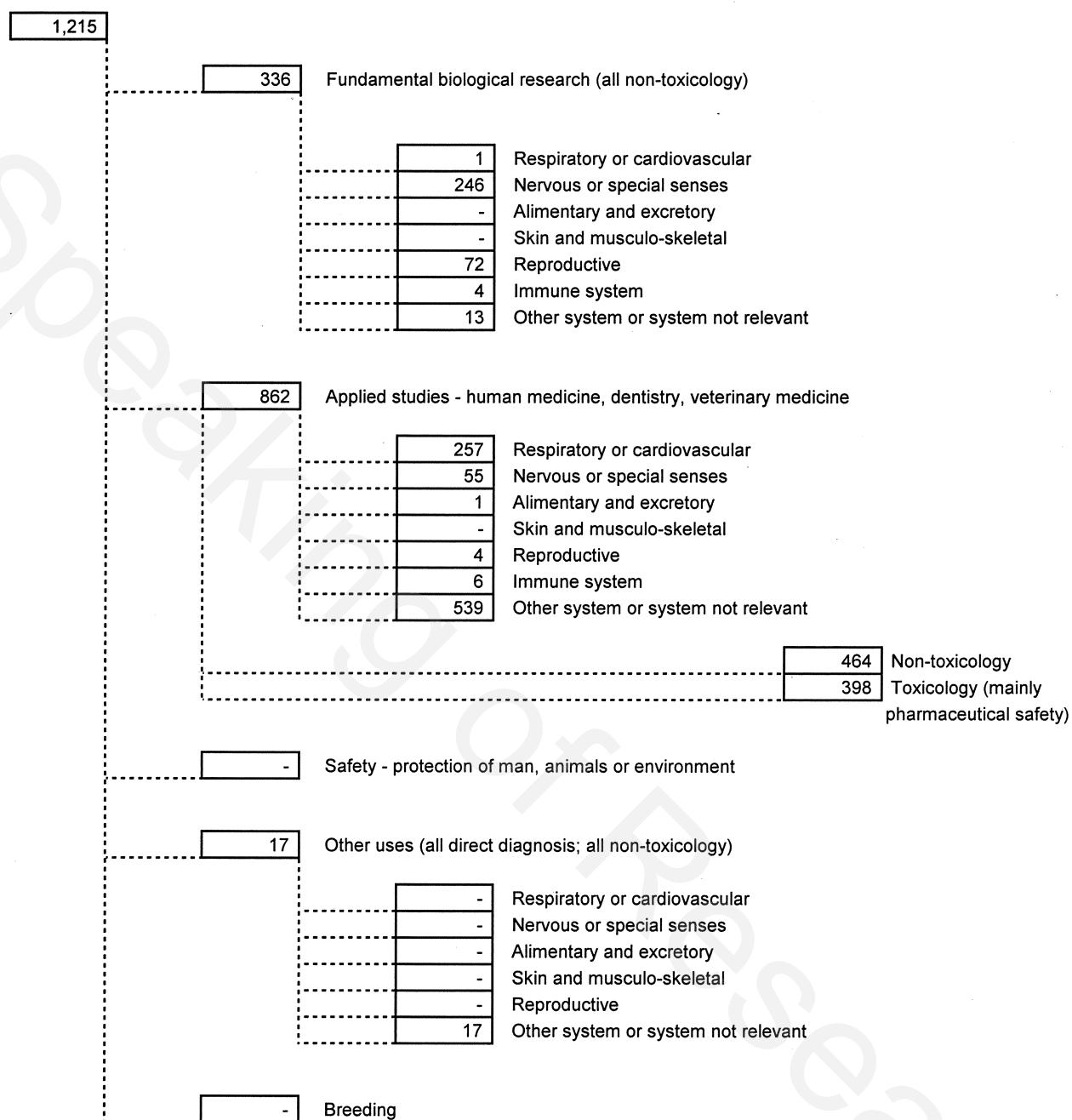
**Table 18b Tree table - scientific procedures involving dogs, 2003**



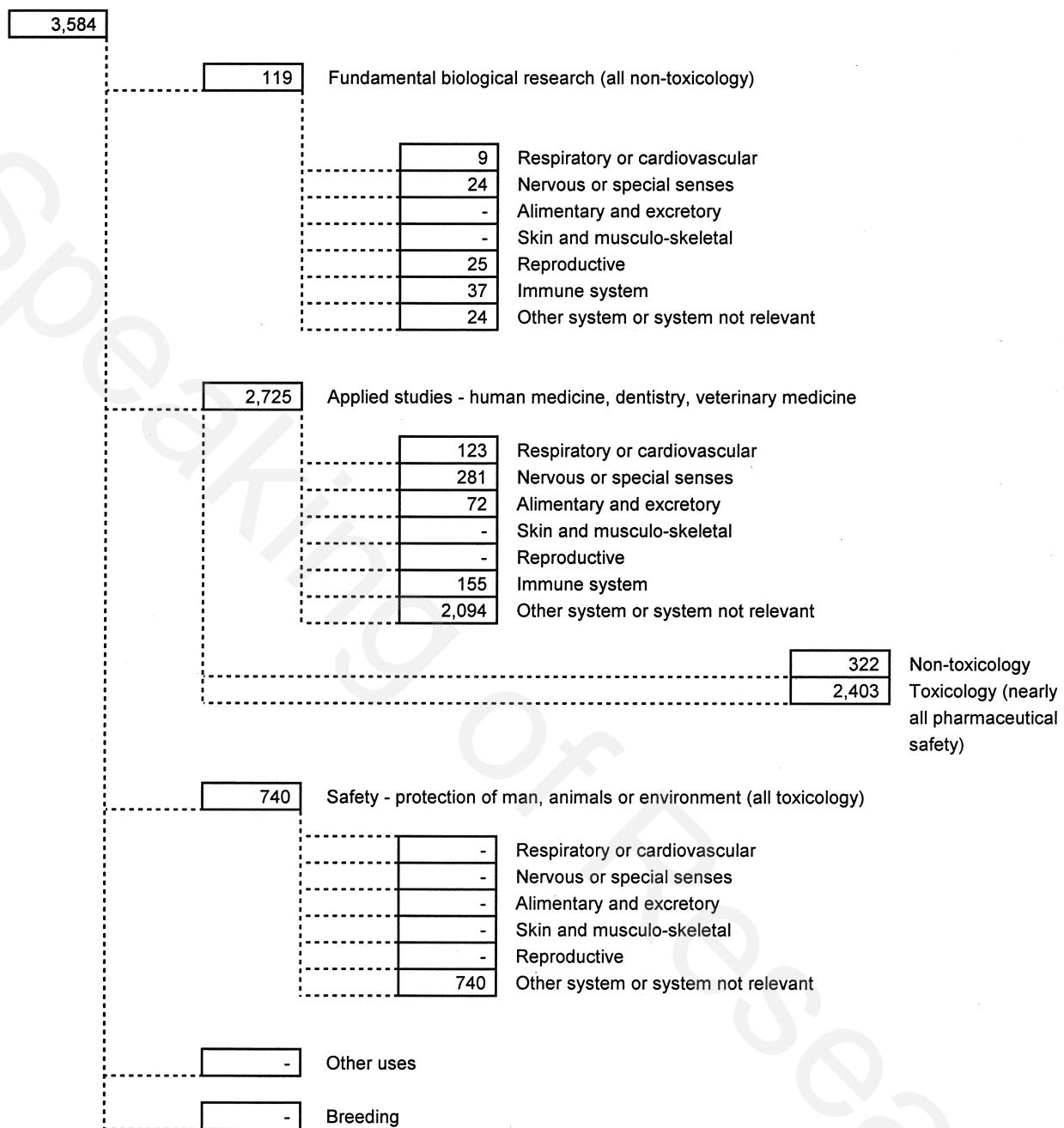
**Table 18c Tree table - scientific procedures involving horses and other equids, 2003**



**Table 18d Tree table - scientific procedures involving New World primates, 2003**



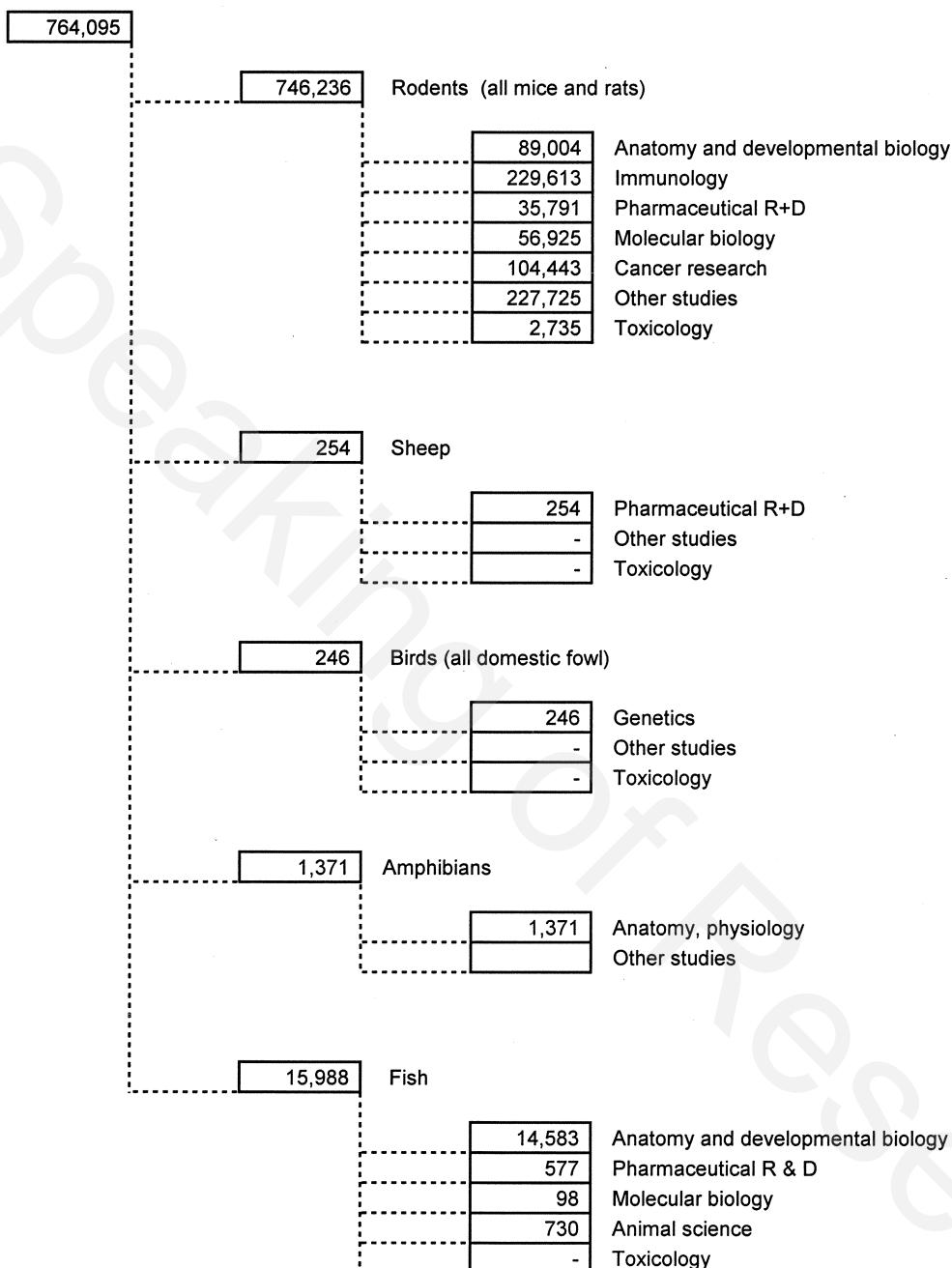
**Table 18e Tree table - scientific procedures involving Old World primates, 2003**



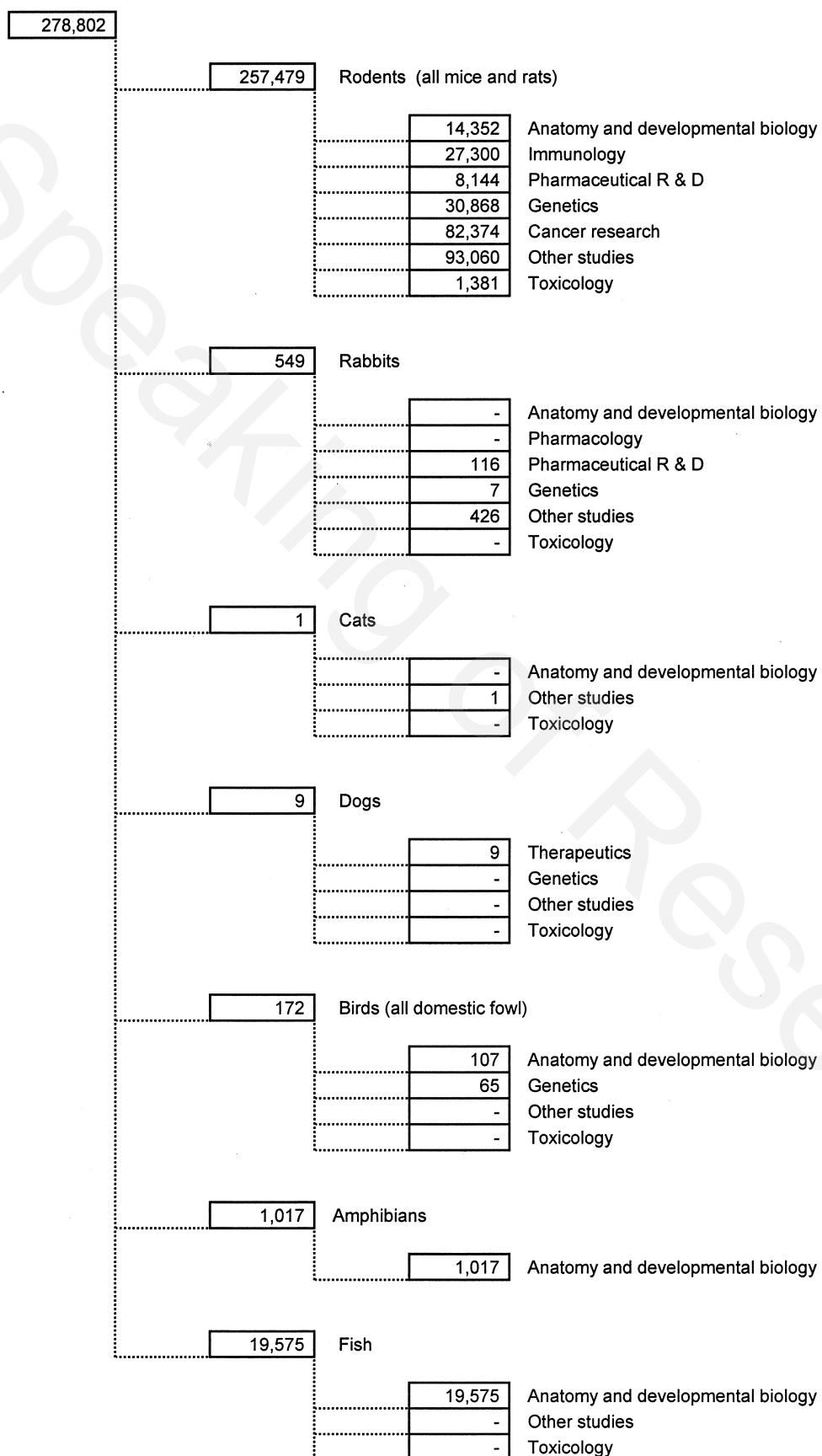
**Table 18f Tree table - scientific procedures involving rabbits, 2003**

25,326		
2,539	Fundamental biological research	
822	Respiratory or cardiovascular	
220	Nervous or special senses	
118	Alimentary and excretory	
128	Skin and musculo-skeletal	
156	Reproductive	
714	Immune system	
381	Other system or system not relevant	
2,193	Non-toxicology	
346	Toxicology	
17,130	Applied studies - human medicine, dentistry, veterinary medicine	
374	Respiratory or cardiovascular	
416	Nervous or special senses	
166	Alimentary and excretory	
496	Skin and musculo-skeletal	
2,159	Reproductive	
1,644	Immune system	
11,875	Other system or system not relevant	
2,728	Non-toxicology	
14,402	Toxicology	
2,934	Safety - protection of man, animals or environment (nearly all toxicology)	
-	Respiratory or cardiovascular	
14	Nervous or special senses	
-	Alimentary and excretory	
1,721	Skin and musculo-skeletal	
192	Reproductive	
1	Immune system	
1,006	Other system or system not relevant	
144	Non-toxicology	
2,790	Toxicology	
2,290	Other uses (all non-toxicology)	
18	Respiratory or cardiovascular	
-	Nervous or special senses	
8	Alimentary and excretory	
4	Skin and musculo-skeletal	
-	Reproductive	
1,673	Immune system	
587	Other system or system not relevant	
78	Education	
-	Forensic	
2,212	Direct diagnosis	
433	Breeding	
426	Respiratory or cardiovascular	
7	Other system or system not relevant	

**Table 18g Tree table - scientific procedures involving genetically modified animals, 2003**



**Table 18h Tree table - scientific procedures involving animals with a harmful genetic defect, 2003**



## Part B

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

Type of designated establishment		Number of licence holders <sup>(1)</sup> reporting countable <sup>(2)</sup> procedures						Licenses reporting non-countable <sup>(2)</sup> procedures only	Number of licence holders <sup>(1)</sup> reporting no procedures	Total licensees	Total	Procedures	
		1 to 50	51 to 100	101 to 200	201 to 400	401 to 600	601 to 800						
Public health laboratories	5	3	1	4	2	2	1	3	21	2	5	28	16,289
Universities, medical schools	527	270	283	269	135	97	68	297	1,946	7	851	2,804	1,130,126
NHS hospitals	9	2	3	4	4	1	1	10	34	-	68	102	24,011
Government departments	24	9	8	14	6	3	2	18	84	1	8	93	72,003
Other public bodies	52	31	31	27	21	14	9	84	269	4	50	323	407,650
Non-profit-making organisations	18	8	11	12	6	6	5	30	96	-	34	130	136,344
Commercial organisations	70	32	26	38	20	22	16	137	361	4	95	460	1,005,358
<b>Total</b>	<b>705</b>	<b>355</b>	<b>363</b>	<b>368</b>	<b>194</b>	<b>145</b>	<b>102</b>	<b>579</b>	<b>2,811</b>	<b>18</b>	<b>1,111</b>	<b>3,940</b>	<b>2,791,781</b>
													<b>100</b>

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

(2) Only procedures on adult or free-living animals (including neonatal and juvenile mammals, and newly-hatched birds) are counted.

Details of procedures on immature forms (e.g. larvae, embryos, fish fry) are 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.

## Part C - historical

**Table 20 Scientific procedures by species of animal, 1988-2003**

Species of animal	Great Britain										Thousands of procedures					
	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997						
Mouse	1,850.5	1,744.9	1,636.3	1,638.9	1,449.0	1,457.3	1,475.0	1,454.9	1,502.1	1,517.9	1,590.8	1,641.9	1,807.0	1,857.7	1,720.3	1,816.9
Rat	860.4	882.3	891.5	881.7	833	819.7	694.4	688.8	636.7	575.9	567.0	535.0	500.2	509.6	496.4	48.1
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	60.0	30.3
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	25.3	12.1
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	10.9	75.5
Ungulate	38.1	34.8	31.1	34.4	33	32.2	55.3	60.3	60.0	68.0	63.6	63.0	37.4	57.3	4.8	4.0
Primate	6.3	5.3	4.5	5	5	5.2	4.7	4.4	3.9	3.7	4.0	3.7	4.0	0.5	0.5	1.7
Other mammal	0.4	0.2	0.8	1.3	2.5	3.2	1	0.8	0.8	0.9	0.9	0.5	0.5	0.8	0.8	121.6
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	166
Reptile/Amphibian	11.3	13.1	11.6	15	19	17.7	17.2	17.3	15.3	14.4	14.6	14.6	17.5	17.6	17.6	174.0
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	1.0
Cephalopod <sup>(1)</sup>	..	..	..	..	..	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	2,656.8	2,659.7	2,714.7	2,622.4	2,732.7	2,791.8

(1) *Octopus vulgaris*, from 1 October 1993.

**Table 21 Scientific procedures (toxicology) by type of legislation, 1995-2003**

Legislative requirements	Great Britain										Thousands of procedures
	1995	1996	1997	1998	1999	2000	2001	2002	2003	2003	
UK requirements only	42.3	25.4	21.9	39.2	37.3	26.2	24.5	23.2	19.8	19.8	19.8
Requirements of one EU country only (1999 onwards)	69.6	60.5	54.1	49.3	5.8	2.9	1.3	1.0	0.7	0.7	0.7
EU requirements					118.7	69.8	73.6	68.2	45.0		
Requirements of non-EU Council of Europe country/ies	48.0	38.2	24.5	25.7	25.2	10.6	4.6	3.7	0.6		
Other international requirements	389.9	441.1	415.0	355.5	33.9	29.2	30.6	30.5	22.6		
Joint requirements (any combination of above)	117.5	155.0	109.6	94.8	247.5	242.1	255.1	295.0	284.8		
Non-legislative purposes										74.3	
Total	677.2	720.2	625.1	564.4	543.2	454.9	455.5	485.8	447.7		

**Table 22 Scientific procedures by use of anaesthesia, 1988-2003**

Level of anaesthesia	Scientific Procedures										Thousands of procedures
	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	
No anaesthesia throughout the procedure <sup>(1)</sup>	2213.1	2094.9	2,205.4	2,223.7	1,960.0	1,792.5	1,751.4	1,767.1	1,690.8	1,723.6	1,636.3
Anaesthesia, with recovery, for part of procedure <sup>(2)</sup>	604.5	568.7	529.8	566.9	579.3	627	632.5	658.2	694.1	702.1	759.5
Terminal Anaesthesia <sup>(3)</sup>	662.7	651.5	472	451.9	386.9	408.2	413.3	300	255.4	246.4	233.9
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

(1) Includes some experiments in which the subject of the study is the anaesthetic agent itself.

(2) May be local, regional or general anaesthesia.

(3) At end of procedure or for whole procedure.

**Table 23 Scientific procedures by type of designated establishment, 1988-2003**

Type of designated establishment <sup>(1)</sup>	Scientific Procedures										Thousands of procedures
	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	
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
Universities, medical schools	777.7	747.6	710.0	727.8	737.0	840.6	832.6	824.1	843.8	934.8	936.1
Polytechnics etc <sup>(2)</sup>	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
Government departments	65.9	58.7	68.7	72.6	65.1	78.1	62.6	78.6	94.2	81.5	86.2
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
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
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
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

(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.

**Table 24 Scientific procedures (non-toxicology) by field of research, 1995-2003**

Field of research	Thousands of procedures								
	1995	1996	1997	1998	1999	2000	2001	2002	2003
Psychology	28.4	31.0	38.8	33.1	33.9	106.9	37.9	39.6	38.2
Pharmaceutical R&D	567.6	504.2	501.5	470.1	481.9	446.7	408.9	365.7	400.4
Cancer research	262.6	257.8	300.9	293.3	267.0	258.4	268.8	258.1	277.4
Ecology	14.5	15.2	11.9	13.7	9.1	12.6	19.8	22.1	32.0
Tobacco	.. <sup>(1)</sup>	0.0	0.0	0.0	0.0	0.1	.. <sup>(1)</sup>	0.0	0.0
Alcohol	3.2	2.2	1.9	0.4	1.2	3.1	3.1	2.3	1.5
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
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

(1) Fewer than 50 procedures

**Table 25 Scientific procedures (toxicology) for safety evaluation, 1992-2003**

Field of research	Thousands of procedures											
	1992	1993	1994	1995 <sup>(1)</sup>	1996	1997	1998	1999	2000	2001	2002	2003
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
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
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
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
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
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
Tobacco	0.2	0	0.03	.. <sup>(2)</sup>	..	..	..	..	..	..	..	..
Alcohol research	1.1	7.3	9.1	.. <sup>(2)</sup>	..	..	..	..	..	..	..	..
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
Pharmaceutical - quality control	..	..	..	83.8	84.3	77.8	74.0	85.6	70.9	72.2	74.5	78.3
Other purposes	..	..	..	62.7	76	67.7	51.4	44.7	48.8	42.5	46.4	49.8
Total	258.6	242	217.2	677.2	720.2	625.1	564.4	543.2	454.9	455.5	485.8	447.7

.. 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 and 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, 1995-2003**

Great Britain	Thousands of procedures								
Primary purpose of the procedure	1995	1996	1997	1998	1999	2000	2001	2002	2003
Fundamental biological research	841.2	884.8	829.4	894.9	803.8	872.8	778.7	864.3	832.9
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
veterinary medicine	199.2	144.1	160.1	181.3	169.6	190.7	182.2	175.0	150.7
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
Education	7.1	6.7	5.9	6.3	5.5	4.7	4.6	4.3	3.7
Training	1.7	1.7	1.6	1.6	1.4	1.3	1.2	1.0	0.9
Forensic enquiries	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Direct diagnosis	65.0	55.8	55.5	52.0	47.8	45.3	34.5	41.3	55.8
Breeding	312.7	391.5	437.0	505.8	639.1	699.6	777.8	791.2	902.6
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

(1) Fewer than 50 procedures

**Table 27 Scientific procedures by primary purpose and genetic status, 1995-2003**

Great Britain	Thousands of procedures								
Primary purpose of procedure	1995	1996	1997	1998	1999	2000	2001	2002	2003
<b>Normal animal</b>									
Fundamental biological research	713.1	724.8	656.2	664.1	621.5	653.2	560.9	584.7	563.4
Applied studies	1,219.2	1,101.1	1,043.8	969.4	937.9	857.7	810.5	780.6	779.7
Safety	208.9	219.0	200.8	170.1	153.3	161.1	153.5	185.4	151.3
Other uses	73.0	64.2	62.8	59.9	54.7	51.3	40.1	46.7	59.6
Breeding	53.5	72.2	83.0	89.2	126.7	152.8	179.8	165.5	194.9
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
<b>Animal with harmful genetic defect</b>									
Fundamental biological research	53.8	43.9	43.3	57.5	55.1	54.5	46.8	63.8	47.7
Applied studies	40.7	41.0	50.1	42.7	42.9	50.8	44.6	37.7	40.7
Safety	0.2	0.7	0.3	-	-	-	(1)	-	0.1
Other uses	(1)	(1)	0.2	(1)	0.1	0.1	0.1	(1)	0.4
Breeding	131.9	148.0	142.8	159.1	152.9	151.5	155.3	158.4	190.0
Total	226.6	233.7	236.6	259.3	251.0	256.9	246.8	259.9	278.8
<b>Genetically modified animal</b>									
Fundamental biological research	74.3	116.2	129.9	173.2	127.2	165.1	171.0	215.8	221.9
Applied studies	12.7	14.2	11.7	16.5	24.9	21.2	17.0	26.6	24.0
Safety	0.1	-	-	0.3	-	0.1	0.1	0.2	0.1
Other uses	1.0	-	(1)	(1)	(1)	(1)	(1)	(1)	0.4
Breeding	127.2	171.2	211.1	257.6	359.5	395.4	442.7	467.3	517.7
Total	215.3	301.6	352.8	447.6	511.6	581.8	630.8	710.0	764.1
<b>All animals</b>									
Fundamental biological research	841.2	884.8	829.4	894.9	803.8	872.8	778.7	864.3	832.9
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
Safety	209.2	219.7	201.0	170.1	153.3	161.2	153.6	185.6	151.4
Other uses	74.0	64.2	63.0	59.9	54.9	51.4	40.3	46.7	60.4
Breeding	312.6	391.5	437.0	505.8	639.1	699.6	777.8	791.2	902.6
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

(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 2003, 2,273 personal licences were granted and 2,492 were revoked. On 31 December 2003 there were 14,040 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 benefit (to humans, other animals or the environment) which is likely to accrue from the work. Adequate consideration must also have been given to the feasibility of using alternative methods not involving living animals. The holder of a project licence undertakes overall responsibility for the scientific direction and control of the work and is responsible for making the statistical returns on which this publication is based. New project licence applicants are required to complete an accredited training course before the licence is granted.
10. When making an application for a project licence, the applicant and the Home Office agree 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, 2003, the number granted during 2003 and the number revoked during 2003 (normally either at the licence holder's request or because the licence had run the maximum allowed term of 5 years). The total figures are subdivided into severity bandings.

#### **Project licences**

<i>Severity band</i>	<i>In force on 31/12/2003</i>		<i>Granted during 2003</i>		<i>Revoked during 2003</i>	
	<i>Number</i>	<i>%</i>	<i>Number</i>	<i>%</i>	<i>Number</i>	<i>%</i>
Mild	1,174	39	312	31	353	37
Moderate	1,662	56	426	55	530	56
Substantial	58	2	16	2	20	2
Unclassified	83	3	20	2	44	5
<b>Total</b>	<b>2,977</b>		<b>774</b>		<b>947</b>	

#### **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, 2003, the number granted during 2003 and the number revoked during 2003. The figures are subdivided for different types of establishment.

#### **Certificates of Designation**

<i>Establishment type</i>	<i>In force on 31/12/2003</i>	<i>Granted during 2003</i>	<i>Revoked during 2003</i>
Commercial concern	85	2	4
Higher education	84	1	3
Quango	31	2	2
Government	10	1	-
Non-profit	13	-	1
NHS hospital	6	-	1
Public health	3	-	-
<b>Total</b>	<b>232</b>	<b>6</b>	<b>11</b>

15. Of the 232 certificates of designation active on 31 December 2003, 227 were registered as user establishments, 144 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/comrake/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 (Command 5729 - January 2003)
- Inter-Departmental group on the 3Rs
- 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. Considerable progress has been made over recent years in providing appropriate training for those involved in research with animals. The 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. There are now plans to introduce mandatory introductory training for Named Animal Care and Welfare Officers in 2004 (two bodies were given confirmation towards the end of 2003 that they had been accorded the status of course accreditors for that purpose).

### **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.

22. A number of new administrative steps including additional record keeping requirements were introduced to ensure the effectiveness of these changes.

### **Animals Scientific Procedures Division**

23. 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.

24. 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.

25. On 31 December 2003, 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.

26. 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***

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

28. 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.

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

30. At 31 December 2003, there were 26 inspectors in post. The distribution of inspectors was:

	Chief Inspector	Superintending Inspectors	Inspectors
London	1	1	6
Cambridge		1	4
Dundee		2	3
Shrewsbury			4
Swindon			4
Total	1	4	21

31. In 2003, the Inspectorate carried out 3,703 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, 2,576 were for the purpose of inspection of designated establishments and work in progress. Well over fifty percent of the visits to designated departments were unannounced. The remaining 1,127 visits were for the purpose of maintaining scientific or professional skills, representing the Home Office or furthering Home Office policy.

#### ***Performance against published target***

32. From April 2002, the Licensing Section and the Inspectorate were together committed to process at least 85% of applications for project licences within 35 working days.

33. Data for 2003 indicated that the average processing time for all applications was 28 working days. Seventy four 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.

#### ***The Animal Procedures Committee***

34. 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.

35. 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.

36. 2003 was a busy period for the APC, as will be evident in due course in the report of its work for that year that will be presented to Parliament. The Committee launched two major reports in July - one on use of non-human primates, the other on the cost benefit assessment required when project licence applications are made under the 1986 Act. It was also asked by the Home Office Minister to undertake a thorough review of the annual statistics as featured in this publication. More information about the Committee and its work can be found on its website at <http://www.apc.gov.uk/>

#### ***Recent developments***

37. On 20 January 2003 the Government published its response to the report of the House of Lords Select Committee on Animals in Scientific Procedures. A joint Government/scientific community working group was then set up to consider how to take forward some of the key issues raised. These issues were (a) streamlining the project licence application process and form, (b) publishing abridged details of project licences and (c) considering the future of section 24 of the Animals (Scientific Procedures) 1986 (the "confidentiality clause"). By the end of the year the Home Office Minister concerned, Caroline Flint MP, had considered a report from the joint working group, and had agreed to further work being progressed in various ways on all the issues concerned. The Select Committee's report itself was debated in the House of Lords on 17 October.

38. On 25 February 2003 the Inter-Departmental Data Sharing Group - chaired by the Home Office and consisting also of representatives of other Government Departments with an interest in regulatory animal testing - agreed new terms of reference. Its focus was to be more on application and promotion of the 3Rs - replacement of animals in testing where

possible, reduction to minimise their numbers when they have to be used, and then refinement of procedures to minimise their suffering. The Group accordingly changed its name to the Inter-Departmental Group on the 3Rs. Its main concern during 2003 was to formulate advice for Ministers on implementation of the recommendation by House of Lords Select Committee that there should be a national centre for research into the 3Rs. This work was ongoing at the end of the year.

39. In May 2003 the Home Office Minister concerned – then Bob Ainsworth MP – wrote to Ministers in other interested Government Departments, inviting them to review implementation 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, led by the Inter-Departmental Group on the 3Rs, was in progress as the year ended.

40. On 10 June the European Commission announced that work on revising Directive 86/609/EC, which relates to use of animals in scientific procedures and is the basis of the Animals (Scientific Procedures) Act 1986 in the UK, was shortly to begin. The work was initially to be taken forward through a Technical Expert Working Group, sub-groups of which began their deliberations during the course of the year.

### **Summary of infringements**

41. In the published statistics for 2000 details were given of new streamlined procedures for handling infringements. Action on 42 infringements was completed under these procedures in 2003, eleven more than last year's total. The reason for this increase was due to the carry over of a number of class three infringements which took place in 2002 but on which administrative action could not be completed until 2003.

#### ***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. One Class One infringement was dealt with in the reporting period. This infringement occurred in an academic establishment and was discovered by the inspector.

#### ***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. Twenty Class Two infringements were dealt with in the reporting period. Academic establishments were involved in eleven, commercial establishments in six, and Quango's in the remaining three. Thirteen were self-reported and seven discovered by the inspector.

#### ***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 appear to be options. 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. Twenty-one infringements in this category had action completed on them in the reporting period.

48. Ten were reported by licensees to the Home Office, nine were discovered and reported by Inspectors, and two were discovered by the Home Office following allegations made by an animal welfare organisation.

49. A total of seventeen establishments had Class Three infringements reported. Academic establishments were involved in nine, commercial establishments in four, QUANGO's in three, and a National Health Service establishment in one.

#### ***Nature of Class Three Infringements***

50. As in previous years, the nature of the infringements varied in severity. In two cases, regulated procedures were performed without appropriate personal licence authority in breach of section 3(a) of the 1986 Act; in nine cases without

appropriate project licence authority in breach of section 3(b); in three cases without either authority, and in one case without appropriate personal licence authority and at a place not specified in the personal licence and the project licence in breach of sections 3(a) and (c) of the 1986 Act. In two cases regulated procedures were applied to animals that had previously completed a series of regulated procedures, without the authority for their further use; in one case there was inadequate supervision of animals; in one case severity limits were exceeded; 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 areas within the establishment 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, 40 licence holders were admonished; 9 were required to attend relevant modules of an accredited training course; 5 holders of certificates of designation were required to review the systems of control at their establishments in order to prevent recurrence; and 2 non-licensees were sent letters of censure. Revocation action was recommended in two cases; the holder of a Certificate of Designation, and the holder of a personal licence. In these cases the certificate and licence were voluntarily returned to the Home Office in advance of any formal action.

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 2003

## OFFICIAL USE ONLY

Serial  
Number

Project licence  
number

Establishment  
code

Dear Project Licence Holder

This form sets out the arrangements for the 2003 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 2003. 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 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 2004**, 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 2004 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.

Yours faithfully  
**PAUL VALLENDER**  
Animals Scientific Procedures Division  
Communities 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 2003?  
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 ..... Email address .....

<b>Section 2</b>	Select the appropriate codes by referring to the enclosed notes.		<b>01</b>	<b>02</b>	<b>03</b>	<b>04</b>
<b>Species</b> Which animals were used in the procedure?		<b>Row 1</b>				
 <b>CITES</b> Is animal on the CITES list? (see notes)		<b>Row 2</b>				
<b>Stage of Development</b> What was the stage of development of the animal?		<b>Row 3</b>				
 <b>Genetic Status</b> Were the animals genetically abnormal?		<b>Row 4</b>				
 <b>Source</b> From where were the animals obtained?		<b>Row 5</b>				
 <b>Anaesthesia</b> Were the animals anaesthetised?		<b>Row 6</b>				
 <b>NMBA</b> Was an NMBA administered?		<b>Row 7</b>				
<b>Primary Purpose</b> What was the primary purpose of the procedure?		<b>Row 8</b>				
 <b>Body System</b> What was the primary target body system for the procedure?		<b>Row 9</b>				
<b>TOXICOLOGY</b> Purpose Use List A	<b>ALL WORK OTHER THAN TOXICOLOGY</b> Field of Research Use List B		<b>Row 10</b>			
<b>Type of Test</b> Use List A	<b>Production</b> Use List B		<b>Row 11</b>			
<b>Legislative Requirements</b> Use List A	<b>Techniques</b> Use List B		<b>Row 12</b>			
<b>Number of Procedures</b> Enter the total number of procedures for each column			<b>Row 13</b>			
<b>Number of animals used for the first time</b> Enter the total number of animals used for the first time in regulated procedures			<b>Row 14</b>			
<b>Number of animals Reused for the first time this year</b> Enter the total number of animals reused for the <u>first time this year</u> in regulated procedures (see Notes) If no animals were reused this should be set to zero			<b>Row 15</b>			

PPL NO:

FORM SERIAL NO:

PPL NO:

**FORM SERIAL NO:**

## GENERAL NOTES

1. It is a condition of every project licence that the project licence holder should 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:

AP & CU, 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/ccpd/abcu.htm](http://www.homeoffice.gov.uk/ccpd/abcu.htm)

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 will be returned to the licence holder. 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

### ROW 1 : SPECIES

Select the appropriate code from the list below.

#### MAMMAL

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 undergone pain, suffering, distress or lasting harm during the field trials.

R1 Mouse  
R2 Rat  
R3 Guinea-pig  
R4 Hamster  
R5 Gerbil  
R9 Other rodent (please append a note indicating species used)

L1 Rabbit  
C1 Cat  
C2 Dog - beagle  
C3 - greyhound  
C4 - other including cross-bred dogs  
C5 Ferret  
C9 Other carnivore (please append a note indicating species used)

U1 Horse, donkey and cross-bred equids  
U2 Pig  
U3 Goat  
U4 Sheep  
U5 Cattle  
U6 Deer  
U7 Carmelid  
U9 Other ungulate (please append a note indicating species used)

**Primate**  
P1 - prosimian  
- new world monkey  
P2 - marmoset, tamarin  
P3 - squirrel, owl or spider monkey  
P4 - other new world monkey  
- old world monkey  
P5 - macaque  
P6 - baboon  
P7 - other old world monkey  
- ape  
P8 - gibbon  
P9 - great ape  
J9 Other Mammal (please append a note indicating species used)

**BIRD**  
T1 Domestic fowl (*Gallus domesticus*)  
T2 Turkey  
T3 Quail (*Coturnix coturnix*)  
T4 Quail (spp. other than *C. coturnix*)  
T9 Other bird (please append a note indicating species used)

**REPTILE**  
D1 Any reptilian species

**AMPHIBIAN**  
M1 Any amphibian species

**FISH**  
F1 Any fish species

**CEPHALOPOD**  
F5 Octopus vulgaris

### ROW 2 : SPECIES

Animals of endangered species 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(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.

1 the species used in this procedure is listed in Appendix 1 or Annex C.1.  
0 the species is not so listed.

Some examples of CITES codes:

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

### ROW 3 : STAGE OF DEVELOPMENT

Select the appropriate code from the list below.

1 Adult animal, free-living (including neonatal and juvenile mammals and newly-hatched birds).  
2 Larval/embryonic/foetal animal. DO NOT COUNT THESE ANIMALS – ENTER "0" IN ROWS 13, 14 AND 15.

### 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, guinea-pig, hamster, gerbil, rabbit, dog, cat, ferret, primate and quail (*Coturnix coturnix*)**.

**Also: pigs, if genetically modified  
sheep, if genetically modified**

**Enter:**

0 If the species is NOT listed in schedule 2.

**For schedule 2 species enter:-**

1 If the animals were acquired from within own designated establishment.  
2 If the animals were acquired from another designated establishment in the UK (e.g. a university; commercial breeder).  
3 If the animals were acquired from non-designated sources in the UK.  
4 If the animals were acquired from other countries **within** the EU other than the UK (See list at LIST A, ROW 12 below).  
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).  
6 If the animals were acquired from other sources.

#### Non-EU ETS 123 countries (code 5 above)

Cyprus Switzerland  
Norway Turkey

### ROW 6 : ANAESTHESIA

Select the most appropriate numeric code from the list below.

0 **No anaesthesia throughout the procedure.**

Include procedures without anaesthesia which end by a Schedule 1 method of killing even if this consisted of an anaesthetic overdose. Use this code also for the study of potential anaesthetic agents.

1 **General anaesthesia with recovery.**

Used at any stage of the procedure irrespective of other uses of anaesthesia.

2 **Local or regional anaesthesia.**

Used at any stage of the procedure.

3 **General anaesthesia without recovery.**

Used at the end of a procedure which did not otherwise involve anaesthesia. (See note below).

4 **General anaesthesia without recovery.**

Used throughout the procedure.

#### NOTE

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.

#### 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 appliances 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 EITHER list A OR LIST B should be used to complete these rows within a column. A mixture of A and B codes within a column is not permitted.**

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 safety-related 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. The OECD test references are examples 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 safety-related 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)**

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)**

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	

**REMEMBER: 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
- 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
- B20 Botany and plant pathology
- B21 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 } 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

- B50 Ascites model for production of monoclonal antibodies
- B51 Production and maintenance of infectious agents
- B52 Production and maintenance of vectors (e.g. insects)
- B53 Production and maintenance of neoplasms
- B54 Initial immunisation for subsequent *in vitro* or *in vivo* production of monoclonal antibodies
- B55 Production of polyclonal antibodies
- B56 Production of other biological material (e.g. plasma, tissues)

#### 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.

- B61 Animals used to generate founder **genetically modified** 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.
- B62 **Genetically modified** animals generated by recognised 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 the revised 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 wild-type 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 the revised 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 wild-type 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.

- B91 Direct interference with any part of the organs of special 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
- B94 Induction of psychological stress integral to the procedure
- B95 Use of aversive training stimuli
- B96 Exposure to ionising radiation at doses intended to produce a potentially adverse effect on the animal
- B97 Inhalation – DO NOT USE FOR FISH
- B98 Thermal injury } where the study of such injury or trauma
- B99 Physical trauma } was the purpose of the procedure
- 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.

### ROW 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 re-use. 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:

- (i) when their use for a scientific purpose consisted of what would otherwise have been non-regulated procedures (i.e. non-invasive 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.

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 a 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 output, 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 (75) 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 (50) 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 (10) animals are moved to the project licence of a collaborator in the UK in order to set up their own breeding colony. Ten (10) 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

## 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
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 October 2004 if they are to be taken into account in time for the next publication (covering procedures started in 2004).

Comments should be sent to:

Research Development and Statistics Directorate,  
Room 503, Allington Towers,  
19 Allington Street  
LONDON SW1E 5EB

or email: [publications.rds@homeoffice.gsi.gov.uk](mailto:publications.rds@homeoffice.gsi.gov.uk)

# Speaking of Research



Published by TSO (The Stationery Office) and available from:

**Online**

[www.tso.co.uk/bookshop](http://www.tso.co.uk/bookshop)

**Mail, Telephone, Fax & E-mail**

TSO

PO Box 29, Norwich NR3 1GN

Telephone orders/General enquiries 0870 600 5522

Order through the Parliamentary Hotline Lo-Call 0845 7 023474

Fax orders 0870 600 5533

Email [book.orders@tso.co.uk](mailto:book.orders@tso.co.uk)

Textphone 0870 240 3701

**TSO Shops**

123 Kingsway, London WC2B 6PQ

020 7242 6393 Fax 020 7242 6394

68-69 Bull Street, Birmingham B4 6AD

0121 236 9696 Fax 0121 236 9699

9-21 Princess Street, Manchester M60 8AS

0161 834 7201 Fax 0161 833 0634

16 Arthur Street, Belfast BT1 4GD

028 9023 8451 Fax 028 9023 5401

18-19 High Street, Cardiff CF10 1PT

029 2039 5548 Fax 029 2038 4347

71 Lothian Road, Edinburgh EH3 9AZ

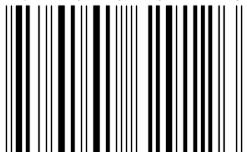
0870 606 5566 Fax 0870 606 5588

**TSO Accredited Agents**

(See Yellow Pages)

and through good booksellers

ISBN 0-10-162912-5



9 780101 629126