



Home Office

BUILDING A SAFE, JUST
AND TOLERANT SOCIETY

Statistics of Scientific Procedures on Living Animals Great Britain 2001

Cm 5581
£14.75

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HOME OFFICE

Statistics of Scientific Procedures on Living Animals

GREAT BRITAIN
2001

Presented to Parliament by the Secretary of State for the
Home Department
by Command of Her Majesty
July 2002

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STATISTICS OF SCIENTIFIC PROCEDURES ON LIVING ANIMALS GREAT BRITAIN 2001

INTRODUCTORY NOTES

1. The statistics in this publication relate to experiments or other scientific procedures on living animals which were subject to the provisions of the Animals (Scientific Procedures) Act 1986 during the year from 1 January 2001. 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. The statistics are compiled from, and largely based on, 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 C. 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 8-15 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 in 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 and 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. To complete the return, project licence holders were asked to classify their procedures. The current classification system dates from 1995 and was modified from 1999 onwards in the areas relating to source of animals, production and breeding, toxicology and legislation. Fuller details are given in paragraphs 9, 11, 12, 15 A (iii) and 15 B (ii) below.

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

Description of statistical tables

5. Project licence holders were asked to answer 15 questions about the procedures performed (see form at Appendix C), 12 of which identify individual characteristics explained more fully in paragraphs 8-15 below. The flowchart on page 23 shows the relationship between the tables and the data in Part A.

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

7. 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 the previous years' publications are given at the end of the publication.

PART A TABLES - PROCEDURES IN 2001

Some tables have been reorganised for this publication. Tables 7 and 17 (use of anaesthesia) have been combined and simplified into one table (table 4b). Table 6 has been discontinued. Tables 13, 15 and 16 now appear in the same format as Table 12. Unaffected tables retain the same numbers as in previous publications.

Species of animal

8. All tables in Part A are classified by species of animal. The full classification is used in Tables 1, 5 and 10, 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 2001 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 completely blank.

Genetic status of animal

9. 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)

10. 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, 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 permitted only for training in microvascular surgery.
- (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 antibody and other tissue production.
- (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)

11. 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 2001 were: mouse, rat, guinea-pig, hamster, gerbil, rabbit, cat, dog, ferret, primate and quail (*Coturnix coturnix*); also pigs 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."

In columns 3-6 of the table, 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)

12.

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 C.

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 the codes, see Appendix C 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 C at List B, row 11.

Target body system (Table 4a - renumbered; previously table 4)

13. 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

14. **Use of anaesthesia (Table 4b)**

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

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 way of disposal as cited in Schedule 1 of the Act) is not a regulated procedure and should not be recorded as such in the above table.

The use of neuromuscular blocking agents (N MBA) is relatively uncommon and for this reason such use is not shown in the table but is described in the text.

Type of procedure

15. 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 C) 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 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 C 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)

16. 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)

17. 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

18. 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.

19. Some of the historical tables appearing in previous publications have been discontinued because of the lack of comparability with data prior to 1995, 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.

20. 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 data in the rest of the table are comparable.

21. 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 2001 was just over 2.62 million, down 92,000 (3.4 per cent) on 2000. This is the lowest number of procedures reported since the Animals (Scientific Procedures) Act started to come into force in 1987. The number of animals used for the first time was 2.57 million, down 75,000 (2.8 per cent) on 2000.
- Mice, rats and other rodent species were used in the majority of procedures – 85 per cent of the total.
- Dogs, cats, horses and non-human primates, accorded special protection by the Act, were collectively used in less than 1 per cent of the procedures.
- Use of all non-human primate species rose by 8 per cent in 2001.
- Over 99 per cent of procedures carried out on animals listed in Schedule 2 of the Act used animals acquired from designated establishments in the United Kingdom.
- The use of genetically normal animals has decreased from 2.27 million in 1995 to 1.74 million in 2001, a drop of 23 per cent over this period.
- The use of animals with naturally occurring harmful genetic defects decreased by 4 per cent compared with 2000.
- Genetically modified animals were used in 631,000 regulated procedures, representing 24 per cent of all procedures in 2001, compared with 8 per cent in 1995. This is an increase in use of 8 per cent over the use in 2000, and was mainly for breeding (68 per cent of the animals – the rest were used in research programmes).
- 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 severity of the procedure.
- Almost 50 per cent of non-toxicological work involved research in the fields of pharmaceutical research and development, immunology, and cancer research.
- Procedures for toxicological purposes accounted for 17 per cent of all procedures started in 2001. This proportion is the same as that recorded in 2000. Since 1995, procedures for toxicological purposes have fallen from 677,000 to 455,000, a fall of 222,000 or just under 33 per cent.
- The majority of toxicology/safety procedures (86 per cent) were performed to conform to legislative requirements. Procedures carried out for non-legislative purposes include studies for the refinement or replacement of live animal use in safety testing as well as ecological studies.
- Pharmaceutical safety/efficacy evaluation purposes accounted for 61 per cent of all procedures for toxicology, other safety and efficacy evaluations.
- No procedures were performed in 2001 for the purpose of evaluating the safety of cosmetic products, cosmetics ingredients, or tobacco.

COMMENTARY

OVERALL PICTURE

Procedures started in 2001

The number of scientific procedures started in 2001 was just over 2.62 million (Table 1), a fall of about 92,000 (3.4 per cent) compared to 2000, and reversed the rise reported in that year. Although there has been a downward trend in the annual number of experiments or scientific procedures since 1976, this trend has levelled out in recent years. This is mainly due to the increased use of genetically modified animals, which is likely to continue (see Figure 2A and related text).

Some 2.57 million animals were used for the first time in procedures started in 2001 (Table 1a). This was about 75,000 (2.8 per cent) fewer than in 2000, broadly reflecting the number of procedures started.

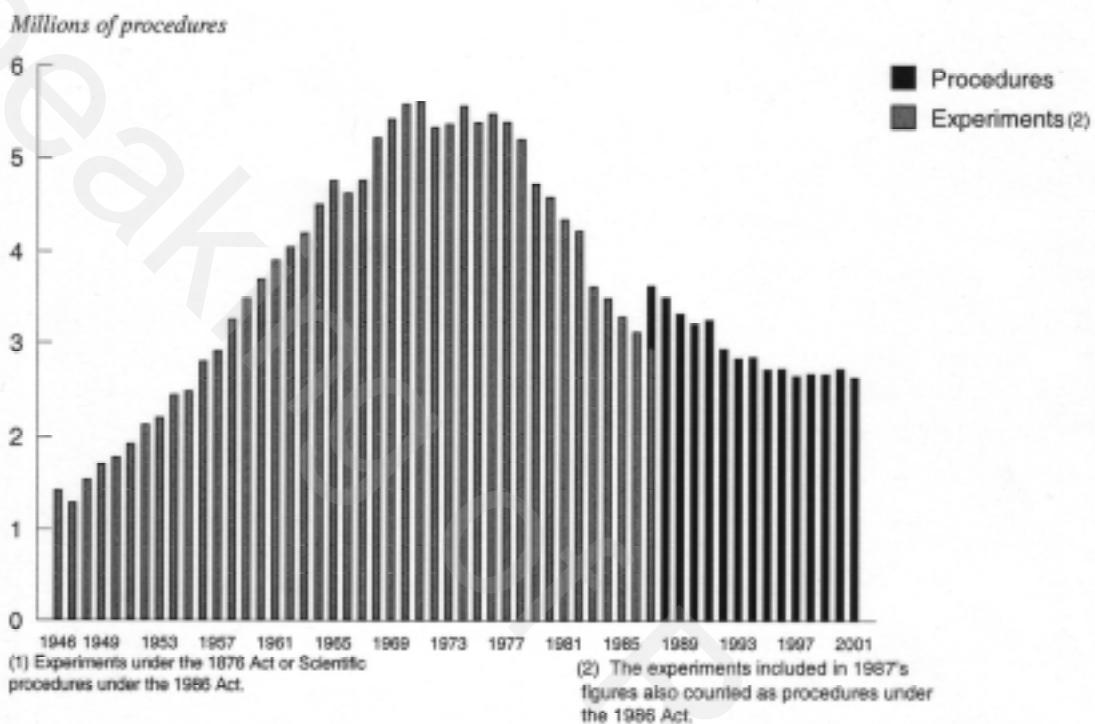


Figure 1: Experiments or procedures commenced each year, 1946-2001⁽¹⁾

Species used (Tables 1 and 1a and Figure 2)

The species of animals involved in the largest numbers of procedures in 2001 were mice (63 per cent of procedures, compared with 59 per cent in 2000); rats (19 per cent, compared with 20 per cent in 2000); guinea pigs (2 per cent, the same as in most recent years); birds (5 per cent, similar to 2000), fish (6.5 per cent, down from 9 per cent in 2000, and partly reversing that year's rise), ungulates (1.4 per cent) and rabbits (1.3 per cent).

Dogs (0.3 per cent of all procedures in 2001), cats (0.06 per cent) and non-human primates (0.15 per cent) were involved in relatively small numbers of procedures (a combined total of 13,511 in 2001), and the total use of these three groups rose by 376 procedures (3 per cent) from 2000.

There were falls in procedures using the majority of species (see below), but the principal increase in 2001 was in procedures involving mice (up 51,000), mainly due to their increased use in breeding procedures. Other species showing increases were reptiles (up about 1,600), beagle dogs (up 400), squirrel monkeys, macaques, most birds, and amphibians.

There were also increases (relatively small in numbers, but in proportion between a third and two-thirds in total) in procedures using species classified as 'other' in 2001: the use of 'other' rodents was up 841,

'other' carnivores up 334, 'other' mammals up 319, 'other' birds up 281 and 'other' ungulates up 10. In 2001 the 'other carnivore' category included badgers, weasels, wild cats, foxes and seals, all used for research relevant to those species. The increase in use of other carnivores was partly due to work on ecological and population studies. The 'other mammals' included species such as shrews, bats, voles and hares.

There were decreases in procedures using most species, but notably rats (down 35,000 procedures), fish (down 72,000, partly reversing the increase of the previous year), sheep (down 17,800), cattle (down 4,500), guinea pigs (down 9,400), rabbits (down 5,900) and pigs (down 2,700). Other species recorded smaller declines in use, including cats (down 233) and horses (down 467). The general decrease in the use of farm animals was mainly due to the outbreak of foot and mouth disease in 2001, which curtailed research by limiting the movement of animals.

No procedures were performed in 2001 on greyhound dogs, camelids, prosimians, baboons, Great Apes, gibbons, non-specified new-world primates and non-specified old-world primates, or *octopus vulgaris*, the single cephalopod species protected by the Act. The Government stated in November 1997 that it would no longer issue licences to use Great Apes in scientific procedures. No Great Apes have been used since the current legislation (the 1986 Act) was introduced in 1987.

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

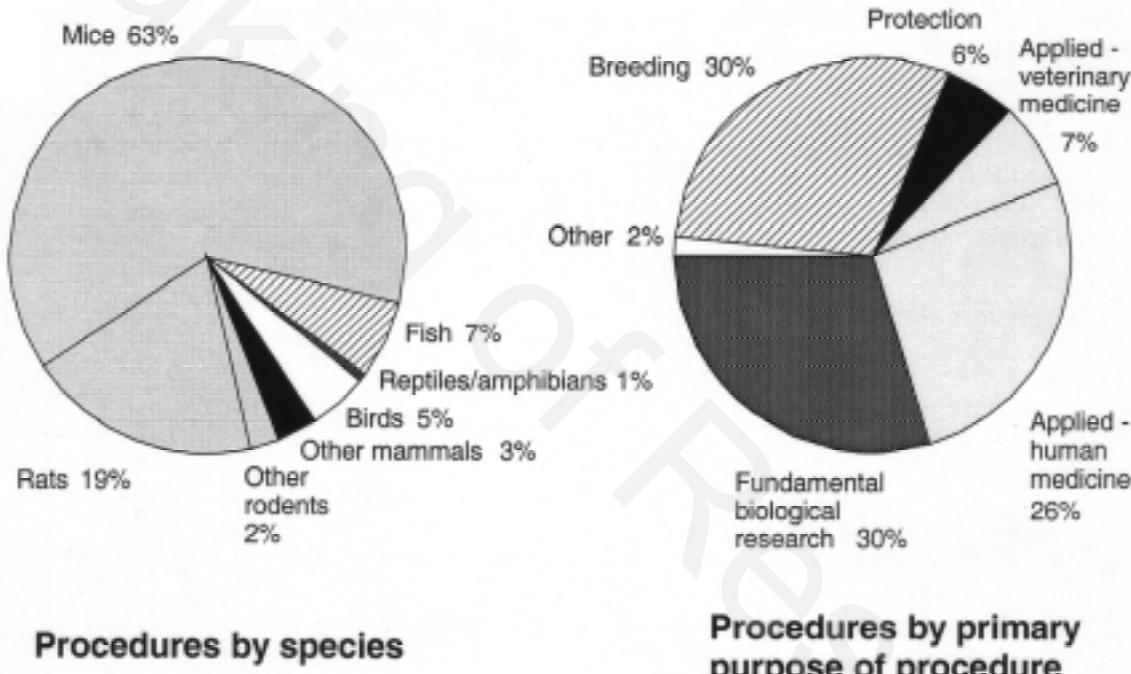


Figure 2: Procedures by species of animal and primary purpose of procedure, 2001

Primary purpose (Tables 1 and 1a, and Figure 2)

In 2001, the main purposes for performing scientific procedures were for fundamental biological research, and breeding, each accounting for just under 780,000 procedures or each just less than 30 per cent of the total. Applied studies into human medicine or dentistry was the only other significant category, with 690,000, representing 26 per cent of procedures started in 2001. All categories except breeding registered a year-on-year fall in the number of procedures: fundamental research was down 94,000 or 11 per cent, applied studies into human medicine was down 49,000 or 7 per cent and procedures undertaken for direct diagnosis of disease fell by 11,000 or 24 per cent.

All categories show a declining trend except breeding, where the increase over the number of such procedures in 2000 was 11 per cent, (and where over twice the number of procedures were conducted for this purpose than in 1995). Numbers of procedures for applied studies in veterinary medicine have been fluctuating over the last seven years.

Source (Table 2, 2.1 and 2.2)

In 2001, 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).

In total, 99 per cent (2.25 million) of procedures carried out on animals listed in Schedule 2 used animals acquired from designated establishments in the United Kingdom, 57 per cent from the user's own establishment, and 43 per cent from another designated establishment. The number of procedures involving Schedule 2 listed animals obtained from sources outside the EU in 2001 fell by 663 to just over 9,400, and of these, 8,000 were obtained from outside Europe (62 per cent of which were mice). 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 46 per cent of the Schedule 2 listed species which were obtained from sources outside the UK were either harmful mutant or genetically modified animals. They were almost all mice, and the remainder were rats. Eighty nine per cent of harmful mutant and 96 per cent of genetically modified animals were obtained from within the licensee's own designated establishment.

Just over 47 per cent of all procedures performed on non-human primates used animals acquired from designated sources within the United Kingdom. The recent closure of the main non-human primate supplying establishment has resulted in more project licence holders sourcing such animals directly from abroad. 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 and cats 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 or cat. As in the case of the non-human primates above, the closure of the major cat breeder has resulted in increased breeding at licensees' own establishments, as well as increased importation. A shortfall in supply of appropriate dogs from designated suppliers in the UK has also led to increased importation.

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.

Some 357,000 procedures, down 91,000 (20 per cent) on 2000, were performed on species not listed in Schedule 2.

Genetic status (Table 3, 3.1, 3.2, 3.3, figure 2A)

Two out of every three procedures started in 2001 involved normal animals. However, from 2000 to 2001 there was an overall decrease of about 131,000 procedures involving genetically normal animals. In the slightly longer term, the use of genetically normal animals has decreased from 2.27 million in 1995 to 1.74 million, a drop of 23 per cent over this period.

Some 247,000 procedures (9.4 per cent) started in 2001 involved animals with a naturally occurring harmful genetic defect, 10,000 fewer than in 2000. The animals were mostly mice (207,000 procedures) and rats (29,000). Other than procedures associated with maintenance of breeding colonies, the work with mice was split reasonably evenly between fundamental biological research and applied studies. The 25 procedures involving dogs noted in this table as having harmful genetic defects, were for studies of naturally-occurring eye diseases relevant to both dogs and man. After a slow increase a few years ago, the number of procedures using animals with a harmful genetic defect has tended to fluctuate more in recent years, and the percentage of all procedures represented by these has also risen slowly but the trend is now static (from 8.4 per cent in 1995 to 9.4 per cent in 2001).

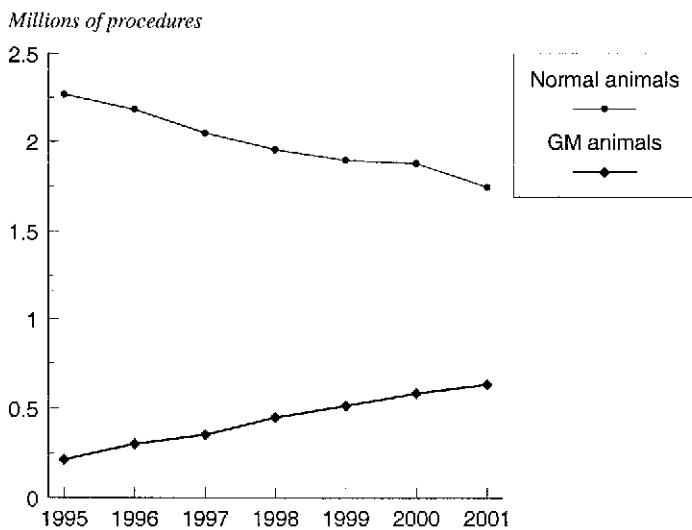


Figure 2A: Procedures involving normal, and genetically modified, animals, 1995-2001

The use of genetically modified (GM) animals was identified as a separate category in this report for the first time in 1990; this category reached some 631,000 procedures in 2001, 49,000 (8 per cent) more than in 2000. Almost a quarter of all procedures in 2001 involved genetically modified animals, and all but 11,400 of these procedures involved mice. Moreover, GM and mutant animals (see above) accounted for about half of all mouse use in 2001. The decrease in the number of procedures involving GM rats for breeding was offset by an increase in their use for fundamental studies. Use of GM pigs fell, but there was a rise in the number of procedures using GM sheep, amphibians and fish. Except for rats, rabbits and amphibians, the main use of GM animals was their actual breeding, which has been reported using separate coding since 1995. In contrast to the earlier slow rise in the use of animals with natural harmful genetic defects, the main regulated use of GM animals has more than doubled since 1995 and in percentage terms now represents about 24 per cent of all scientific procedures, compared with 8 per cent in 1995. This increase has however been more than offset by the decline in the use of genetically normal animals.

Table 3.1 shows normal animals used only in breeding programmes. Nearly all these animals were mice (98 per cent), the remainder being rats, pigs, sheep, fowl and amphibians. Comparison with 2000 shows similar use to last year. Table 3.2 shows that most harmful mutant animals used were again mice (84 per cent). This table also shows that patterns of species use were very similar to those in 2000. Nearly two thirds of all these animals were used for maintenance of breeding colonies; fewer than one per cent were used in toxicology. An increase in procedures for maintenance of the breeding colony was offset by a decrease in use for production and other non-breeding purposes. Table 3.3 shows that the pattern of species and use of GM animals is broadly similar to last year, with increases in most areas, but use of rats, ungulates and rabbits has fallen, and there was also a fall in the number of procedures conducted for production and non-breeding purposes, and for toxicology.

Target body system (Table 4a)

In 2001, about 147,000 procedures (6 per cent of the total) were concerned with the respiratory or cardiovascular system or blood; 399,000 (15 per cent) with the nervous system or special senses; 70,000 (3 per cent) with the alimentary system (including the liver); 111,000 (4 per cent) with the skin, skeletal or muscle system; 229,000 (9 per cent) with reproduction; 445,000 (17 per cent) with the immune system; 146,000 (6 per cent) with a single other body system not already mentioned; and 395,000 procedures, a further 15 per cent, were aimed at more than one body system. The remaining 680,000 procedures, over one-quarter of all procedures, were those in which the body system or systems affected were not relevant. The proportion of procedures for the different target body systems is broadly similar to the use in recent years.

Use of anaesthesia (Table 4b)

About 60 per cent of procedures did not use anaesthesia. 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. Local anaesthesia was used in 233,000 procedures (down 8,000 from the year 2000, and just under 9 per cent of the total), mainly in mice (216,000 – usually for tissue collection for genetic analysis) and various ungulates (9,000). Anaesthesia without recovery was used in 269,000 procedures, about 10 per cent of the total (up 64,500 from the year 2000).

Neuromuscular blocking agents (NMBA) were reported in less than one per cent of procedures, mainly in conjunction with general anaesthesia. Three quarters of these procedures were carried out under general anaesthesia without recovery. Sixty embryonic domestic fowl were given an NMBA without anaesthetic while *in ovo* for fundamental anatomical studies. The NMBA was not used in place of an anaesthetic.

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 2.2 million procedures, in which 2.1 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 2001. There was a fall of 93,000 in the number of such procedures and of 76,000 in the number of animals used, compared with 2000, almost exactly reflecting the fall in the overall number of procedures. Some of this decrease was due to the reversal in the use of fish, primarily for behavioural studies related to fish husbandry and fish disease research conducted in 2000. Of the procedures started in 2001, 1.49 million (69 per cent) were performed on mice and 346,000 (16 per cent) on rats, 117,000 (5 per cent) on birds (mainly domestic fowl) and 117,000 (5 per cent) on fish. A total of 2,400 procedures used dogs, 1,600 used cats and 1,500 used non-human primates.

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

Of the various fields of research, the largest single category was pharmaceutical research and development, which accounted for 409,000 procedures (19 per cent of all non-toxicology procedures), mainly on rodents. Immunology (392,000) and cancer research (269,000) represented around 18 and 12 per cent of this total respectively; a wide range of species was used in immunology but mice and rats accounted for all but 0.5 per cent of the procedures carried out for cancer research. Anatomy, physiology, parasitology and molecular biology 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 2000 were: psychology (down 69,000, reversing the rise last year), pharmaceutical research and development (down 38,000), microbiology (down 28,000), molecular biology (down 19,000, reversing the rise of the last two years) and nutrition (down 15,000, reversing the rise reported last year). Increases were reported principally for immunology (up 36,000, part of a rising trend), pathology (up 16,000, also an upward trend), parasitology (up 18,000), physiology (up 14,000) and cancer research (up 10,000).

Animals with harmful genetic defects (Table 5.1) were used across a wide range of disciplines, except for clinical surgery, dentistry, zoology, botany, animal science, ecology, and research related to the use of tobacco or alcohol. The principal disciplines for which such animals were used were: cancer research (68,000 or 28 per cent of all procedures involving animals with harmful mutations), immunology (38,000 or 16 per cent), and 'other' use, i.e. disciplines not otherwise specified, 56,000 or 23 per cent. With the exception of rodents and rabbits, the use of other species with harmful genetic defects was mainly for research relevant to those species.

There was a broadly similar spread of disciplines involving genetically modified animals (Table 5.2), except that the greatest use was for immunology (176,000 or 28 per cent of procedures using GM animals), cancer research (107,000 or 17 per cent) and anatomy, which includes developmental biology (85,000 or 14 per cent).

Production of biological materials (Table 8)

In 2001, some 295,000 procedures, 19,000 fewer than in 2000, were for the purposes of production of biological materials. About 38 per cent of these were for the production of infectious agents and, of this particular group, 29 per cent used mice and a further 66 per cent used birds. 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 rabbits or ungulates were also generally used. The remaining 46 per cent of production procedures were to obtain other biological material such as tissues or plasma, 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 fall of 623 to 4,809, reversing the slight rise last year.

In 2001, 1,200 procedures were performed (all on mice) for the production of monoclonal antibodies using the ascites model, an increase on last year but still considerably lower than the 3,000 performed in 1999. With the exception of ten procedures where supplementary enquiries have raised concern regarding their justification, all other procedures using the ascites method in 2001 were authorised in accordance with the policy set out above.

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 152,000 procedures, representing 7 per cent of non-toxicological procedures, fell into this category in 2001, just slightly lower than the number reported in 2000. The number of these procedures has fluctuated from year to year but in 2001 was the lowest since this category of procedure was separately identified in 1995. There were some increases, principally in procedures involving inhalation (up 9,800 on 2000) and aversive training (up 4,600) but these were matched by decreases, particularly in procedures involving interference with the brain (down 8,000) and radiation (down 4,900). Inhalation procedures used mainly rodents, and aversive training involved mainly rats and birds. Rats were the main species used for procedures involving interference with the brain, and mice for radiation.

TOXICOLOGY OR OTHER SAFETY OR EFFICACY EVALUATION

Purpose (Tables 10, 10a)

Procedures for the purpose of toxicology or safety and efficacy evaluation accounted for 455,000, or just over 17 per cent, of the total number of procedures carried out in 2001. This was almost exactly the same number as in 2000. These procedures used 443,000 animals for the first time (Table 10a), a very small rise of just over 1,076 from 2000.

Since 1995, procedures for toxicological purposes have fallen from 677,000 to 455,000, a fall of 222,000 or just under 33 per cent.

Of those procedures started in 2001, 170,000 (37 per cent) used mice; a further 155,000 (34 per cent) used rats, and other rodents were used in 29,200 procedures (6 per cent). Some 54,000 (12 per cent of the total) used fish, 23,000 used rabbits, birds were used in 10,000 procedures, and dogs (beagles) in 5,600. Other species accounted for less than 2 per cent of all toxicology procedures; 2,500 used non-human primates but only 12 used cats. Species for which there was a fall in the number of toxicological procedures in 2001 included: guinea pigs (down 6,000 or 18 per cent), rabbits (down 2,600 or 10 per cent) domestic fowl (down 3,900 or a third), and new-world primates (down 500 or 66 per cent). There were few species with

a significant rise in use but procedures involving reptiles (numbering 1,500) appeared for the first time; dogs were up 1,100, also fish (up 8,600) and old-world primates (up 400).

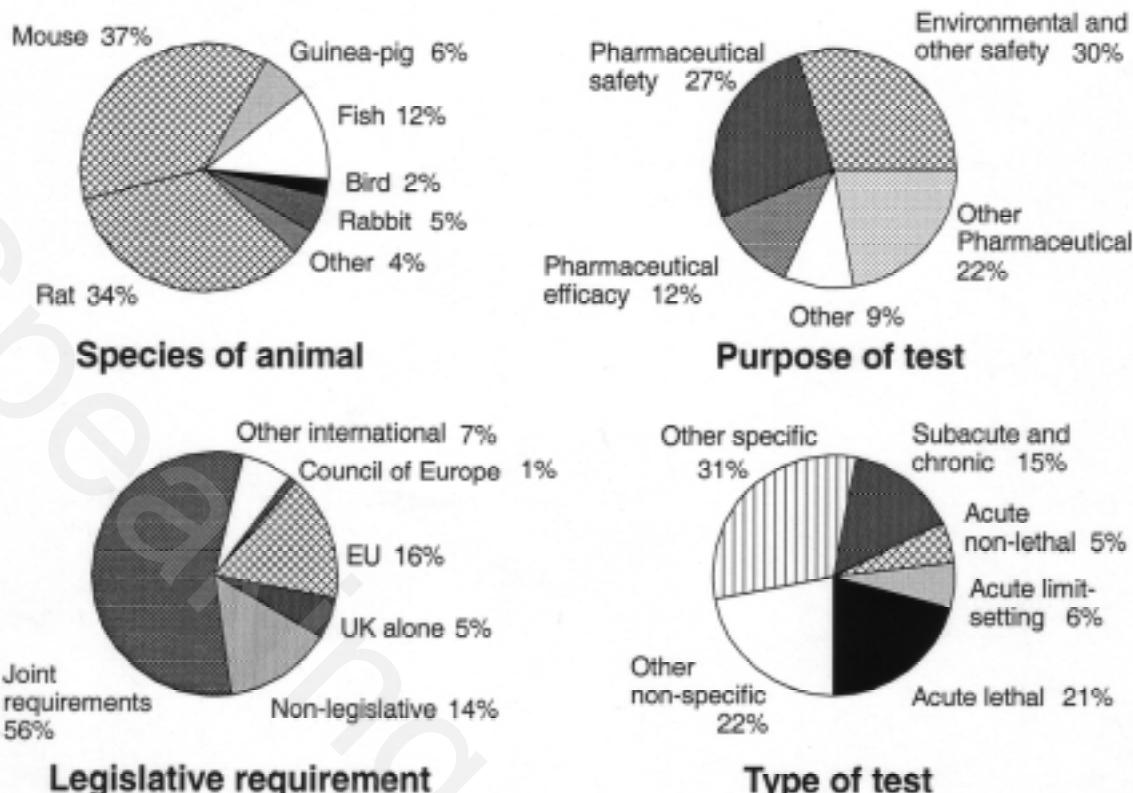


Figure 3: Procedures (toxicology) by species of animal, purpose of test, legislative requirement and type of test, 2001

Only about one in every 500 procedures involving genetically modified animals was carried out for toxicology, and all of the animals so used were mice (see Table 3.3). A broadly similar picture emerged in the case of animals with harmful genetic defects (Table 3.2).

Safety, efficacy testing, and quality control of pharmaceutical products accounted for nearly 54 per cent of toxicology procedures in 2001. The next most common purposes were safety evaluation of substances used in industry (53,000) and in agriculture (41,000), and evaluation of environmental pollution (38,000).

There were increases in procedures performed to evaluate environmental pollution (up 3,200), and substances used in agriculture (up 5,700). Pharmaceutical ADME and residue testing was up 11,400 and, to a lesser extent, safety testing (up 6,400) and quality control (up 1,300). Method development also was up, by 1,800. All other categories showed a fall in the number of procedures; the principal decreases being for pharmaceutical efficacy testing (down 17,000), toxicology research (down 4,900) and 'other' toxicology, not defined elsewhere in the table (down 2,400).

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 2001. Table 14 has therefore been omitted from this year's publication. Since 1995 there has been no safety testing of tobacco or tobacco products and there are no licences in force for procedures of this kind.

Legislative requirements (Table 11)

Of the total of 455,000 toxicology or safety procedures in 2001, 86 per cent were performed to comply with legislation or other regulations. Only 24,500 procedures (5 per cent) were performed to satisfy UK legislation alone; about 75,000 (16 per cent) were performed to satisfy the requirements of either a single

EU country (excluding the UK) or the EU in general; a further 4,600 (1 per cent) to meet the requirements of Council of Europe countries outside the EU; and 30,600 (7 per cent) for other international legislation. The majority of procedures performed to fulfil legislative requirements (255,000, or 56 per cent) were used to satisfy a combination of the above requirements. The remaining 66,000 procedures, 14 per cent of toxicology and safety work, 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. During 1999 an announcement was made by the Home Office that acute lethal toxicology testing using the OECD Guideline 401 would no longer be licensed if a scientifically suitable alternative was available, regardless of the preferences of regulators. In 2001 acute quantitative lethal toxicity tests accounted for 71,000 procedures or 16 per cent of all toxicology work. Tests were reported in this category for the following purposes: safety testing of substances used in agriculture, safety testing of substances used in industry, pharmaceutical safety and shellfish toxicity testing. None of these tests was carried out according to OECD Guideline 401. Acute lethal concentration tests accounted for 23,500 procedures (5 per cent), and acute limit-setting lethal toxicity tests another 27,500 procedures (6 per cent). There was an overall increase in the use of procedures for acute safety testing from 123,000 in 2000 to 147,000 in 2001, partly reversing the fall in such procedures last year.

A further 43,000 (9 per cent) were carried out for subacute toxicity or limit-setting tests. This was 2,600 fewer than in 2000. Of the remainder, other, non-specified, toxicological tests (mainly using mice and rats) accounted for the greatest single proportion with 100,000 procedures (22 per cent of the total), a fall of about 18,600 on 2000. 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 11,700 procedures carried out on rabbits for pyrogenicity testing (1,620 fewer than in 2000), 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 1,450 procedures carried out on rabbits to test for clinical signs in the eye (500 fewer than in 2000); 48,000 procedures (11 per cent), mainly on rats, to test for reproductive toxicity; and 20,800 procedures (5 per cent) on rodents to test for skin sensitisation, mainly on 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 39,000 procedures carried out on rats for reproductive toxicity other than teratogenic testing (Table 12) is split mainly between safety testing both of pharmaceuticals (see Table 15), and non-pharmaceuticals (Table 13). Two out of three of these tables show a slight increase in the number of procedures against the comparable figures for 2000: non-pharmaceuticals up 4,500 (3 per cent), pharmaceutical safety up 2,000 (0.8 per cent) and other safety down 6,000 or 13 per cent.

Table 14 no longer appears because there was no testing of cosmetics or ingredients intended primarily for cosmetics in 2001 (see Appendix A).

Rodenticide trials

It is impractical to collect accurate figures on the number of animals affected in field trials of rodenticidal substances. In 2001, a single project licence holder made a positive return, estimating that a total of 799 wild rats 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). No procedures were reported in 2001 on animals included in this category.

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 (Table 19)

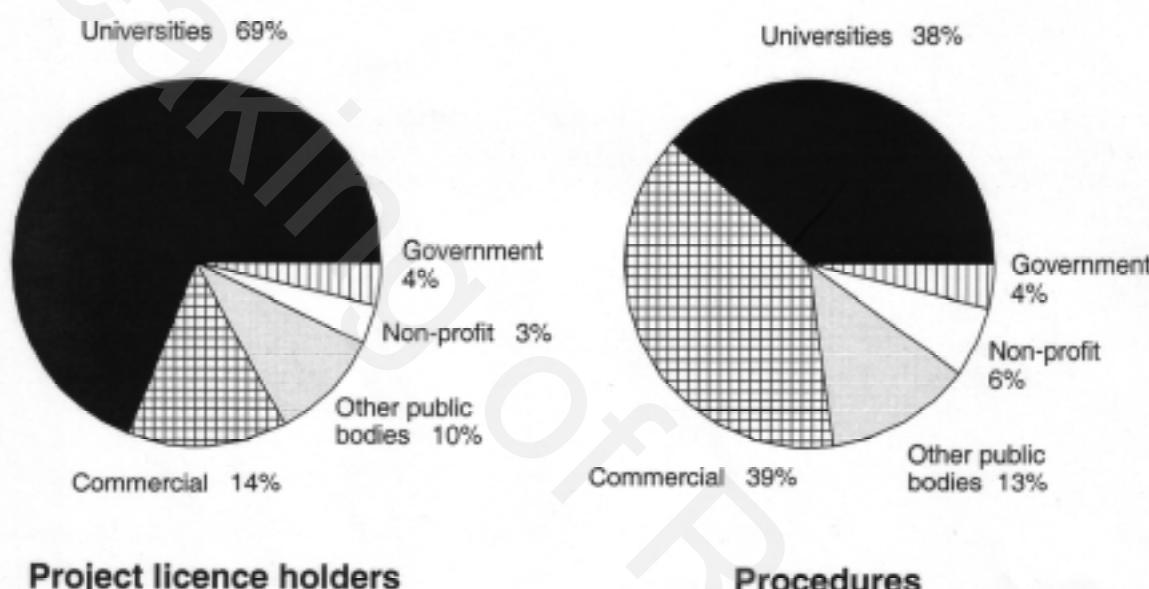


Figure 4: Project licence holders and procedures started in 2001, by type of designated place (note: only those project licence holders reporting procedures in 2001 are included)

Returns

Returns were received in respect of 3,970 project licences in 2001, 40 fewer than in 2000. Only fifteen licensees failed to make returns. Just under 2,800 licensees reported starting procedures in 2001, some 80 fewer than in 2000. Of these, about 2,000 (73 per cent, as against 68 per cent in 2000), reported starting more than 50 procedures. The holders of about 1,200 project licences (30 per cent of all licensees) reported starting no procedures in 2001 (Table 19). This was very similar to the position in 2000.

Project licensees and designated places

Sixty nine per cent of the projects on which procedures were started were based at universities or other academic establishments (including medical schools and former polytechnics) but they accounted for only just over 38 per cent of the number of procedures. Projects at commercial organisations reported 39 per cent of the procedures started in 2001, and accounted for 14 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 nearly 40 per cent. The proportion of procedures carried out by commercial licensees has fallen from 60 per cent in 1987 to 39 per cent in 2001 (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, but in 2001 fell back slightly to just below the level reported by commercial firms. 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 (though in 2001 the biggest fall was in procedures conducted in universities). The number of procedures started in other types of establishment has tended to fluctuate over the last eleven years.

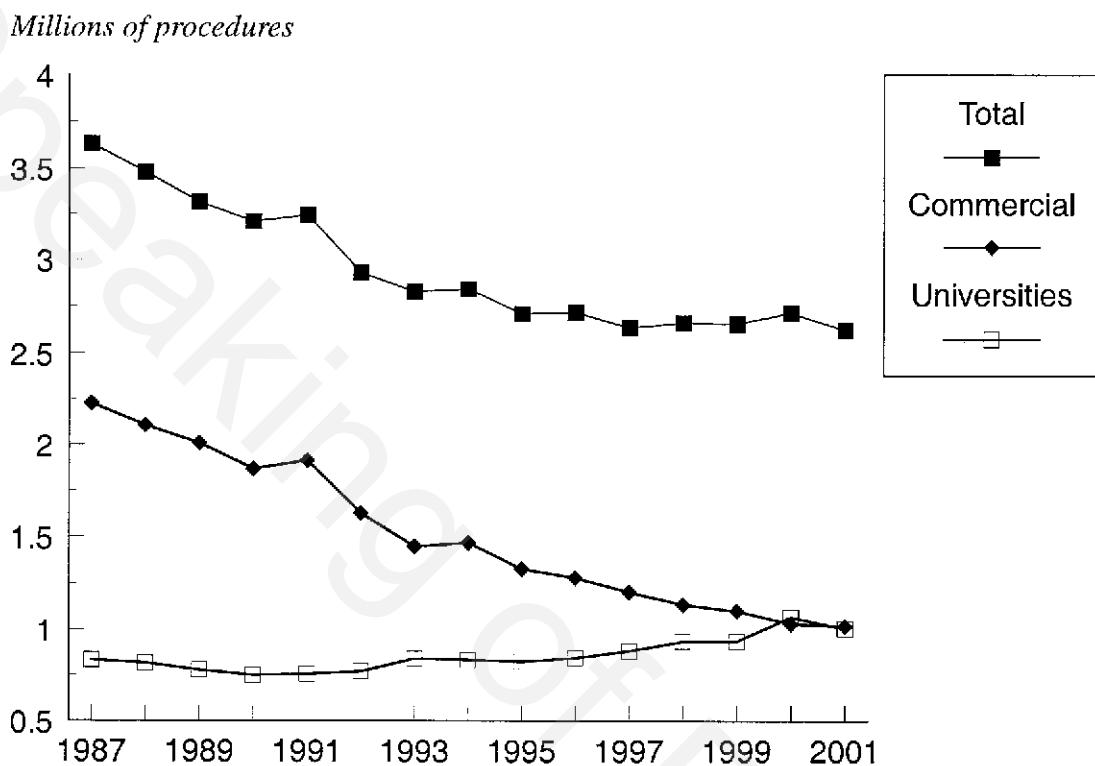


Figure 5: Procedures by type of establishment, 1987-2001. The graph shows the two types of institution responsible for the largest number of procedures (and therefore have most impact on the overall number of procedures started each year).

Historical tables

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

Feedback

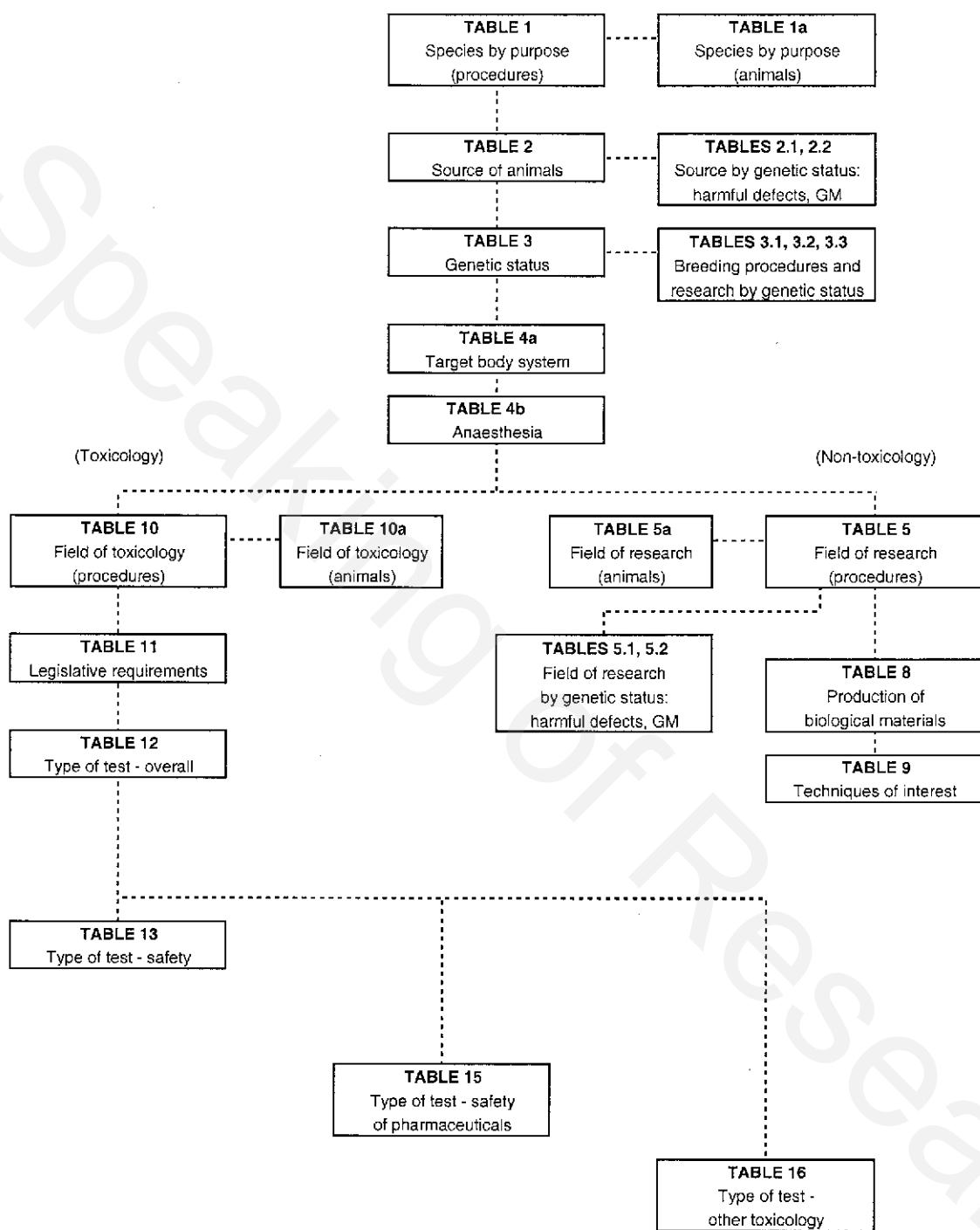
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Organisation Chart: Relationship between the tables in part A, 2001



Notes

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

GM = genetically modified

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

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

Species of animal	Great Britain 2001	Number of procedures						Total
		Fundamental biological research	Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Protection of man, animals or environment	Training	Forensic enquiries	
Mammal								
Mouse	490,203	369,410	21,101	24,437	1,498	-	9,327	741,681
Rat	149,043	258,507	2,257	63,965	898	1,188	97	24,291
Guinea pig	3,755	25,612	1,869	16,015	921	-	77	48,249
Hamster	4,261	1,037	1,837	154	-	-	-	18
Gerbil	666	2,281	-	-	10	-	-	7,307
Other rodent	2,026	6	504	520	-	-	-	2,957
Rabbit	4,452	19,081	1,576	4,698	134	-	-	3,056
Cat	366	38	1,176	-	-	-	3,641	159
Dog	276	6,229	325	228	-	-	-	33,741
Beagle	-	-	-	-	-	-	-	1,580
Greyhound	-	-	-	-	-	-	-	7,263
Other including cross-bred dogs	4	-	663	-	-	-	-	-
Ferret	235	780	14	-	12	-	9	6
Other carnivore	969	-	3	-	-	-	33	682
Horse, donkey and cross-bred equids							76	1,074
Pig	515	-	331	-	-	-	26	1,048
Goat	3,028	477	1,697	-	-	-	7,924	8,805
Sheep	164	8	157	6	-	-	580	5,854
Cattle	6,983	944	1,377	59	8	-	7	342
Deer	1,829	1,415	-	51	-	-	4	18,758
Camelid	-	-	-	-	-	-	-	3,414
Other ungulate	-	-	-	-	-	-	-	188
Primate	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-
New World monkey	472	762	-	-	-	-	105	1,339
marmoset, tamarin	-	50	-	-	-	-	-	50
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-
Other: New World monkey	-	-	-	-	-	-	-	-

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	Training	Forensic enquiries	Direct diagnosis	Breeding		
Old World monkey	334	2,258	-	-	-	-	-	-		
Macaque	-	-	-	-	-	-	-	2,597		
Baboon	-	-	-	-	-	-	-	-		
Other Old World monkey	-	-	-	-	-	-	-	-		
Apes	-	-	-	-	-	-	-	-		
Gibbon	-	-	-	-	-	-	-	-		
Great ape	-	-	-	-	-	-	-	-		
Other mammal	753	-	1	22	-	-	-	776		
Bird	18,831	322	90,025	313	117	-	-	-		
Domestic fowl (<i>Gallus domesticus</i>)	221	50	3,507	-	-	-	-	111,344		
Turkey	188	-	-	-	-	-	-	3,909		
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	188		
Quail (spp. other than <i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	1,300		
Other bird	8,610	-	422	1,081	-	-	-	10,117		
Reptile	114	1,535	-	-	-	-	-	-		
Any reptilian species	12,359	8	-	-	-	-	-	1,649		
Amphibian	67,806	525	51,939	38,390	-	-	-	15,850		
Any amphibian species	-	-	-	-	-	-	-	-		
Fish	-	-	-	-	-	-	-	-		
Any fish species	-	-	-	-	-	-	-	-		
Cephalopod	-	-	-	-	-	-	-	-		
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-		
Total	778,651	689,920	182,196	153,553	4,585	1,188	30	34,488	777,831	2,622,442

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

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	Training	Forensic enquiries	Direct diagnosis	Breeding	Total
Mammal									
Mouse	489,211	368,599	21,101	24,437	1,498	-	9,327	741,593	1,655,766
Rat	147,968	248,966	2,257	63,965	881	1,188	97	24,291	489,613
Guinea pig	3,755	25,549	1,869	16,015	149	-	50	-	47,387
Hamster	4,078	1,037	1,837	154	-	-	-	18	7,124
Gerbil	666	2,281	-	-	10	-	-	-	2,957
Other rodent	2,026	6	501	520	-	-	-	-	3,053
Rabbit	4,401	9,438	1,049	4,617	112	-	3,580	159	23,356
Cat	355	38	338	-	-	-	-	-	731
Dog	266	4,781	185	214	-	-	14	-	5,460
Beagle	-	-	-	-	-	-	-	-	-
Greyhound	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	3	-	76	-	-	-	9	6	94
Ferret	211	769	14	-	12	-	33	-	1,039
Other carnivore	870	-	3	-	-	-	76	-	949
Horse, donkey and cross-bred equids	179	-	132	-	9	-	329	-	649
Pig	2,577	475	1,697	-	-	-	580	72	5,401
Goat	134	8	157	6	-	-	7	-	312
Sheep	6,092	845	1,262	59	8	-	4	1,441	10,664
Cattle	1,565	67	1,175	51	-	-	-	-	2,910
Deer	-	-	-	-	-	-	-	-	67
Camelid	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	10	-	-	-	10
Primate	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-
New World monkey	436	582	-	-	-	-	105	-	1,123
marmoset, tamarin	-	-	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-	-

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

Species of animal	Fundamental biological research	Primary purpose of the procedure						Total	Number of animals
		Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Protection of man, animals or environment	Education	Training	Forensic enquiries	Direct diagnosis	
Old World monkey	285	1,929	-	-	-	-	-	5	-
Macaque	-	-	-	-	-	-	-	-	2,219
Baboon	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-
Other mammal	753	-	1	22	-	-	-	-	776
Bird	18,831	322	89,073	313	117	-	-	1,580	94
Domestic fowl (<i>Gallus domesticus</i>)	221	6	3,507	-	-	-	-	46	-
Turkey	188	-	-	-	-	-	-	-	110,330
Quail (<i>Colurnix colurnix</i>)	-	-	-	-	-	-	-	-	3,780
Quail (spp. other than <i>Colurnix colurnix</i>)	8,610	-	312	1,081	-	-	-	-	188
Other bird	-	-	-	-	-	-	-	4	-
Reptile	114	227	-	-	-	-	-	-	341
Any reptilian species	-	-	-	-	-	-	-	-	-
Amphibian	6,251	5	-	2,304	-	-	-	-	9,648
Any amphibian species	-	525	51,906	38,390	-	-	-	-	-
Fish	67,206	-	-	-	-	-	-	-	-
Any fish species	-	-	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-
Total	767,319	666,388	178,452	153,458	3,696	1,188	4	19,495	777,713
									2,567,713

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

Species of animal	Source					Number of procedures Total
	Animals acquired from within own designated establishment	Animals acquired from another designated breeding or supplying establishment in the UK	Animals acquired from non-designated sources in the UK	Animals acquired from sources within the EU (outside the UK)	Animals acquired from Council of Europe countries who are signatories to ETS123	
Mouse	1,147,326	501,229	23	2,787	1,241	5,051
Rat	121,758	377,602	166	440	45	235
Guinea pig	648	47,583	-	18	-	-
Hamster	4,220	3,087	-	-	-	-
Gerbil	620	1,643	-	688	-	6
Rabbit	3,461	30,065	215	-	-	-
Cat	975	211	11	383	-	-
Dog	2,294	4,344	357	222	-	728
Ferret	347	701	24	-	-	2
Pig (genetically modified)	54	-	-	-	-	-
Sheep (genetically modified)	552	-	-	-	-	-
Primate	1,090	786	-	8	-	2,102
Quail (<i>Coturnix coturnix</i>)	-	188	-	-	-	-
Animals not listed	-	-	-	-	-	356,906
Total	1,283,345	967,439	796	4,546	1,286	8,124
						356,906
						2,622,442

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

Species of animal	Source				Number of procedures Total
	Animals acquired from within own designated establishment	Animals acquired from another designated breeding or supplying establishment in the UK	Animals acquired from non-designated sources in the UK	Animals acquired from sources within the EU (outside the UK)	
Mouse	191,960	13,640	-	15	207,074
Rat	27,157	1,599	-	56	28,882
Guinea pig	-	-	-	-	-
Hamster	18	-	-	-	18
Gerbil	-	-	-	-	-
Rabbit	157	-	-	-	157
Cat	-	-	-	-	-
Dog	25	-	-	-	25
Ferret	-	-	-	-	-
Primate	-	-	-	-	-
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-
Animals not listed	219,317	15,239	-	71	10,688
Total				1,529	10,688
					246,844

(1) The * animals not listed in Schedule 2* here were 298 domestic fowl and 10,390 fish.

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

Species of animal	Source				Total
	Animals acquired from within own designated establishment	Animals acquired from another designated breeding or supplying establishment in the UK	Animals acquired from sources within the EU (outside the UK)	Animals acquired from Council of Europe countries who are signatories to ETS 123	
Mouse	599,299	15,212	-	2,054	619,386
Rat	3,017	278	-	-	3,295
Guinea pig	-	-	-	-	-
Hamster	-	-	-	-	-
Gerbil	-	-	-	-	-
Rabbit	15	-	-	-	15
Cat	-	-	-	-	-
Dog	-	-	-	-	-
Ferret	-	-	-	-	-
Pig (genetically modified)	54	-	-	-	54
Sheep (genetically modified)	552	-	-	-	552
Primate	-	-	-	-	-
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-
Animals not listed	-	-	-	-	-
Total	602,937	15,490	-	2,054	630,759
			508	2,313	7,457
					7,457

(1) The "animals not listed in Schedule 2" here were 2 domestic fowl, 595 amphibians and 6,860 fish.

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

Great Britain 2001		Primary purpose of procedure	Genetic status			Number of procedures
Species of animal			Normal animal	Animal with harmful genetic defect	Genetically modified animal	
Mouse	Fundamental biological research	287,155	37,710	165,338	56	490,203
	Applied studies	332,316	41,509	16,686	-	390,511
	Safety	24,351	30	56	-	24,437
	Other uses	10,680	136	9	-	10,825
	Breeding	176,695	127,689	437,297	-	741,681
	Total	831,197	207,074	619,386	-	1,657,657
Rat	Fundamental biological research	141,752	5,052	2,239	-	149,043
	Applied studies	257,626	3,078	60	-	260,764
	Safety	63,965	-	-	-	63,965
	Other uses	2,183	-	-	-	2,183
	Breeding	2,543	20,752	996	-	24,291
	Total	468,069	28,882	3,295	-	500,246
Guinea pig	Fundamental biological research	3,755	-	-	-	3,755
	Applied studies	27,481	-	-	-	27,481
	Safety	16,015	-	-	-	16,015
	Other uses	998	-	-	-	998
	Breeding	-	-	-	-	-
	Total	48,249	-	-	-	48,249
Hamster	Fundamental biological research	4,261	-	-	-	4,261
	Applied studies	2,874	-	-	-	2,874
	Safety	154	-	-	-	154
	Other uses	-	-	-	-	-
	Breeding	-	18	-	-	18
	Total	7,289	18	-	-	7,307
Gerbil	Fundamental biological research	666	-	-	-	666
	Applied studies	2,281	-	-	-	2,281
	Safety	-	-	-	-	-
	Other uses	10	-	-	-	10
	Breeding	-	-	-	-	-
	Total	2,957	-	-	-	2,957
Other rodent	Fundamental biological research	2,026	-	-	-	2,026
	Applied studies	510	-	-	-	510
	Safety	520	-	-	-	520
	Other uses	-	-	-	-	-
	Breeding	-	-	-	-	-
	Total	3,056	-	-	-	3,056
Rabbit	Fundamental biological research	4,439	-	13	-	4,452
	Applied studies	20,657	-	-	-	20,657
	Safety	4,698	-	-	-	4,698
	Other uses	3,775	-	-	-	3,775
	Breeding	-	157	2	-	159
	Total	33,569	157	15	-	33,741
Cat	Fundamental biological research	366	-	-	-	366
	Applied studies	1,214	-	-	-	1,214
	Safety	-	-	-	-	-
	Other uses	-	-	-	-	-
	Breeding	-	-	-	-	-
	Total	1,580	-	-	-	1,580
Dog - Beagle	Fundamental biological research	276	-	-	-	276
	Applied studies	6,554	-	-	-	6,554
	Safety	228	-	-	-	228
	Other uses	205	-	-	-	205
	Breeding	-	-	-	-	-
	Total	7,263	-	-	-	7,263
Dog - Other	Fundamental biological research	4	-	-	-	4
	Applied studies	653	10	-	-	663
	Safety	-	-	-	-	-
	Other uses	-	9	-	-	9
	Breeding	-	6	-	-	6
	Total	657	25	-	-	682
Ferret	Fundamental biological research	235	-	-	-	235
	Applied studies	794	-	-	-	794
	Safety	-	-	-	-	-
	Other uses	45	-	-	-	45
	Breeding	-	-	-	-	-
	Total	1,074	-	-	-	1,074

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

Species of animal	Primary purpose of procedure	Genetic status			Number of procedures
		Normal animal	Animal with harmful genetic defect	Genetically modified animal	
Other Carnivore	Fundamental biological research	969	-	-	969
	Applied studies	3	-	-	3
	Safety	-	-	-	-
	Other uses	76	-	-	76
	Breeding	-	-	-	-
	Total	1,048	-	-	1,048
Horse, Donkey etc	Fundamental biological research	515	-	-	515
	Applied studies	331	-	-	331
	Safety	-	-	-	-
	Other uses	7,959	-	-	7,959
	Breeding	-	-	-	-
	Total	8,805	-	-	8,805
Pig	Fundamental biological research	3,028	-	-	3,028
	Applied studies	2,174	-	-	2,174
	Safety	-	-	-	-
	Other uses	580	-	-	580
	Breeding	18	-	54	72
	Total	5,800	-	54	5,854
Goat	Fundamental biological research	164	-	-	164
	Applied studies	165	-	-	165
	Safety	6	-	-	6
	Other uses	7	-	-	7
	Breeding	-	-	-	-
	Total	342	-	-	342
Sheep	Fundamental biological research	6,983	-	-	6,983
	Applied studies	2,321	-	-	2,321
	Safety	59	-	-	59
	Other uses	8,425	-	-	8,425
	Breeding	418	-	552	970
	Total	18,206	-	552	18,758
Cattle	Fundamental biological research	1,829	-	-	1,829
	Applied studies	1,415	-	-	1,415
	Safety	51	-	-	51
	Other uses	119	-	-	119
	Breeding	-	-	-	-
	Total	3,414	-	-	3,414
Deer	Fundamental biological research	188	-	-	188
	Applied studies	-	-	-	-
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	188	-	-	188
Other Ungulate	Fundamental biological research	-	-	-	-
	Applied studies	-	-	-	-
	Safety	10	-	-	10
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	10	-	-	10
Marmoset, Tamarin	Fundamental biological research	472	-	-	472
	Applied studies	762	-	-	762
	Safety	-	-	-	-
	Other uses	105	-	-	105
	Breeding	-	-	-	-
	Total	1,339	-	-	1,339
Squirrel, Owl or Spider monkey	Fundamental biological research	-	-	-	-
	Applied studies	50	-	-	50
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	50	-	-	50
Macaque	Fundamental biological research	334	-	-	334
	Applied studies	2,258	-	-	2,258
	Safety	-	-	-	-
	Other uses	5	-	-	5
	Breeding	-	-	-	-
	Total	2,597	-	-	2,597
Other Mammal	Fundamental biological research	753	-	-	753
	Applied studies	1	-	-	1
	Safety	22	-	-	22
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	776	-	-	776

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

Great Britain 2001

Species of animal	Primary purpose of procedure	Genetic status			Number of procedures Total
		Normal animal	Animal with harmful genetic defect	Genetically modified animal	
Domestic Fowl	Fundamental biological research	18,533	298	-	18,831
	Applied studies	90,347	-	-	90,347
	Safety	313	-	-	313
	Other uses	1,759	-	-	1,759
	Breeding	92	-	2	94
	Total	111,044	298	2	111,344
Turkey	Fundamental biological research	221	-	-	221
	Applied studies	3,557	-	-	3,557
	Safety	-	-	-	-
	Other uses	131	-	-	131
	Breeding	-	-	-	-
	Total	3,909	-	-	3,909
Quail (<i>Colurnix columinx</i>)	Fundamental biological research	188	-	-	188
	Applied studies	-	-	-	-
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	188	-	-	188
Quail (spp. other than <i>Colurnix columinx</i>)	Fundamental biological research	-	-	-	-
	Applied studies	-	-	-	-
	Safety	1,300	-	-	1,300
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	1,300	-	-	1,300
Other bird	Fundamental biological research	8,610	-	-	8,610
	Applied studies	422	-	-	422
	Safety	1,081	-	-	1,081
	Other uses	4	-	-	4
	Breeding	-	-	-	-
	Total	10,117	-	-	10,117
Reptile	Fundamental biological research	114	-	-	114
	Applied studies	1,535	-	-	1,535
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	1,649	-	-	1,649
Amphibian	Fundamental biological research	11,885	-	474	12,359
	Applied studies	8	-	-	8
	Safety	2,304	-	-	2,304
	Other uses	978	-	-	978
	Breeding	80	-	121	201
	Total	15,255	-	595	15,850
Fish	Fundamental biological research	61,196	3,714	2,896	67,806
	Applied studies	52,163	-	301	52,464
	Safety	38,390	-	-	38,390
	Other uses	2,093	-	-	2,093
	Breeding	-	6,676	3,663	10,339
	Total	153,842	10,390	6,860	171,092
All species	Fundamental biological research	560,917	46,774	170,960	778,651
	Applied studies	810,472	44,597	17,047	872,116
	Safety	153,467	30	56	153,553
	Other uses	40,137	145	9	40,291
	Breeding	179,846	155,298	442,687	777,831
TOTAL		1,744,839	246,844	630,759	2,622,442

Species not listed had no procedures

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

Species of animal	Generation of founder genetically modified animals	Number of procedures		
		Normal animals within genetically modified breeding colonies	Normal animals within harmful mutant breeding colonies	Totals
Mouse	73,233	97,537	5,925	176,695
Rat	1,579	964	-	2,543
Other Rodent	-	-	-	-
Rabbit	-	-	-	-
Cat	-	-	-	-
Dog	-	-	-	-
Ferret	-	-	-	-
Other Carnivore	-	-	-	-
Horse and other equids	-	-	-	-
Pig	-	18	-	18
Sheep	402	16	-	418
Other Ungulates	-	-	-	-
New World monkey	-	-	-	-
Old World monkey	-	-	-	-
Other Mammal	-	-	-	-
Bird	92	-	-	92
Reptile / Amphibian	80	-	-	80
Fish	-	-	-	-
Total	75,386	98,535	5,925	179,846

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 ⁽¹⁾	Used in further regulated procedures	Used in production and other procedures ⁽²⁾	Used in safety evaluation studies ⁽³⁾	Number of procedures Totals
Mouse	127,689	13,324	38,553	27,052	456	207,074
Rat	20,752	1,003	4,794	2,333	-	28,882
Other Rodent	18	-	-	-	-	18
Rabbit	157	-	-	-	-	157
Cat	-	-	-	-	-	-
Dog	6	9	10	-	-	25
Ferret	-	-	-	-	-	-
Other Carnivore	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-
Other Ungulates	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-
Old World monkey	-	-	-	-	-	-
Other Mammal	-	-	-	-	-	-
Bird	-	-	-	298	-	298
Reptile / Amphibian	-	-	-	-	-	-
Fish	6,676	10	3,704	-	-	10,390
Total	155,298	14,346	47,359	29,385	456	246,844

(1) See Annex A of Appendix C

(2) Includes production of various biological materials (codes B50-B56 in Appendix C); also includes procedures not concerned with production (code B79)

(3) Reported using A codes in rows 10-12 (see Appendix C)

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 ⁽¹⁾	Used in further regulated procedures	Used in production and other procedures ⁽²⁾	Used in safety evaluation studies ⁽³⁾	Number of procedures Total
Mouse	15,947	421,350	81,717	63,239	35,827	1,306	619,386
Rat	171	825	801	1,037	461	-	3,295
Other Rodent	-	-	-	-	-	-	-
Rabbit	-	2	-	-	13	-	15
Cat	-	-	-	-	-	-	-
Dog	-	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-
Other Carnivore	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-
Pig	-	54	-	-	-	-	54
Sheep	-	552	-	-	-	-	552
Other Ungulates	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-
Old World monkey	-	-	-	-	-	-	-
Other Mammal	-	-	-	-	-	-	-
Bird	2	-	-	-	-	-	2
Reptile / Amphibian	43	78	19	190	265	-	595
Fish	495	3,168	2,554	-	643	-	6,860
Total	16,658	426,029	85,091	64,466	37,209	1,306	630,759

(1) See Annex A of Appendix C

(2) Includes production of various biological materials (codes B50-B56 in Appendix C); also includes procedures not concerned with production (code B79)

(3) Reported using A codes in rows 10-12 (see Appendix C)

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

Species of animal	Great Britain 2001							Number of procedures
	Respiratory	Cardiovascular	Nervous	Senses	Alimentary	Body systems	Musculo-skeletal	
Mammal								
Mouse	36,583	33,626	199,789	6,219	25,441	33,302	38,114	155,325
Rat	24,236	29,925	170,737	3,113	19,588	2,856	8,067	39,752
Other rodent	9,922	1,313	8,728	386	1,963	11,140	665	1,468
Rabbit	729	2,112	583	299	330	3,221	405	3,616
Cat	-	18	131	57	262	9	22	-
Dog	425	892	57	29	288	155	4	547
Ferret	307	61	184	74	-	-	-	73
Other carnivore	-	16	-	14	-	-	-	442
Horse, donkey and cross-bred equids	5	18	1	-	46	-	-	146
Other ungulate	1,502	694	991	7	3,158	303	247	240
Primate	-	331	264	41	41	-	-	-
New World monkey	33	56	461	23	22	6	-	-
Old World monkey	-	-	9	12	95	581	-	-
Other mammal	2,434	1,401	5,656	409	16,296	1,122	2,001	442
Bird	-	487	194	196	1,535	-	1,339	4,347
Reptile, amphibian	-	-	499	50	1,162	3,125	4,041	52
Fish	-	-	-	-	-	-	17,609	36,770
Total	76,176	70,850	388,284	10,928	70,237	55,820	54,905	229,341
								444,858
								146,404
								394,650
								679,909
								2,622,442
								Total

Table 4b Scientific procedures by species of animal and level of anaesthesia
New table: replaces previous tables 7 and 17

Species of animal	No anaesthesia	General anaesthesia, with recovery	Local anaesthesia	Type of anaesthesia	Number of procedures	
					General anaesthesia at end of procedure, without recovery	General anaesthesia throughout, without recovery
Mouse	1,030,132	331,663	215,885	56,138	23,839	1,657,657
Rat	275,739	129,632	5,306	46,664	42,905	500,246
Other rodent	44,444	10,978	323	2,619	3,205	61,569
Rabbit	23,638	2,019	770	4,764	2,550	33,741
Cat	985	430	-	-	165	1,580
Dog	4,815	993	1,138	366	633	7,945
Ferret	351	569	-	41	113	1,074
Other carnivore	352	696	-	-	-	1,048
Horse and other equids	586	15	8,194	-	-	10
Other ungulates	23,963	3,165	760	264	414	28,566
New World monkey	996	245	-	7	141	1,389
Old World monkey	1,504	991	-	57	45	2,597
Other mammal	698	10	1	55	12	776
Bird	54,185	215	256	72,057	145	126,858
Reptile / Amphibian	14,115	1,973	-	127	1,284	17,499
Fish	74,568	86,209	-	5,156	5,159	171,092
Total	1,551,071	569,803	232,633	188,315	80,620	2,622,442

Note: general anaesthesia may include the use of neuromuscular blocking agents (NMBA). These account for less than 1 per cent of all procedures.

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

Species of animal	Field of research										Number of procedures		
	Anatomy	Physiology	Biochemistry	Psychiatry	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Clinical medicine	Clinical surgery	
Mammal													
Mouse	150,803	69,747	22,939	12,829	38,100	331,476	34,504	32,708	30,865	216,502	14,557	3,955	70
Rat	16,939	43,440	13,383	14,098	7,197	15,738	1,011	2,135	30,928	167,720	3,327	4,299	2,226
Guinea pig	17	1,139	8	-	15	2,136	585	928	2,017	13,634	-	77	-
Hamster	152	988	63	277	12	1,419	130	2,219	-	361	56	-	-
Gerbil	57	59	-	48	-	91	102	269	-	2,331	-	-	-
Other rodent	-	-	-	-	-	-	-	-	-	-	-	-	-
Rabbit	54	1,667	357	-	262	3,988	535	168	502	2,497	102	84	193
Cat	12	178	-	-	16	100	20	9	13	307	-	-	-
Dog	-	-	-	-	-	-	-	-	-	-	-	-	-
Beagle	-	34	-	-	-	-	60	-	-	1,442	-	4	-
Greyhound	-	-	-	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	-	4	-	-	57	-	17	6
Ferret	27	165	-	38	-	159	56	-	30	511	-	-	-
Other carnivore	-	-	-	14	-	-	79	-	-	-	-	-	-
Horse, donkey and cross-bred equids	9	196	-	-	-	307	7,925	-	-	-	-	-	-
Pig	14	134	14	258	410	198	823	9	31	231	31	15	-
Goat	-	98	-	-	-	20	4	157	-	125	144	127	174
Sheep	1,105	1,023	444	16	563	279	8,149	1,529	57	782	560	404	246
Cattle	-	314	-	-	-	36	185	115	-	160	-	27	-
Deer	-	-	-	-	-	-	-	-	-	-	-	-	-
Camelid	-	-	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-	-	-	-
New World monkey	14	110	-	-	-	-	-	-	-	-	-	-	-
Marmoset, tamarin	-	-	-	-	-	-	-	-	-	-	-	-	-
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	Field of research							Pharmacology	Parasitology	Microbiology	Immunology	Pathology	Biochemistry	Physiology	Anatomy	Great Britain 2001
	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery	Parasitology	Microbiology	Immunology									
Old World monkey																
Macaque	13	24	-	-	1	-	69	54	-	-	6	219	-	-	5	-
Baboon	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Apes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other mammal	-	159	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Bird																
Domestic fowl (<i>Gallus domesticus</i>)	147	538	422	5,269	1,376	9,276	7,864	75,476	45	247	-	-	-	-	-	-
Turkey	-	-	-	-	-	-	4	714	1,445	-	1,091	-	-	-	-	-
Quail (<i>Coturnix coturnix</i>)	188	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other bird	43	351	-	1,357	-	-	495	111	164	-	-	-	-	-	-	-
Reptile																
Any reptilian species	-	50	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Amphibian																
Any amphibian species	7,944	1,883	906	-	-	52	-	620	305	12	-	-	-	-	-	-
Fish	18,623	28,419	784	3,533	8,421	25,881	5,783	4,004	-	-	301	6,201	-	-	-	-
Any fish species																
Cephalopod		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>																
Total	196,161	150,716	39,320	37,873	56,408	391,941	70,145	122,079	65,287	408,947	25,011	9,004	2,917	-	-	-

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

Species of animal	Field of research						Ecology	Animal welfare	Other	Tobacco	Alcohol	Total
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology						
Mammal												
Mouse	78,715	102,213	261,879	400	70	10	8,858	78	99	73,739	48	2,403
Rat	2,414	5,064	5,662	1,982	-	17	-	112	7,194	2	-	678
Guinea pig	-	-	129	-	-	-	-	-	-	-	-	345,638
Hamster	-	-	85	24	195	62	-	8	-	-	-	20,687
Gerbil	-	-	-	-	-	-	-	-	-	-	-	6,041
Other rodent	-	-	-	-	-	-	-	-	-	-	-	2,957
Rabbit	-	-	44	114	-	289	-	-	1,557	56	-	2,637
Cat	60	-	-	-	853	2	28	170	25	178	-	10,950
Dog	20	-	-	-	-	-	-	-	-	-	-	1,568
Beagle	-	-	-	-	88	-	-	-	-	-	55	-
Greyhound	-	-	-	-	-	-	-	-	-	-	-	1,703
Other including cross-bred dogs	-	9	-	-	587	-	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids	-	-	-	-	-	-	-	-	-	-	-	-
Pig	385	41	15	83	-	-	-	16	519	-	-	-
Goat	-	-	-	48	-	-	-	-	-	-	-	-
Sheep	392	30	-	549	-	-	1,998	40	152	-	-	18,288
Cattle	-	285	-	253	-	-	-	153	-	16	-	2,679
Deer	-	67	-	-	-	-	-	121	-	-	-	188
Camelid	-	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	10	-	-	10
Primate	-	-	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-	-	-	-	-	1,077
marmoset, tamarin	-	-	-	-	-	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	-	50
Other New World monkey	-	-	-	-	-	-	-	-	-	-	-	-

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

Species of animal	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	Number of procedures		
														Total		
Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-	393	-
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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Octopus vulgaris	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	106	83,595	108,763	268,757	7,951	3,472	55	12,571	19,853	1,765	81,170	48	3,081	2,166,976		

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

Species of animal	Number of animals											
	Great Britain 2001		Field of research		Field of research		Field of research		Field of research			
	Anatomy	Physiology	Biochemistry	Psychiatry	Pathology	Immunology	Microbiology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Mammal												
Mouse	150,514	69,569	22,905	12,751	38,006	331,419	34,504	32,708	30,816	215,691	14,508	3,955
Rat	16,374	43,293	13,383	13,474	7,151	15,738	1,011	2,135	30,784	158,191	3,327	4,279
Guinea pig	17	1,139	8	-	15	2,136	558	156	2,017	13,571	-	77
Hamster	152	988	63	277	12	1,419	130	2,036	-	351	56	-
Gerbil	57	59	-	48	-	91	102	269	-	2,331	-	-
Other rodent	-	-	-	-	-	20	501	121	90	-	-	-
Rabbit	54	1,665	349	-	262	3,957	479	146	496	2,383	102	84
Cat	12	177	-	-	16	94	10	-	12	297	-	193
Dog	-	-	-	-	-	-	-	-	-	-	-	-
Beagle	-	30	-	-	-	60	-	-	-	565	-	4
Greyhound	-	-	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	3	-	-	57	-	17	6
Ferret	27	165	-	14	-	199	56	-	30	600	-	-
Other carnivore	-	-	-	-	-	-	79	-	-	-	-	-
Horse, donkey and cross-bred equids	9	78	-	-	-	108	330	-	13	31	-	15
Pig	14	134	14	241	410	198	823	9	31	124	144	127
Goat	-	68	-	-	-	20	4	157	-	-	1	8
Sheep	1,105	557	442	16	563	234	1,192	1,529	45	613	560	404
Cattle	-	209	-	-	-	126	1,103	115	-	160	-	27
Deer	-	-	-	-	-	-	-	-	-	-	-	-
Camelid	-	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-	-	-	-	-	-
marmoset, tamarin	-	-	-	-	-	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	-	-
Other New World monkey	14	96	-	-	-	-	8	9	108	448	47	-

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

Species of animal	Field of research								Number of animals					
	Anatomy	Physiology	Biochemistry	Psychiatry	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery	
Old World monkey	11	16	-	1	-	60	45	-	8	65	-	-	5	-
Macaque	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Baboon	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Apes	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Great ape	-	159	-	-	-	-	-	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Bird	147	538	422	5,269	1,376	8,324	7,802	75,476	45	247	-	-	-	-
Domestic fowl (<i>Gallus domesticus</i>)	-	-	-	-	-	4	585	1,445	-	1,091	-	-	-	-
Turkey	188	-	-	-	-	-	-	-	-	-	-	-	-	-
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Quail (spp other than <i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other bird	43	351	-	1,357	-	495	111	164	-	-	-	-	-	-
Reptile	-	50	-	-	-	-	-	-	-	-	-	-	-	-
Any reptilian species	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Amphibian	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Any amphibian species	3,863	1,427	129	-	-	52	-	620	262	9	-	-	-	-
Fish	18,623	28,419	784	3,533	8,421	25,881	5,783	4,004	-	301	6,201	-	-	-
Any fish species	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	191,724	149,387	38,499	37,116	56,268	390,646	55,218	121,090	64,814	396,989	24,982	8,984	2,863	

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

Species of animal	Number of animals										Total		
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol
Mammal													
Mouse	26	78,606	102,189	261,780	400	70	10	8,858	78	99	73,739	-	2,403
Rat	-	2,414	5,064	5,682	1,977	-	17	-	-	112	7,177	48	678
Guinea pig	-	-	-	128	-	-	-	-	-	2	-	-	335,041
Hamster	-	-	85	24	195	62	-	8	-	-	-	-	19,825
Gerbil	-	-	-	-	-	-	-	-	-	-	-	-	5,858
Other rodent	-	-	-	-	-	289	-	-	-	-	-	-	2,957
Rabbit	-	-	44	112	-	2	28	-	1,557	56	-	-	2,634
Cat	60	-	-	-	47	-	-	-	151	25	170	-	10,702
Dog	-	-	-	-	-	-	-	-	-	-	-	-	725
Beagle	-	-	-	-	-	-	-	-	-	-	1	-	660
Greyhound	-	-	-	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	9	-	-	-	-	-	-	-	-	2	-	94
Ferret	-	-	-	-	-	-	-	-	-	-	-	-	991
Other carnivore	-	-	-	-	-	420	-	-	-	-	-	-	-
Horse, donkey and cross-breed equids	-	-	-	-	-	-	-	-	-	-	-	-	-
Pig	354	41	15	83	-	-	16	434	-	2	-	-	949
Goat	-	-	-	48	-	-	-	-	-	-	-	-	606
Sheep	392	30	-	359	-	-	20	-	-	671	-	503	4,110
Cattle	-	149	-	129	-	-	-	-	-	-	-	-	306
Deer	-	67	-	-	-	-	-	-	-	-	-	-	10,224
Camelid	-	-	-	-	-	-	-	-	-	-	-	-	2,223
Other ungulate	-	-	-	-	-	-	-	-	-	-	-	-	67
Primate	-	-	-	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	10
marmoset, tamarin	-	-	-	-	-	-	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	871

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

Species of animal	Number of animals													
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	Total
Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	211
Macaque	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Baboon	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ape	-	-	-	-	-	-	-	-	-	-	-	-	-	754
Gibbon	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Mammal	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Bird	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Domestic fowl (<i>Gallus domesticus</i>)	627	38	-	1,906	-	-	40	-	257	-	-	-	-	102,516
Turkey	-	-	-	221	-	-	-	-	-	-	-	-	-	3,346
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-	188
Quail (spp. other than <i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other bird	357	-	-	5	1,981	-	-	-	4,749	-	-	-	-	9,613
Reptile	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Any reptilian species	-	-	-	-	-	-	-	-	-	-	-	-	-	114
Amphibian	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Any amphibian species	-	-	-	87	136	-	-	-	823	-	-	-	-	7,408
Fish	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Any fish species	-	344	1,049	-	636	129	-	-	716	11,210	1114	-	-	116,148
Cephalopod	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	86	83,319	108,689	267,844	6,008	3,472	55	11,881	19,129	1,336	81,091	48	3,081	2,124,779

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

Great Britain 2001		Number of procedures																										
Species of animal		Anatomy			Physiology		Biochemistry		Psychology		Pathology		Immunology		Microbiology		Parasitology		Pharmacology		Pharmaceutical R&D		Therapeutics		Clinical medicine		Clinical surgery	
Mammal		9,120	1,880	1,708	52	3,273	399	37,679	437	385	40	15,082	1,089	12	-	-	-	-	-	-	-	-	-	-				
Mouse		1,276	4,157	5,201	496	399	529	-	-	50	166	4,792	71	1,768	-	-	-	-	-	-	-	-	-	-				
Rat		18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Hamster		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Other rodent		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Rabbit		6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Dog		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Other including cross-bred dogs		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Bird		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Domestic fowl (<i>Gallus domesticus</i>)		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Fish		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Any fish species		10,390	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-				
Total		20,810	6,037	6,909	548	3,672	38,208	437	435	206	19,884	1,177	1,784	-	-	-	-	-	-	-	-	-	-	-				

Great Britain 2001		Number of procedures																												
Species of animal		Dentistry			Genetics		Molecular biology		Cancer research		Nutrition		Zoology		Botany		Animal science		Ecology		Animal welfare		Other		Tobacco		Alcohol		Total	
Mammal		-	-	-	12,383	6,819	67,172	48	-	-	-	-	-	-	-	-	-	-	-	-	21	49,408	-	-	-	-	206,618	28,882		
Mouse		-	-	-	2,253	-	-	-	855	-	-	-	-	-	-	-	-	-	-	-	6,871	-	-	-	-	-	18	-		
Rat		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Hamster		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Other rodent		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Rabbit		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Dog		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	157			
Other including cross-bred dogs		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	25			
Bird		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Domestic fowl (<i>Gallus domesticus</i>)		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	298			
Fish		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	10,390			
Any fish species		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	246,388			
Total		-	14,934	6,819	68,027	48	-	-	-	-	-	-	-	-	-	-	-	-	-	-	21	56,432	-	-	-	-	-	246,388		

Table 5.1 (Continued)

Great Britain 2001		Number of procedures																												
Species of animal		Dentistry			Genetics		Molecular biology		Cancer research		Nutrition		Zoology		Botany		Animal science		Ecology		Animal welfare		Other		Tobacco		Alcohol		Total	
Mammal		-	-	-	12,383	6,819	67,172	48	-	-	-	-	-	-	-	-	-	-	-	-	21	49,408	-	-	-	-	206,618	28,882		
Mouse		-	-	-	2,253	-	-	-	855	-	-	-	-	-	-	-	-	-	-	-	6,871	-	-	-	-	-	18	-		
Rat		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Hamster		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Other rodent		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Rabbit		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Dog		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Other including cross-bred dogs		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Bird		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Domestic fowl (<i>Gallus domesticus</i>)		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Fish		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Any fish species		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
Total		-	14,934	6,819	68,027	48	-	-	-	-	-	-	-	-	-	-	-	-	-	-	21	56,432	-	-	-	-	-	246,388		

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

Species of animal	Field of research										Number of procedures	
	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery	Immunology	Pathology	Psychiatry	Biochemistry	Anatomy
Mammal												
Mouse	78,512	45,603	11,217	7,056	11,659	176,279	6,047	740	8,087	41,199	2,718	2,020
Rat	465	1,340	36	67	-	30	-	-	108	60	-	-
Other rodent	-	-	-	-	15	-	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-	-	-	-	-	-
Pig	-	-	-	-	-	-	-	-	-	-	-	-
Sheep	-	-	-	-	-	-	-	-	-	-	-	-
Bird	-	-	-	-	-	-	-	-	-	-	-	-
Domestic fowl (<i>Gallus domesticus</i>)	-	-	-	-	-	-	-	-	-	-	-	-
Amphibian	-	-	-	-	-	-	-	-	-	-	-	-
Any amphibian species	595	-	-	-	-	-	-	-	-	-	-	-
Fish	-	-	-	-	-	-	-	-	-	-	-	-
Any fish species	5,791	-	-	-	-	-	-	-	-	-	-	-
Total	85,363	46,943	11,253	7,123	11,674	176,399	6,047	740	8,195	42,112	2,772	2,020

Table 5.2 (Continued)

Species of animal	Field of research										Number of procedures		
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol
Mammal													
Mouse	-	-	26,807	61,802	106,594	55	-	-	7,887	-	-	-	-
Rat	-	-	-	1,189	-	-	-	-	-	-	-	-	-
Other rodent	-	-	-	-	-	-	-	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-	-	-	-	-	-	-
Pig	-	-	-	-	-	-	-	-	-	-	-	-	-
Sheep	-	-	-	-	-	-	-	-	-	-	-	-	-
Bird	-	2	-	-	-	-	-	-	-	-	-	-	-
Domestic fowl (<i>Gallus domesticus</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-
Amphibian	-	-	-	-	-	-	-	-	-	-	-	-	-
Any amphibian species	-	-	-	-	-	-	-	-	-	-	-	-	-
Fish	-	-	52	-	-	-	-	-	716	-	-	-	-
Any fish species	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	26,809	63,043	106,594	55	-	-	-	8,603	-	-	23,618	-
												180	618,080
													3,295
													2
													595
													54
													552
													15
													54
													552
													6,860
													629,453
													629,453

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

Species of animal	Infectious agents	Production				Other ⁽¹⁾	Number of procedures
		Vectors	Neoplasms	Monoclonal antibodies (ascites model)	Monoclonal antibodies (initial immunisation)		
Mouse	32,412	3,101	20,129	1,209	4,202	7,463	60,996
Rat	2,221	123	430	-	505	137	35,458
Other Rodent	2,002	1,397	12	-	43	681	917
Rabbit	102	82	-	-	40	5,086	379
Cat	-	9	-	-	-	16	6
Dog	-	-	-	-	-	-	515
Ferret	-	-	-	-	-	189	59
Other Carnivore	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	1	5,321
Other Ungulates	263	-	-	-	19	1,244	8,525
New World monkey	1	-	-	-	-	-	189
Old World monkey	-	-	-	-	-	-	131
Other Mammal	-	-	-	-	-	-	-
Bird	75,117	-	-	-	-	323	1,600
Reptile / Amphibian	-	-	-	-	-	-	6,050
Fish	1,150	-	-	-	-	66	15,030
Total	1113,263	4,712	20,571	1,209	4,809	15,206	135,176
							1,872,025
							2,166,976

(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	Number of procedures	Techniques of particular interest						All other techniques	Total		
		Interference with organs of special sense	Injection into brain	Interference with brain	Psychological stress	Aversive training	Radiation	Inhalation	Thermal injury	Physical trauma	
Mouse	6,570	24,055	5,104	4,954	1,041	6,081	23,529	218	2,439	1,413,528	1,487,519
Rat	8,814	803	24,076	4,224	5,036	1,132	10,563	113	3,513	287,364	345,638
Other rodent	392	169	1,278	104	-	-	8,635	-	131	21,613	32,322
Rabbit	39	-	79	6	-	-	459	15	182	10,170	10,950
Cat	85	-	90	-	-	-	-	-	-	1,393	1,568
Dog	14	-	-	-	-	-	39	-	-	2,332	2,385
Ferret	40	-	-	-	-	-	292	-	-	694	1,026
Other carnivore	-	-	-	-	-	-	20	-	-	1,028	1,048
Horse and other equids	1	-	-	-	-	-	-	-	-	8,761	8,762
Other ungulates	18	16	88	-	-	12	482	17	231	25,199	26,063
New World monkey	46	-	160	-	26	-	-	-	-	895	1,127
Old World monkey	19	-	10	-	-	-	-	-	-	364	393
Other mammal	12	-	-	-	-	-	-	-	-	742	754
Bird	155	-	24	246	4,817	-	-	-	-	111,674	116,916
Reptile / Amphibian	188	-	7	-	-	-	-	-	-	13,529	13,724
Fish	85	-	125	748	-	-	-	-	-	115,823	116,781
Total	16,478	25,043	31,041	10,282	10,920	7,225	44,019	363	6,496	2,015,109	2,166,976

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	General safety/efficacy evaluation				
				Household	Food additives	Other foodstuffs		
Mammal								
Mouse	78	4,796	3,895	563				
Flat	683	23,754	30,163	2,692				
Guinea pig	-	2,802	12,433	176				
Hamster	-	-	40	-				
Gerbil	-	-	-	-				
Other rodent	-	-	-	-				
Rabbit	208	48	-	-				
Cat	-	1,083	3,369	38				
Dog	-	-	-	-				
Beagle	-	-	120	31				
Greyhound	-	-	-	-				
Other including cross-bred dogs	-	-	-	-				
Ferret	-	-	-	-				
Other carnivore	-	-	-	-				
Horse, donkey and cross-bred equids	-	-	-	-				
Pig	-	-	-	6				
Goat	-	-	-	6				
Sheep	-	-	-	-				
Cattle	-	-	-	12				
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	Other foodstuffs	Finished cosmetics	Cosmetics ingredients
Old World monkey	-	-	-	-	-	-	-	-
Macaque	-	-	-	-	-	-	-	-
Baboon	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-
Apes	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-
Great Ape	-	-	-	-	-	-	-	-
Other mammal	22	-	-	-	-	-	-	-
Domestic fowl (<i>Gallus domesticus</i>)	-	-	-	239	-	-	-	-
Turkey	-	-	-	-	74	-	-	-
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i>)	6	1,294	-	-	-	-	-	-
Other bird	-	264	-	-	-	-	-	-
Reptile	-	-	-	-	-	-	-	-
Any reptilian species	2,240	-	-	-	-	-	-	-
Amphibian	-	-	-	-	-	-	-	-
Any amphibian species	-	-	-	-	-	-	-	-
Fish	35,008	6,574	2,680	-	-	-	-	-
Any fish species	-	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-
Total	38,245	40,998	52,685	590	3,464	6	-	-

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

Species of animal	Great Britain 2001						Number of procedures Total			
	Pharmaceutical safety/efficacy evaluation		Toxicology or other safety/efficacy evaluation							
	Safety testing	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other	
Mammal										
Mouse	31,153	28,515	62,121	12,417	12,295	-	662	1,224	12,419	170,138
Rat	64,907	5,773	468	14,485	6,218	-	311	3,036	1,736	154,608
Guinea pig	3,287	2,570	426	332	194	-	857	438	-	27,562
Hamster	696	-	-	-	104	-	-	-	-	1,266
Gerbil	-	-	-	-	-	-	-	-	-	-
Other rodent	-	-	-	-	-	-	-	-	-	-
Rabbit	11,732	847	4,730	171	159	-	424	112	-	22,791
Cat	-	-	-	12	-	-	-	-	-	12
Dog	4,371	-	4	716	76	-	12	34	119	5,560
Beagle	-	-	-	-	-	-	-	-	-	-
Greyhound	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	-	-	-	-	-
Ferret	38	-	-	10	-	-	-	-	-	48
Other carnivore	-	-	-	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids	24	18	-	-	-	-	-	-	-	-
Pig	412	614	-	179	23	-	46	12	-	-
Goat	-	-	-	-	-	-	-	-	-	6
Sheep	134	7	184	128	-	-	16	1	-	470
Cattle	152	362	150	59	-	-	-	-	-	735
Deer	-	-	-	-	-	-	-	-	-	-
Camelid	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-
New World monkey	218	-	-	-	-	-	-	-	-	262
marmosat, tamarin	-	-	-	-	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-	-	-
								10	-	-

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

Species of animal	Great Britain 2001						Number of procedures		
	Pharmaceutical safety/efficacy evaluation		Toxicology or other safety/efficacy evaluation		Other purposes				
	Safety testing	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other
Old World monkey									
Macaque	1,988	-	-	-	204	-	-	-	6
Baboon	-	-	-	-	-	-	-	-	2,204
Other Old World monkey	-	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-
Great Ape	-	-	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-	-	22
Bird									
Domestic fowl (<i>Gallus domesticus</i>)	1,017	6,006	20	288	-	-	-	-	170
Turkey	214	160	-	60	-	-	-	-	7,814
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	434
Quail (spp. other than <i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-
Other bird	75	55	-	-	-	-	-	-	1,300
Reptile	-	-	-	-	-	-	-	-	394
Any reptilian species	-	-	-	-	-	-	-	-	-
Amphibian	-	-	-	-	-	-	-	-	1,535
Any amphibian species	-	-	-	-	-	-	-	-	-
Fish									
Any fish species	1,494	7,679	-	766	80	-	-	-	54,311
Cephalopod	-	-	-	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-
Total	121,912	53,032	72,154	29,851	20,684	-	2,334	4,897	14,614
									455,466

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	
Mammal						
Mouse	78	4,796	3,895	-	-	-
Rat	659	23,754	30,163	376	2,692	6
Guinea pig	-	2,802	12,453	176	-	-
Hamster	-	-	40	-	-	-
Gerbil	-	-	-	-	-	-
Other rodent	208	48	-	-	-	-
Rabbit	-	1,054	3,317	38	-	-
Cat	-	-	-	-	-	-
Dog	-	-	120	18	-	-
Beagle	-	-	-	-	-	-
Greyhound	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	-
Ferret	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-
Horse, donkey and cross-bred equids	-	-	-	-	-	-
Pig	-	-	-	-	-	-
Goat	-	-	-	-	-	-
Sheep	-	-	-	-	-	-
Cattle	-	-	12	-	-	-
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	
Old World monkey	-	-	-	-	-	-
Macaque	-	-	-	-	-	-
Baboon	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-
Ape	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-
Great Ape	-	-	-	-	-	-
Other mammal	22	-	-	-	-	-
Bird	-	239	-	-	-	-
Domestic fowl (<i>Gallus domesticus</i>)	-	-	74	-	-	-
Turkey	-	-	-	-	-	-
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i>)	6	1,294	-	-	-	-
Other bird	-	264	-	-	-	-
Reptile	-	-	-	-	-	-
Any reptilian species	2,240	-	-	-	-	-
Amphibian	35,008	6,574	2,680	-	-	-
Any amphibian species	-	-	-	-	-	-
Fish	-	-	-	-	-	-
Any fish species	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-
<i>Octopus vulgaris</i>	-	-	-	-	-	-
Total	38,221	40,969	52,620	590	3,463	6

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

Species of animal	Number of animals					
	Total					
	Pharmaceutical safety/efficacy evaluation		Toxicology or other safety/efficacy evaluation		Other purposes	
	Safety testing	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety
Mammal						
Mouse	31,153	28,515	62,121	12,417	12,295	-
Ret	64,899	5,773	468	14,485	6,218	-
Guinea pig	3,287	2,570	4,467	332	194	-
Hamster	696	426	-	-	104	-
Gerbil	-	-	-	-	-	-
Other rodent	-	-	-	-	-	-
Rabbit	6,293	823	216	171	159	-
Cat	-	-	-	6	-	-
Dog	4,162	-	-	239	64	-
Beagle	-	-	-	-	-	-
Greyhound	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	-
Ferret	38	-	10	-	-	-
Other carnivore	-	-	-	-	-	-
Horse, donkey and cross-bred equids	24	18	-	-	-	-
Pig	411	614	-	179	23	-
Goat	-	-	-	-	-	-
Sheep	104	7	184	128	-	-
Cattle	135	351	134	55	-	-
Deer	-	-	-	-	-	-
Camelid	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-
Primate	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-
marmoset, tamarin	-	-	-	-	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-
	210	-	-	32	-	-
						10
						252
						-

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 evaluation	Quality control	Toxicology research	Tobacco safety	Medical device safety	Method development	Other
Old World monkey	1,916	-	-	92	-	-	-	-
Macaque	-	-	-	-	-	-	-	2,008
Baboon	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-
Great Ape	-	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-	-
Bird	1,017	6,006	20	288	-	-	-	170
Domestic fowl (<i>Gallus domesticus</i>)	214	160	-	60	-	-	-	-
Turkey	-	-	-	-	-	-	-	-
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-
Other bird	75	55	-	-	-	-	-	-
Reptile	-	-	-	227	-	-	-	-
Any reptilian species	-	-	-	-	-	-	-	-
Amphibian	-	-	-	-	-	-	-	-
Any amphibian species	-	-	-	-	-	-	-	-
Fish	1,494	7,679	-	766	80	-	-	30
Any fish species	-	-	-	-	-	-	-	-
Cephalopod	-	-	-	-	-	-	-	-
Octopus vulgaris	-	-	-	-	-	-	-	-
Total	116,128	52,997	67,620	29,250	19,364	-	2,249	4,882
								14,575
								442,934

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	Other safety / Toxicology	
Mouse	UK requirements only	1,100	3,645	120	4,865
	One EU country only (not UK)	64	-	-	64
	EU requirements, incl. European Pharmacopoeia	664	17,029	9,193	26,886
	Requirements of (non-EU) Council of Europe	-	157	32	189
	Requirements of other countries	1,523	2,436	814	4,773
	Any combination of above	3,762	93,924	1,020	98,706
	Non-legislative purposes	2,219	17,015	15,421	34,655
	Total	9,332	134,206	26,600	170,138
Rat	UK requirements only	763	1,101	6	1,870
	One EU country only (not UK)	504	-	-	504
	EU requirements, incl. European Pharmacopoeia	8,879	3,465	-	12,344
	Requirements of (non-EU) Council of Europe	172	1,881	203	2,256
	Requirements of other countries	12,452	846	377	13,675
	Any combination of above	32,544	71,283	2,817	106,644
	Non-legislative purposes	2,360	7,057	7,998	17,315
	Total	57,674	85,633	11,301	154,608
Other Rodent	UK requirements only	615	3,364	257	4,236
	One EU country only (not UK)	474	-	-	474
	EU requirements, incl. European Pharmacopoeia	1,721	3,812	95	5,628
	Requirements of (non-EU) Council of Europe	6	150	70	226
	Requirements of other countries	4,659	240	102	5,001
	Any combination of above	7,932	3,332	672	11,936
	Non-legislative purposes	306	880	560	1,746
	Total	15,713	11,778	1,756	29,247
Rabbit	UK requirements only	222	2,333	83	2,638
	One EU country only (not UK)	111	-	-	111
	EU requirements, incl. European Pharmacopoeia	314	7,200	24	7,538
	Requirements of (non-EU) Council of Europe	49	12	-	61
	Requirements of other countries	1,565	395	115	2,075
	Any combination of above	2,342	7,159	288	9,789
	Non-legislative purposes	13	381	185	579
	Total	4,616	17,480	695	22,791
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	-	-	12	12
	Total	-	-	-	12

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
Dog	UK requirements only	-	114	-	114
	One EU country only (not UK)	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	88	-	88
	Requirements of (non-EU) Council of Europe	-	-	16	16
	Requirements of other countries	2	24	-	26
	Any combination of above	213	4,487	183	4,883
	Non-legislative purposes	13	378	42	433
	Total	228	5,091	241	5,560
Ferret	UK requirements only	-	-	-	-
	One EU country only (not UK)	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	-	5	5
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	-	-	-	-
	Any combination of above	-	43	-	43
	Non-legislative purposes	-	-	-	-
	Total	-	48	-	48
Horse and other equids	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	-	42	1	43
	Non-legislative purposes	-	-	-	-
	Total	-	42	1	43
Other Ungulates	UK requirements only	-	262	10	272
	One EU country only (not UK)	6	28	-	34
	EU requirements, incl. European Pharmacopoeia	9	678	-	687
	Requirements of (non-EU) Council of Europe	-	102	-	102
	Requirements of other countries	1	138	46	185
	Any combination of above	8	880	3	891
	Non-legislative purposes	-	293	39	332
	Total	24	2,381	98	2,503

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

Species	Great Britain 2001	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	-	242	-	-	252
	Any combination of above	-	10	-	-	10
Old World monkey	Non-legislative purposes	-	252	10	-	262
	Total	-	252	10	-	262
	UK requirements only	-	4	-	-	4
	One EU country only (not UK)	-	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	485	-	-	485
	Requirements of (non-EU) Council of Europe	-	-	-	-	-
Other Mammal	Requirements of other countries	-	17	-	-	17
	Any combination of above	-	1,658	12	-	1,670
	Non-legislative purposes	-	28	-	28	28
	Total	-	2,192	12	-	2,204
	UK requirements only	-	-	-	-	-
	One EU country only (not UK)	-	-	-	-	-
Bird	EU requirements, incl. European Pharmacopoeia	-	-	-	-	-
	Requirements of (non-EU) Council of Europe	-	-	-	-	-
	Requirements of other countries	-	-	-	-	-
	Any combination of above	-	-	-	-	-
	Non-legislative purposes	-	22	-	-	22
	Total	-	22	-	-	22
Reptile / Amphibian	UK requirements only	-	290	-	-	290
	One EU country only (not UK)	-	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	60	-	-	-	60
	Requirements of (non-EU) Council of Europe	362	1,017	-	-	1,379
	Requirements of other countries	-	30	-	-	30
	Any combination of above	316	267	-	-	583
	Non-legislative purposes	1,133	5,415	160	6,708	6,708
	Total	6	876	10	892	892
	UK requirements only	1,877	7,895	170	-	9,942
	One EU country only (not UK)	-	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	-	-	-	-
	Requirements of (non-EU) Council of Europe	-	-	-	-	-
	Requirements of other countries	-	-	-	1,535	1,535
	Any combination of above	-	-	-	-	-
	Non-legislative purposes	2,240	-	-	-	2,240
	Total	2,240	-	-	1,535	3,775

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

Great Britain 2001

Species	Legislative requirements	Toxicological purpose			Number of procedures
		Safety testing other than cosmetics	Pharmaceutical safety	Other safety / Toxicology	
Fish	UK requirements only	10,212	-	30	10,242
	One EU country only (not UK)	102	-	-	102
	EU requirements, incl. European Pharmacopoeia	12,349	6,170	50	18,569
	Requirements of (non-EU) Council of Europe	1,747	-	-	1,747
	Requirements of other countries	2,735	-	-	2,735
	Any combination of above	10,673	2,820	-	13,493
	Non-legislative purposes	6,444	949	30	7,423
	Total	44,262	9,939	110	54,311
All species	UK requirements only	12,912	11,113	506	24,531
	One EU country only (not UK)	1,321	28	-	1,349
	EU requirements, incl. European Pharmacopoeia	24,298	39,949	9,362	73,609
	Requirements of (non-EU) Council of Europe	1,974	2,332	321	4,627
	Requirements of other countries	23,253	4,363	2,989	30,605
	Any combination of above	58,607	191,285	5,166	255,058
	Non-legislative purposes	13,623	27,879	24,185	65,687
	TOTAL	135,988	276,949	42,529	455,466

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

Species of animal	Number of procedures					
	Acute lethal toxicity (1)	Acute lethal concentration (1)	Acute limit setting	Type of toxicological test or procedure Subacute limit-setting or dose ranging	Subacute toxicity	Subchronic and chronic
Mouse	70,516	3,426	6,307	12,454	5,330	1,986
Rat	65	1,873	5,742	9,746	8,643	20,085
Other Rodent	-	76	770	1,445	-	12
Rabbit	-	-	60	22	371	49
Cat	-	-	-	-	-	350
Dog	-	-	42	223	547	1,840
Ferret	-	-	-	-	-	1,488
Other carnivore	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-
Other ungulates	-	-	-	102	112	-
New World monkey	-	-	-	12	50	84
Old World monkey	-	-	-	66	157	580
Other Mammal	680	360	112	86	24	420
Bird	-	-	-	-	-	2,240
Reptile / Amphibian	-	-	-	-	-	-
Fish	-	17,776	14,481	194	1,737	634
Total	71,261	23,511	27,514	24,350	16,971	25,650
					24,743	9,157
						9,423
						7,401

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

Species of animal	Number of procedures							Total	
	Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	Type of toxicological test or procedure	Pyrogenicity	Biocompatibility		
					Toxicokinetics		Enzyme induction for in vitro tests (2)	Immunotoxicology (2)	Other toxicology (2)
Mouse	-	-	-	2,089	9,627	-	600	334	2,652
Rat	39,358	-	-	-	11,118	-	261	638	257
Other Rodent	-	-	201	18,663	55	-	45	237	358
Rabbit	77	1,457	2,849	-	206	11,749	158	-	13
Cat	-	-	-	-	-	-	-	-	-
Dog	-	-	-	-	575	-	-	-	-
Ferret	-	-	-	-	-	-	-	5	43
Other carnivore	-	-	-	-	-	-	-	-	-
Horse and other Equids	-	-	-	-	-	-	-	-	-
Other ungulates	-	-	-	8	137	-	62	10	297
New World Monkey	-	-	-	-	-	-	-	-	-
Old World Monkey	-	-	-	-	-	-	-	-	-
Other Mammal	-	-	-	-	-	-	-	-	-
Bird	320	-	-	-	-	-	-	-	-
Reptile / Amphibian	-	-	-	-	-	-	-	-	-
Fish	8,471	-	-	-	941	-	200	204	713
Total	48,226	1,457	3,050	20,760	11,749	1,326	1,423	4,295	100,189
									455,486

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

Species of animal	Type of toxicological test or procedure						Number of procedures
	Acute lethal toxicity ⁽¹⁾	Acute lethal concentration ⁽¹⁾	Acute limit setting	Acute non - lethal clinical sign	Subacute toxicity	Subchronic and chronic	
Mouse	-	-	51	437	751	490	1,210
Rat	65	1,712	3,915	6,773	2,721	5,272	1,780
Other Rodent	-	-	-	-	-	-	-
Rabbit	-	-	60	-	6	-	-
Dog	-	-	-	4	35	32	-
Horse and other equids	-	-	-	-	-	112	-
Other ungulates	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-
Bird	680	360	112	56	24	-	-
Reptile / Amphibian	-	-	-	-	-	2,240	-
Fish	-	17,557	9,496	14	143	634	1,199
Total	745	19,829	13,634	7,284	3,680	6,428	9,705
						2,990	3,468
							1,415

Table 13: Scientific procedures (toxicology) by species of animal and type of toxicological test: safety testing of substances other than 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	Fyrogenicity	
Mouse	-	-	-	1,401	-	-	820
Rat	24,683	-	-	-	477	-	-
Other Rodent	-	-	36	15,351	-	273	-
Rabbit	-	1,284	2,614	-	-	40	-
Dog	-	-	-	-	-	-	-
Horse and other Equids	-	-	-	-	-	-	-
Other ungulates	-	-	-	-	-	6	-
Other mammal	-	-	-	-	-	-	-
Bird	320	-	-	-	-	-	-
Reptile / Amphibian	-	-	-	-	-	-	-
Fish	8,471	-	-	269	-	-	-
Total	33,474	1,284	2,650	16,752	820	-	523
						173	6,082
						593	10,494
							135,988
							44,262

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

Great Britain 2001		Number of procedures										
Species of animal	Acute lethal toxicity ⁽¹⁾	Acute lethal concentration ⁽¹⁾	Acute limit setting	Acute non-lethal clinical sign	Type of toxicological test or procedure			Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Teratogenicity
Mouse	62,524	37	5,385	11,524	4,017	1,467	3,752	2,306	3,171	5,00		
Rat	-	62	1,172	2,727	5,542	14,465	6,594	3,861	2,553	2,381		
Other Rodent	-	6	552	1,445	-	12	-	-	-	-		
Rabbit	-	-	-	22	365	49	350	-	-	-	3,090	
Cat	-	-	-	-	-	-	-	-	-	-		
Dog	-	-	42	219	471	1,808	1,304	-	-	-		
Ferret	-	-	-	-	-	-	-	-	-	-		
Horse and other equids	-	-	-	-	-	-	-	-	-	-		
Other ungulates	-	-	-	-	102	112	-	-	-	-		
New World monkey	-	-	-	-	12	50	84	66	-	-		
Old World monkey	-	-	-	-	66	157	580	680	-	-		
Bird	-	-	-	-	30	-	420	-	-	-		
Fish	-	189	4,935	180	1,594	-	-	-	-	-		
Total	62,524	294	12,086	16,327	12,308	18,886	14,726	6,167	5,724	5,971		

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

Great Britain 2001		Number of procedures									
Species of animal	Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	For toxicokinetics	Pyrogenicity	Biocompatibility	Enzyme induction for in vitro tests	Immunotoxicology ⁽²⁾	Other toxicology ⁽²⁾	Total
Mouse	-	-	-	-	132	9,492	-	40	50	1,639	28,120
Rat	14,594	-	-	-	10,334	-	-	12	230	19,106	85,633
Other Rodent	-	-	139	2,156	55	-	6	197	328	6,862	11,778
Rabbit	77	128	-	94	-	87	11,673	14	-	13	1,518
Cat	-	-	-	-	-	-	-	-	-	-	705
Dog	-	-	-	-	-	-	-	-	-	5	43
Ferret	-	-	-	-	-	-	-	-	-	42	48
Horse and other Equids	-	-	-	-	-	-	-	-	-	-	
Other ungulates	-	-	-	-	-	-	-	-	-	297	1,738
New World Monkey	-	-	-	-	-	-	-	-	-	4	2,381
Old World Monkey	-	-	-	-	-	-	-	-	-	574	252
Bird	-	-	-	-	-	-	-	-	-	7,309	2,192
Fish	-	-	-	-	-	-	-	-	-	540	7,895
Total	14,671	128	253	2,296	21,579	11,673	260	263	3,102	67,712	276,949

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

Species of animal	Number of procedures									
	Acute lethal toxicity (1)	Acute lethal concentration (1)	Acute limit setting	Acute non-lethal clinical sign	Type of toxicological test or procedure Subacute limit-setting or dose ranging	Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Teratogenicity
Mouse	7,992	3,389	871	493	562	9	240	-	140	-
Rat	-	99	655	246	380	328	-	-	71	15
Other Rodent	-	70	218	-	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-	-	-	-
Dog	-	-	-	-	41	-	72	-	-	-
Horse and other equids	-	-	-	-	-	-	-	-	-	-
Other ungulates	-	-	-	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-	-	-	-
Old World monkey	-	-	-	-	-	-	-	-	-	-
Bird	-	-	-	-	-	-	-	-	-	-
Reptile / Amphibian	-	-	-	-	-	-	-	-	-	-
Fish	-	30	50	-	-	-	-	-	-	-
Total	7,992	3,588	1,794	739	983	337	312	-	211	15

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

Species of animal	Number of procedures									
	Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	Type of toxicological test or procedure Toxicokinetics	Pyrrogenicity	Biocompatibility	Enzyme induction for in vitro tests (2)	Immunotoxicology (2)	Other toxicology (2)
Mouse	81	-	-	-	556	135	-	560	284	143
Rat	-	-	-	-	307	-	-	261	353	27
Other Rodent	-	6	1,156	-	-	-	-	39	-	30
Rabbit	-	45	141	-	119	76	144	-	-	-
Dog	-	-	-	-	20	-	-	-	-	170
Horse and other Equids	-	-	-	-	-	-	-	-	-	108
Other ungulates	-	-	-	-	-	-	-	-	-	1
New World Monkey	-	-	-	-	-	-	-	-	-	36
Old World Monkey	-	-	-	-	-	-	-	-	-	10
Bird	-	-	-	-	-	-	-	-	-	12
Reptile / Amphibian	-	-	-	-	-	-	-	-	-	170
Fish	-	-	-	-	30	-	-	-	-	1,535
Total	81	45	147	1,712	611	76	1,066	637	200	21,983
										42,529

Table 18a Tree table - scientific procedures involving cats, 2001

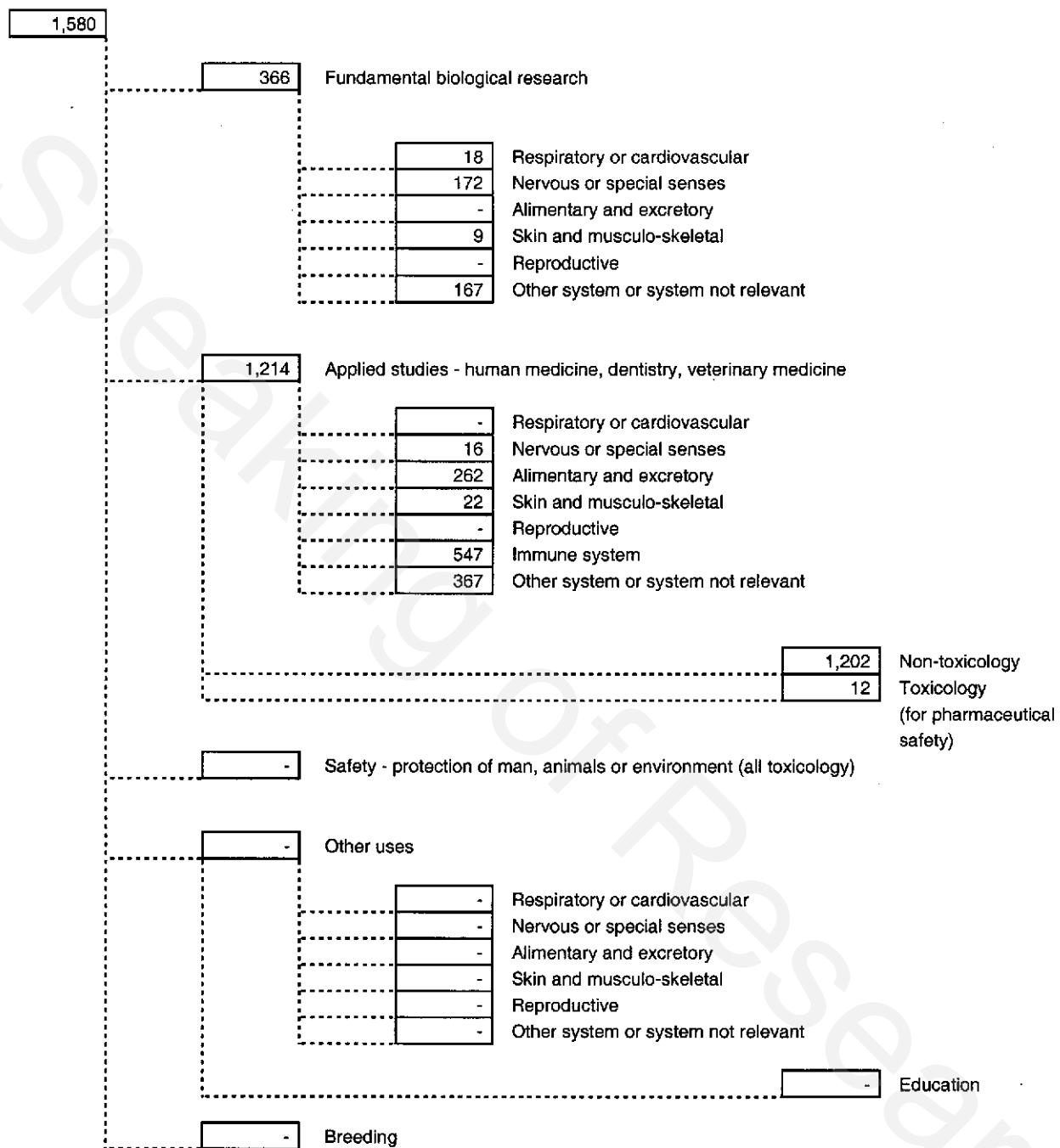


Table 18b Tree table - scientific procedures involving dogs, 2001

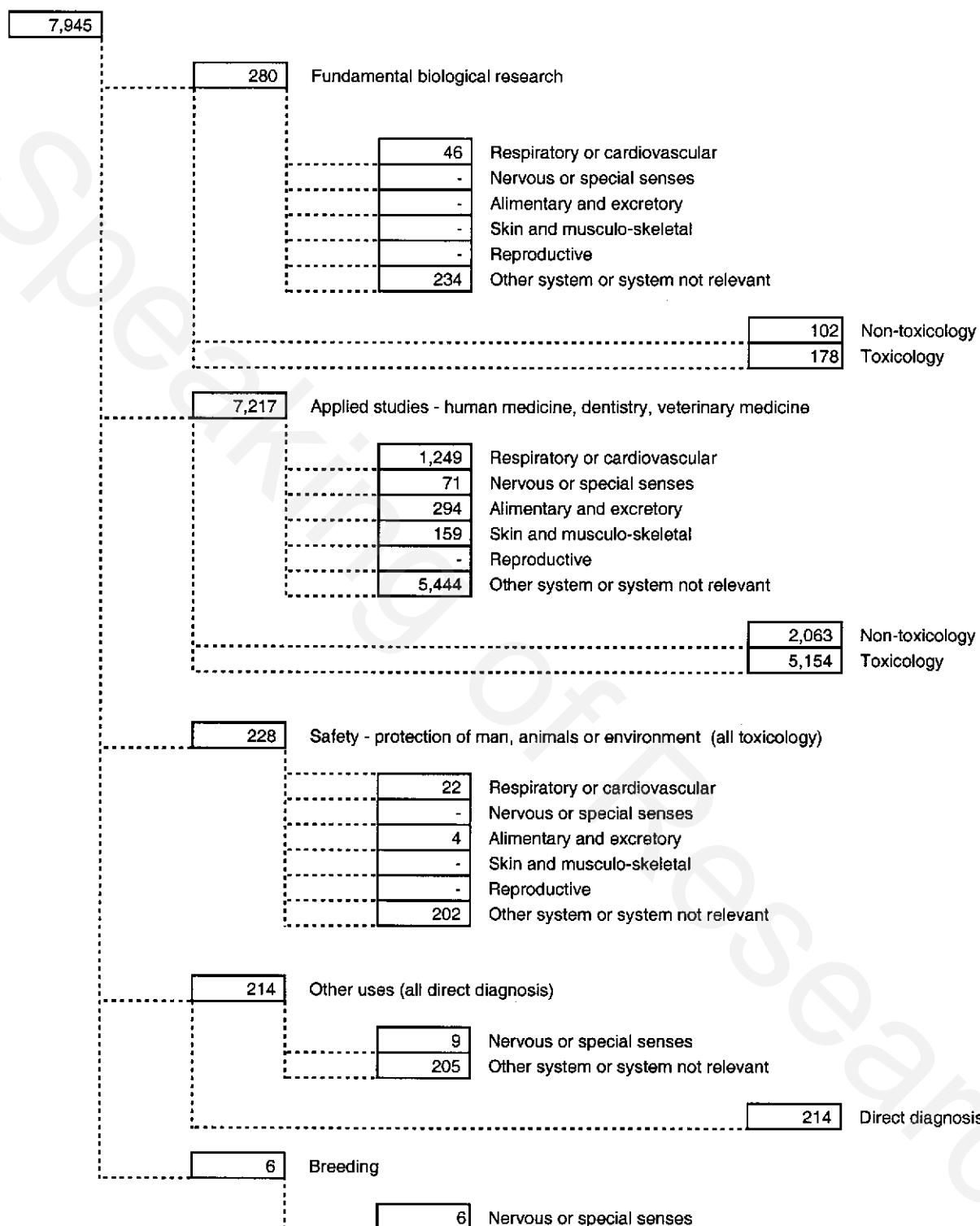


Table 18c Tree table - scientific procedures involving horses and other equids, 2001

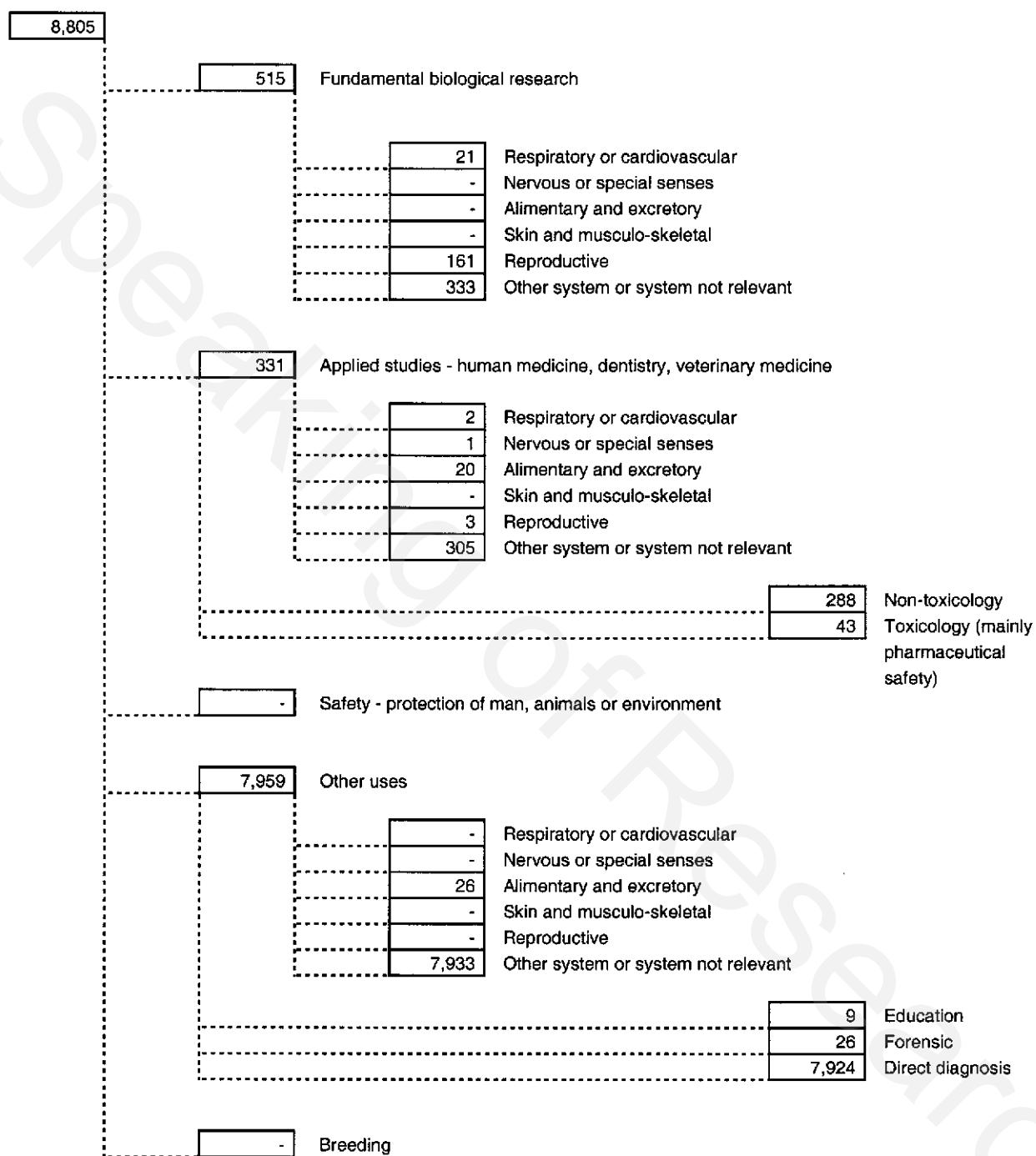


Table 18d Tree table - scientific procedures involving New World primates, 2001

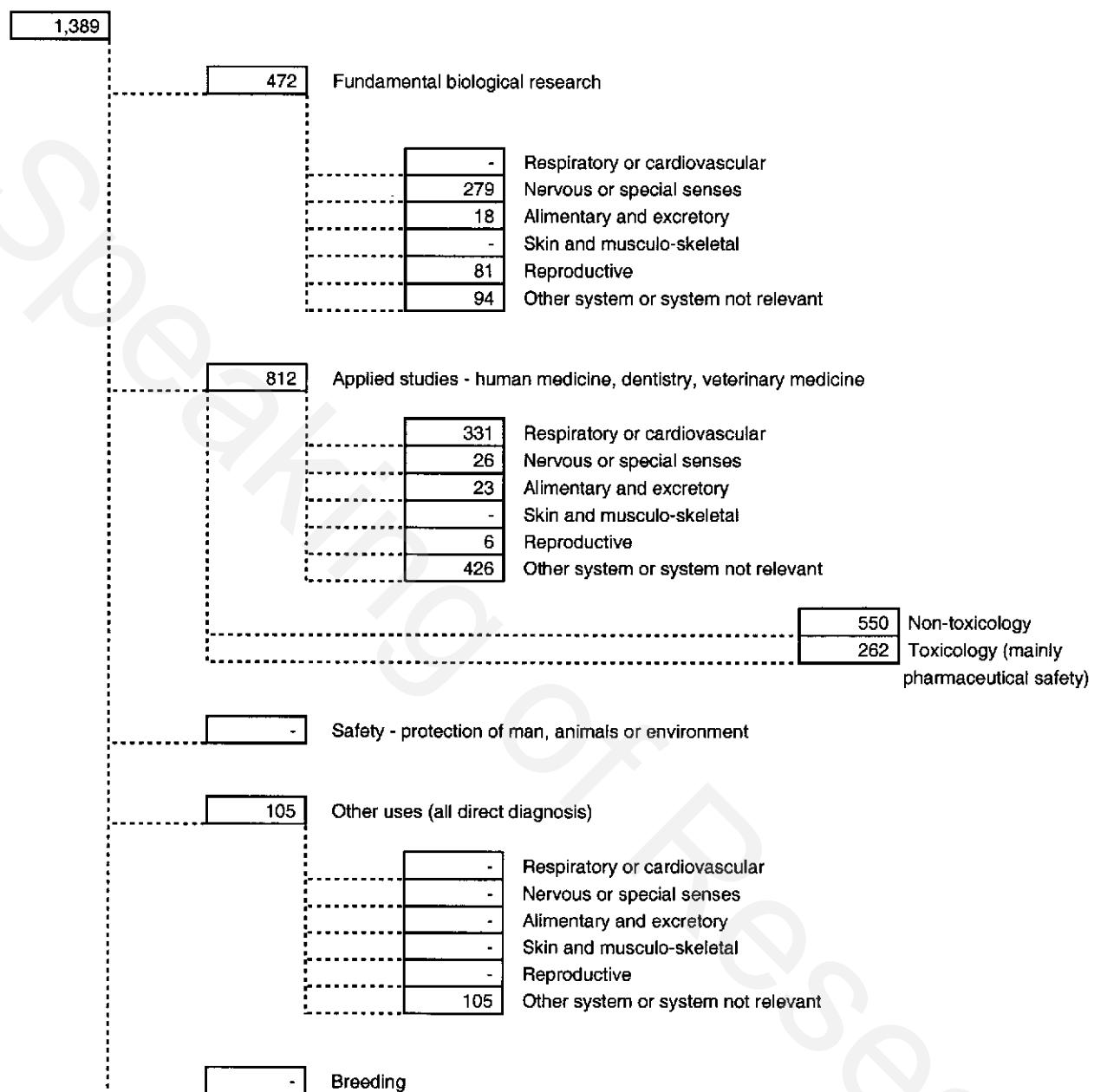


Table 18e Tree table - scientific procedures involving Old World primates, 2001

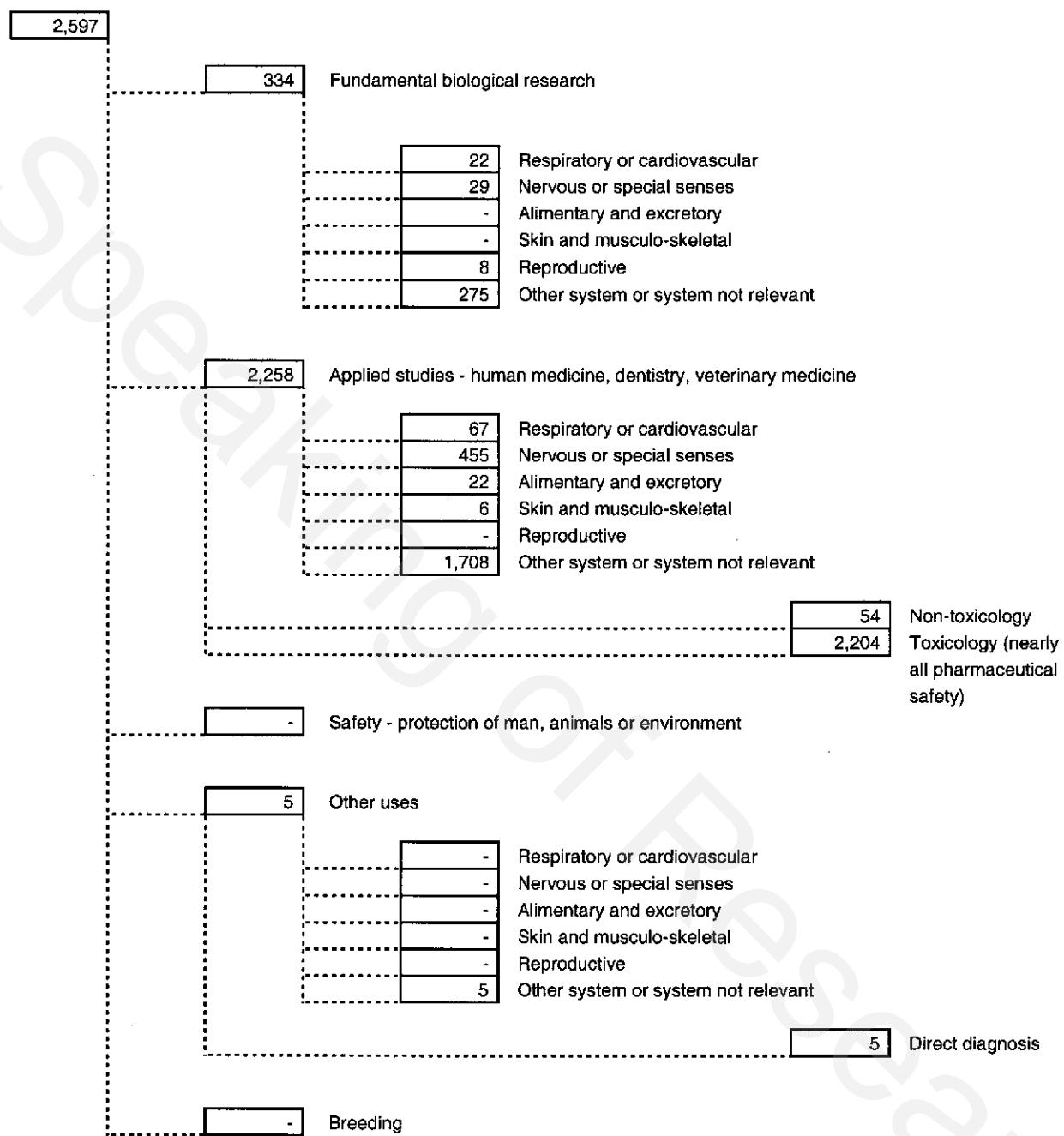


Table 18f Tree table - scientific procedures involving rabbits, 2001

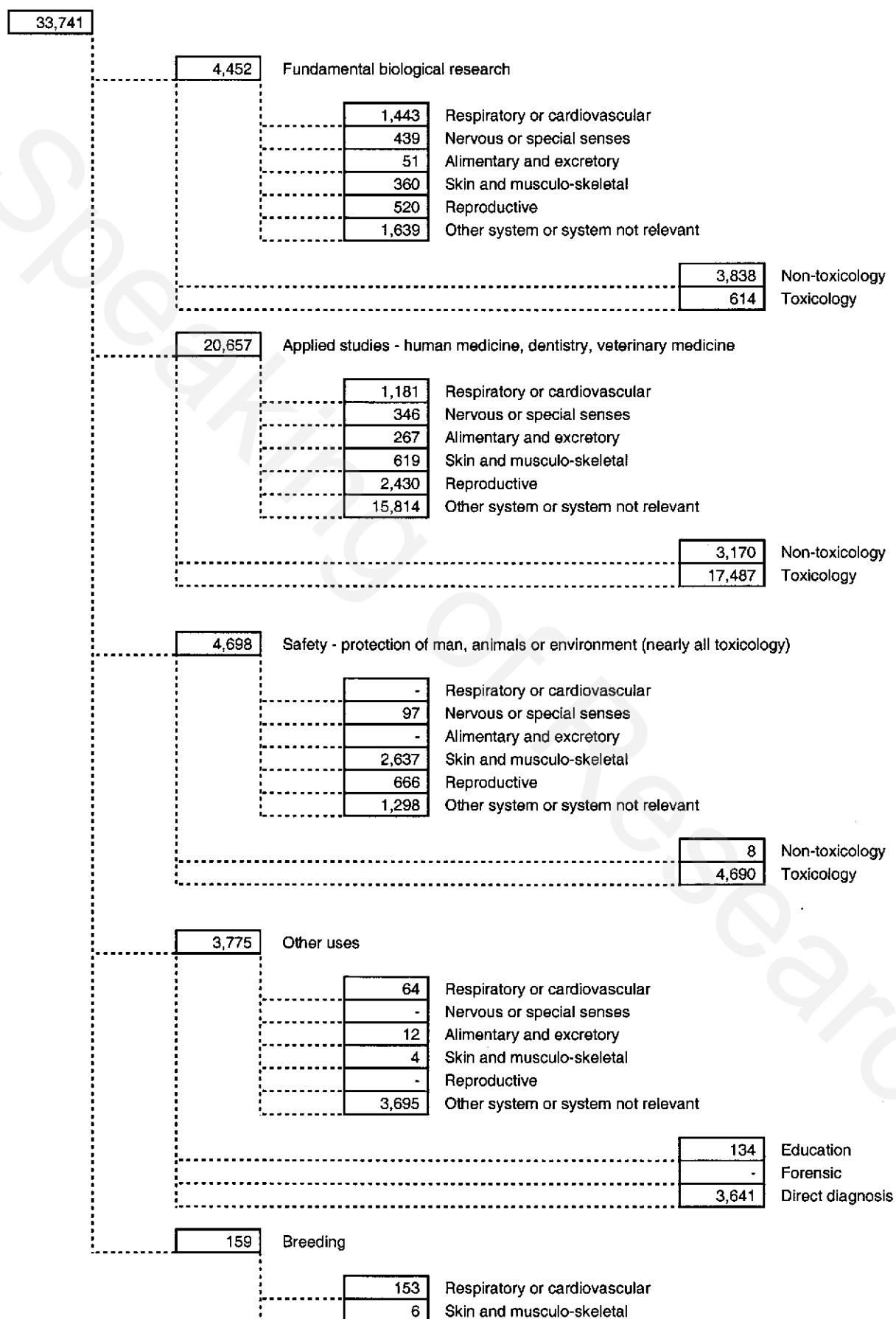


Table 18g Tree table - scientific procedures involving genetically modified animals, 2001

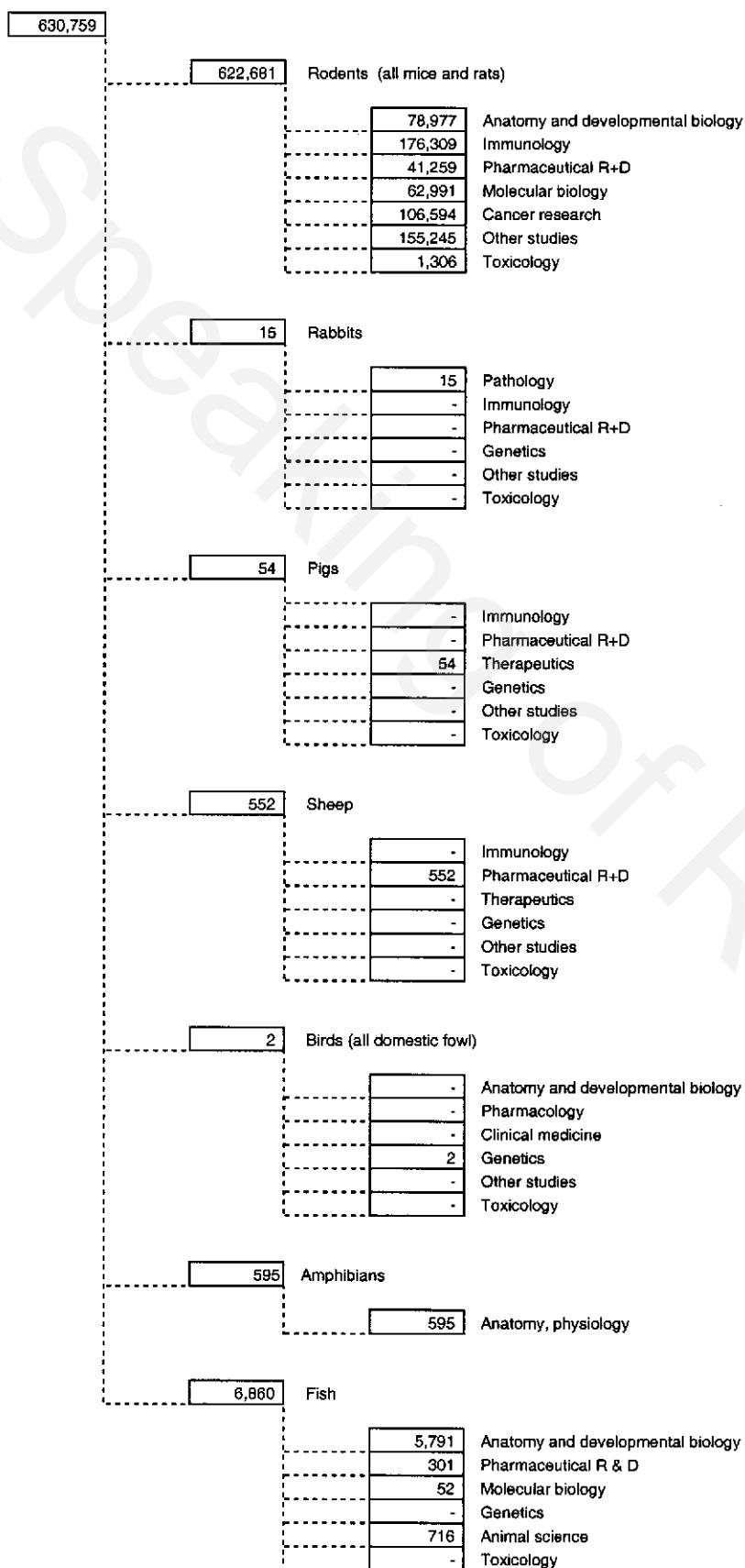
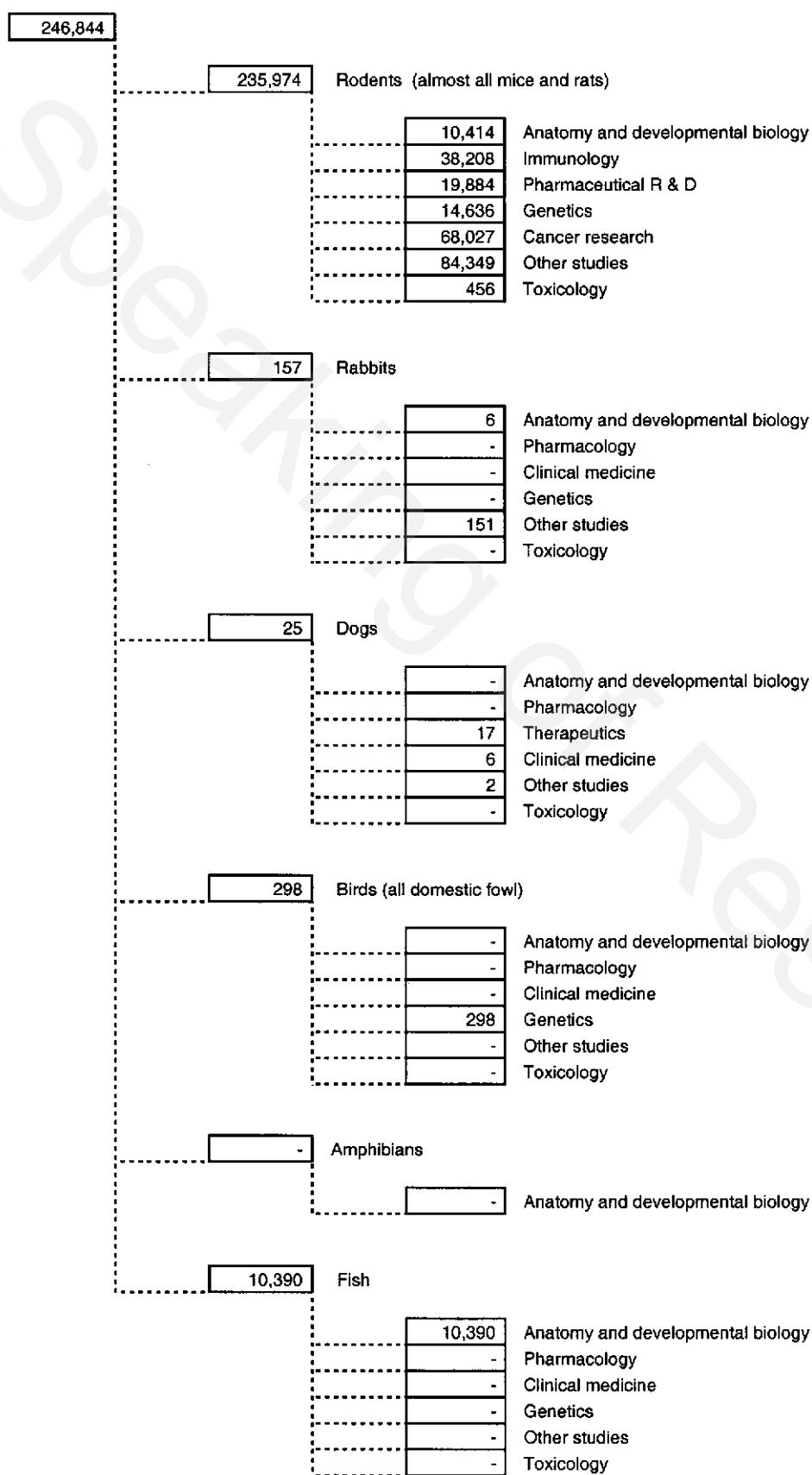


Table 18h Tree table - scientific procedures involving animals with a harmful genetic defect, 2001



Part B

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

Type of designated establishment	Number of licence holders ⁽¹⁾ reporting procedures						Number of licence holders ⁽¹⁾ reporting no procedures	Number of procedures
	Number of procedures		Total		Not counted ⁽²⁾			
	1 to 50	51 to 100	101 to 200	201 to 400	401 to 600	601 to 800	801 to 1,000	More than 1,000
Public health laboratories	5	2	-	3	-	2	3	5
Universities, medical schools	560	291	280	232	137	79	66	263
NHS hospitals	7	4	2	6	2	2	-	7
Government departments	23	10	10	11	9	1	1	14
Other public bodies	58	25	25	32	17	9	10	68
Non-profit making organisations	18	10	7	11	9	4	4	31
Commercial organisations	74	35	31	48	22	11	9	157
Total	745	377	355	343	196	108	93	545
								2,762
								161
								1,200
								2,622,442
								100

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

(2) Details of procedures on immature forms (e.g. larvae or embryos) are collected but not counted (see introductory notes, paragraph 12) and procedures involving field-testing of rodenticides are not included in the main tables (see commentary).

Table 20 Scientific procedures by species of animal, 1987-2001

Species of animal	Great Britain										Thousands of procedures				
	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
Mouse	2017.3	1850.5	1744.9	1,636.3	1,698.9	1,449.0	1,457.3	1,475.0	1,454.9	1,502.1	1,517.9	1,590.8	1,641.9	1,607.0	1,657.7
Rat	866.3	860.4	882.3	891.5	881.7	833	819.7	755.9	694.4	688.8	636.7	575.9	567.0	535.0	500.2
Other rodent	178.6	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
Rabbit	109.9	131.8	89.8	81.5	79.5	70.5	68.8	61.2	53.6	45.0	37.5	41.4	39.7	33.7	
Carnivore	18.7	20.5	21.4	19.3	17.6	15.3	14.1	15.1	15	12.7	11.9	13.9	11.6	11.6	
Ungulate	38.7	38.1	34.8	34.8	31.1	34.4	33	32.2	55.3	60.3	68.0	63.6	63.0	37.4	
Primate	5.1	6.3	5.3	4.5	4.5	5	5	5.2	4.7	4.4	3.9	3.7	4.0	3.7	4.0
Other mammal	0.9	0.4	0.2	0.8	1.3	1.3	2.5	3.2	1	0.8	0.9	0.5	0.5	0.8	
Bird	273.1	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
Reptile/Amphibian	10.5	11.3	11.6	13.1	15	19	17.7	17.2	17.2	17.3	15.3	14.4	14.6	15.6	17.5
Any Fish	112.3	107.5	77.5	106	132	138.3	152.1	139.9	131.1	135.2	119.6	122.3	122.4	243.0	171.1
Cephalopod ¹¹	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total	3,631.4	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	2,639.7	2,656.8	2,714.7	2,622.4

(1) *Octopus vulgaris*, from 1 October 1993.**Table 21** Scientific procedures (toxicology) by type of legislation, 1995-2001

Great Britain	Legislative requirements										Thousands of procedures				
	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	
UK requirements only	42.3	25.4	21.9	39.2	37.3	26.2	24.5	2.9	1.3						
Requirements of one EU country only (1999 onwards)	69.6	60.5	54.1	49.3	118.7	69.8	73.6								
EU requirements															
Requirements of non-EU Council of Europe countries	48.0	38.2	24.5	25.7	31.9	29.2	30.6	4.6							
Other international requirements	389.9	441.1	415.0	355.5	247.5	242.1	255.1								
Joint requirements (any confirmation of above)	117.5	155.0	109.6	94.8	74.7	74.1	65.7								
Non-legislative purposes															
Total	677.2	720.2	625.1	564.4	543.2	454.9	455.5								

Table 22 Scientific procedures by use of anaesthesia, 1987-2001

Great Britain Level of anaesthesia	Scientific Procedures										Thousands of procedures				
	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
No anaesthesia throughout the procedure ⁽¹⁾	2392.4	2213.1	2094.9	2,205.4	2,223.7	1,980.0	1,792.5	1,796.6	1,751.4	1,767.1	1,690.8	1,723.6	1,683.9	1,636.3	1,551.1
Anaesthesia, with recovery, for part of procedure ⁽²⁾	656.6	604.5	588.7	529.8	566.9	579.3	627	632.5	656.2	694.1	698.8	702.1	759.5	873.9	802.4
Terminal Anaesthesia ⁽³⁾	582.4	662.7	651.5	472	451.9	388.9	408.2	413.3	300	255.4	246.4	233.9	213.3	204.5	266.9
Total	3631.4	3480.3	3,315.1	3,207.1	3,242.4	2,928.3	2,827.7	2,842.4	2,708.6	2,716.6	2,636.0	2,659.4	2,656.8	2,714.7	2,622.4

(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, 1987-2001

Great Britain Type of designated establishment ⁽¹⁾	Scientific Procedures										Thousands of procedures				
	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
Public health laboratories	43.7	56.4	58.4	73.2	60.2	63.1	51.5	49.2	45.1	35.1	20.0	19.7	25.2	18.4	15.7
Universities, medical schools	804.9	777.7	747.6	710.0	727.8	737.0	840.6	832.6	824.1	843.8	882.1	934.8	936.1	1,069.7	1,005.7
Polytechnics etc. ⁽²⁾	26.2	36.0	29.0	38.1	26.3	32.8									
NHS hospitals	89.1	89.6	92.7	89.6	76.5	80.1	75.8	83.3	94.4	94.3	71.1	75.0	70.1	40.1	28.3
Government departments	92.7	65.9	58.7	68.7	72.6	65.1	78.1	62.6	78.6	94.2	81.5	86.2	91.8	100.5	84.6
Other public bodies	247.5	231.6	217.5	229.2	244.0	217.8	240.5	239.9	235.5	248.4	259.2	287.9	312.6	338.2	309.2
Non-profit making organisations	98.0	115.7	103.8	132.1	124.0	104.7	91.4	85.8	102.6	118.9	117.7	119.4	119.5	115.0	161.4
Commercial organisations	2,229.3	2,107.4	2,007.3	1,866.2	1,910.9	1,627.7	1,449.9	1,469.1	1,328.4	1,281.8	1,204.3	1,136.6	1,101.6	1,032.8	1,017.7
Total	3,631.4	3,480.3	3,315.1	3,207.1	3,242.4	2,928.3	2,827.7	2,842.4	2,708.6	2,716.6	2,636.0	2,659.4	2,656.8	2,714.7	2,622.4

(1) For 1987 and 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, 1995-2001

Field of research	Thousands of procedures						
	1995	1996	1997	1998	1999	2000	2001
Psychology	28.4	31.0	38.8	33.1	33.9	106.9	37.9
Pharmaceutical R&D	567.6	504.2	501.5	470.1	481.9	446.7	408.9
Cancer research	262.6	257.8	300.9	293.3	267.0	258.4	268.8
Ecology	14.5	15.2	11.9	13.7	9.1	12.6	19.8
Tobacco	.. ⁽¹⁾	0.0	0.0	0.0	0.0	0.1	.. ⁽¹⁾
Alcohol	3.2	2.2	1.9	0.4	1.2	3.1	3.1
Other	1,156.0	1,185.8	1,155.8	1,284.7	1,320.5	1,432.0	1,428.4
Total	2,032.4	1,996.4	2,010.8	2,095.3	2,113.6	2,259.8	2,167.0

(1) Fewer than 50 procedures

Table 25 Scientific procedures (toxicology) for safety evaluation, 1991-2001

Field of research	Thousands of procedures										
	1991	1992	1993	1994	1995 ⁽¹⁾	1996	1997	1998	1999	2000	2001
Protection of man, animal or the environment by toxicology or other safety evaluation:											
Environmental pollution	58.2	59.2	62.9	51.8	35.7	35.7	27.6	34.0	32.3	35.0	38.2
Substances used in agriculture	77.7	77	67.3	68.6	65.6	68.8	53.8	55.8	48.1	35.3	41.0
Substances used in industry	87.2	91.8	80.2	65.9	85.1	80.4	76.2	58.8	57.6	53.9	52.7
Substances used in the household	2.8	2.1	2.2	1.4	1.7	2.6	2.0	1.5	0.3	1.2	0.6
Foodstuffs and food additives	10.9	6.1	7.6	8.2	7.4	3.8	7.5	4.0	4.9	6.0	3.5
Cosmetics and toiletries	3.1	2.2	3.8	3.5	1.9	2.8	1.3	0.6	0.0	0.0	0.0
Tobacco	0.5	0.2	0	0.03	.. ⁽²⁾
Alcohol research	1.3	1.1	7.3	9.1	.. ⁽²⁾
Other safety evaluation	13.8	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
Pharmaceutical - quality control	83.8	84.3	77.8	74.0	85.6	70.9	72.2
Other purposes	62.7	76	67.7	51.4	44.7	48.8	42.5
Total	255.4	258.6	242	217.2	677.2	720.2	625.1	564.4	543.2	454.9	455.5

.. 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, 1995-2001

Primary purpose of the procedure	1995	1996	1997	1998	1999	2000	2001
Fundamental biological research	841.2	884.8	829.4	894.9	803.8	872.8	778.7
Applied studies -							
human medicine or dentistry	1,073.3	1,012.2	945.4	847.3	836.2	739.0	689.9
veterinary medicine	199.2	144.1	160.1	181.3	169.6	190.7	182.2
Protection of man, animals or the environment	209.2	219.7	201.0	170.4	153.3	161.2	153.6
Education	7.1	6.7	5.9	6.3	5.5	4.7	4.6
Training	1.7	1.7	1.6	1.6	1.4	1.3	1.2
Forensic enquiries	0.1	0.1	0.1	0.1	0.1	(1)	(1)
Direct diagnosis	65.0	55.8	55.5	52.0	47.8	45.3	34.5
Breeding	312.7	391.5	437.0	505.8	639.1	699.6	777.8
Total	2,709.6	2,716.6	2,636.0	2,659.7	2,656.8	2,714.7	2,622.4

(1) Fewer than 50 procedures

Table 27 Scientific procedures by primary purpose and genetic status, 1995-2001

Primary purpose of procedure	1995	1996	1997	1998	1999	2000	2001
Normal animal							
Fundamental biological research	713.1	724.8	656.2	664.1	621.5	653.2	560.9
Applied studies	1,219.2	1,101.1	1,043.8	969.4	937.9	857.7	810.5
Safety	208.9	219.0	200.8	170.1	153.3	161.1	153.5
Other uses	73.0	64.2	62.8	59.9	54.7	51.3	40.1
Breeding	53.5	72.2	83.0	89.2	126.7	152.8	179.8
Total	2,267.7	2,181.3	2,046.6	1,952.7	1,894.1	1,876.1	1,744.8
Animal with harmful genetic defect							
Fundamental biological research	53.8	43.9	43.3	57.5	55.1	54.5	46.8
Applied studies	40.7	41.0	50.1	42.7	42.9	50.8	44.6
Safety	0.2	0.7	0.3	-	-	-	(1)
Other uses	(1)	(1)	0.2	(1)	0.1	0.1	0.1
Breeding	131.9	148.0	142.8	159.1	152.9	151.5	155.3
Total	226.6	233.7	236.6	259.3	251.0	256.9	246.8
Genetically modified animal							
Fundamental biological research	74.3	116.2	129.9	173.2	127.2	165.1	171.0
Applied studies	12.7	14.2	11.7	16.5	24.9	21.2	17.0
Safety	0.1	-	-	0.3	-	0.1	0.1
Other uses	1.0	-	(1)	(1)	(1)	(1)	(1)
Breeding	127.2	171.2	211.1	257.6	359.5	395.4	442.7
Total	215.3	301.6	352.8	447.6	511.6	581.8	630.8
All animals							
Fundamental biological research	841.2	884.8	829.4	894.9	803.8	872.8	778.7
Applied studies	1,272.6	1,156.3	1,105.6	1,028.7	1,005.7	929.7	872.1
Safety	209.2	219.7	201.0	170.1	153.3	161.2	153.6
Other uses	74.0	64.2	63.0	59.9	54.9	51.4	40.3
Breeding	312.6	391.5	437.0	505.8	639.1	699.6	777.8
Total	2,709.6	2,716.6	2,636.0	2,659.7	2,656.8	2,714.7	2,622.4

(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.

Scope of the Act

2. The Act controls any experimental or other scientific procedure applied to a 'protected animal' which may have the effect of causing that animal pain, suffering, distress or lasting harm. Such work is referred to in the Act as a 'regulated procedure'. 'Protected animals' are defined as all living vertebrate animals, except man, plus 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.

3. 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.

4. The controls of the 1986 Act do not extend to procedures applied to animals in the course of recognised veterinary, agricultural or animal husbandry practice; procedures for identification of animals for scientific purposes, if this causes no more than momentary pain or distress and no lasting harm; or clinical tests on animals for evaluating a veterinary product under authority of an Animal Test Exemption (issued under the Medicines Act 1968).

Project and Personal Licences

5. Two kinds of licence are required for all scientific work controlled by the Act. The procedures must be part of a programme of work authorised by a project licence and the person applying the regulated procedures must hold a personal licence. No work may be done unless the procedure, the animals used and the place where the work is to be done are specifically authorised in both project and personal licences.

6. A project licence is granted when the 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 now required to complete an accredited training course before the licence is granted.

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.

Designation of premises

8. 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 was added to this list of species in 1993, and ferrets, gerbils, genetically modified pigs and 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.

The Inspectorate

9. The Act gives statutory recognition to the Home Office Animals (Scientific Procedures) Inspectorate and describes the Inspectors' duties. Inspectors hold either a medical or veterinary qualification.

10. 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 also the *reduction* of the number of animals used and the *refinement* of procedures to minimise pain and suffering. These are known as the **3Rs**. Inspectors carry out visits, mainly without notice, to establishments designated under the Act to inspect the premises and to ensure that the establishment's controls are adequate and that the terms and conditions of the licences issued under it are being observed.

11. 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.

12. Appendix B contains details of the numbers of Inspectors and of the number and type of inspections they carry out.

The Animal Procedures Committee

13. The 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.

14. 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.

Guidance and Codes of Practice

15. 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. The following documents have been published, and can also be found at the Home Office website (www.homeoffice.gov.uk)

- 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)

A number of other documents of possible interest have also been placed on the Home Office website.

Education and training

16. 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.

17. 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.

18. 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.

19. During 1995, mandatory training for Named Veterinary Surgeons was also introduced.

The acquisition and use of primates

20. 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.

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

Recent developments

22. In February 2001 the Home Office, together with the British Toxicology Society, the British Society of Toxicological Pathologists and the Department of Health, published Guidance on the Conduct of Regulatory Toxicology and Safety Studies (see paragraph 15 above). It is aimed at those with responsibility for the design and conduct of animal studies carried out under the 1986 Act for regulatory toxicology and safety testing.

23. In March 2001 the then Home Minister concerned, Mike O'Brien MP, announced plans to increase the complement of the Animals (Scientific Procedures) Inspectorate from 21 inspectors to 33.

24. Mike O'Brien also announced in March 2001 that applications for monoclonal antibody production by the ascites method, which the Government had earlier stated it wished to phase out in all but exceptional cases, would in future be determined at Ministerial level (see Commentary as regards table 8 relating to this procedure).

25. In June, July and November 2001 Home Office officials, and the then Minister concerned, Angela Eagle MP, gave evidence to the House of Lords Select Committee on Animals in Scientific Procedures. Minutes of the proceedings are available on the Parliamentary website (www.parliament.uk). The Select Committee is expected to report in the summer of 2002.

26. In November 2001 a report was published of the review conducted by the Animals (Scientific Procedures) Inspectorate into the working of the local ethical review process (ERP) required in each designated establishment. The report, which is on the Home Office website, showed that generally ERP worked well and as intended, but points of best practice were identified for wider dissemination.

APPENDIX B

Operation of the 1986 Act

1. In Great Britain, the Act is administered by the Home Office.
2. Administrative staff operate the licensing system on behalf of the Secretary of State: processing applications for new licences and certificates, and for amendments to existing authorities; and revoking licences as necessary.
3. Inspectors advise the Secretary of State about whether and on what terms applications for licences and certificates should be granted. Inspectors visit establishments (on both an announced and unannounced basis) to monitor facilities, and to ensure compliance with the Act and with the terms of licences and certificates. Inspectors are all highly qualified and experienced in medicine or veterinary science.

Staffing levels

4. The licensing work was carried out at five regional offices: Cambridge, Dundee, London, Shrewsbury and Swindon.
5. On 31 December 2001, there were 22 inspectors in post, and an administrative licensing section with a total complement of 22 staff and managers. A small section of other staff in London was also providing policy support to Ministers, including the production of responses to Parliamentary Questions and correspondence from MPs and the public about the use of animals in scientific procedures. In addition there were three staff providing secretariat support to the Animal Procedures Committee.
6. At the end of the year two of the licensing section posts were vacant.
7. In 2001, the Inspectorate carried out 2,653 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, 2,009 were for the purpose of inspection of designated establishments and work in progress. Two thirds of the visits to designated departments were unannounced. The remaining 644 visits were for the purpose of maintaining scientific or professional skills, representing the Home Office or furthering Home Office policy.
8. At 31 December 2001, the number and distribution of inspectors were:

	Chief Inspector	Superintending Inspectors	Inspectors
London	1	1	5
Cambridge		1	2
Dundee		1	3
Shrewsbury		1	4
Swindon			3
Total	1	4	17

9. During 2002 at least five additional inspectors are to be appointed.

Personal licences

10. During 2001, 2,311 personal licences were granted and 2,633 were revoked. On 31 December, 2001 there were 14,553 active licences. Personal licences continue to be in force until revoked, but they must be reviewed at least every five years.

Project licences

11. 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.
12. 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.

13. The following table details the number of project licences which were active on 31 December, 2001, the number granted during 2001 and the number revoked during 2001 (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 31/12/2001</i>		<i>Granted during 2001</i>		<i>Revoked during 2001</i>	
	<i>Number</i>	<i>%</i>	<i>Number</i>	<i>%</i>	<i>Number</i>	<i>%</i>
Mild	1,296	39	239	40	271	41
Moderate	1,811	55	329	54	361	54
Substantial	63	2	9	2	14	2
Unclassified	139	4	24	4	23	3
Total	3,309		601		669	

Certificates of designation

14. The following table details the number of certificates of designation which were in force on 31 December, 2001, the number granted during 2001 and the number revoked during 2001. The figures are subdivided for different types of establishment.

Certificates of Designation

<i>Establishment type</i>	<i>In force on 31/12/2001</i>	<i>Granted during 2001</i>	<i>Revoked during 2001</i>
Commercial concern	97	4	11
Higher education	87	-	3
Quango	31	-	-
Government	9	-	-
Non-profit	14	2	1
NHS hospital	7	-	-
Public health	3	-	-
Total	248	6	15

15. Of the 248 certificates of designation active on 31 December 2001, 182 were registered as user establishments, 68 as breeding establishments and 21 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.

Performance against Licensing Charter standards

16. Under the licensing Charter, introduced in April 2000, the administrative licensing staff had a target to issue decisions on all types of applications within 15 days of receipt of the Inspector's recommendations. In 2001, 8,934 new licences or amendments to existing licences were granted, and over 94 per cent of these were processed within the agreed target time limit.

SUMMARY OF INFRINGEMENTS

In the published statistics for 2000 details were given of new streamlined procedures for handling infringements. Action on 37 infringements was completed under these procedures in 2001, two less than last year's total.

Class One infringements

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

Eleven such infringements were dealt with in the reporting period. Five arose in academic establishments, four in commercial establishments, and one each in a QUANGO and an NHS Hospital.

Class Two infringements

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.

Eight Class Two infringements were dealt with in the reporting period. Academic establishments were involved in four, commercial establishments in three, and a government department in the one remaining.

Class Three infringements

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.

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

Three were reported by licensees to the Home Office, 10 were discovered and reported by Inspectors, four were reported by the NACWO and one was discovered by the Home Office when a personal licence holder applied for an amendment to a licence.

A total of 14 establishments had Class Three infringements reported. Academic establishments were involved in eight, commercial establishments in three, QUANGO's in two, and one arose in a non-profit making organisation.

No licences were revoked during 2001. However in one case a project licence was surrendered voluntarily before the outcome of a Home Office investigation - revocation would have been the outcome, and the former licence holder was informed of this in writing.

Nature of Class Three Infringements

As in previous years, the nature of the infringements varied in severity. In four cases, regulated procedures were performed without appropriate personal licence authority in breach of section 3(a) of the 1986 Act; in eight cases without appropriate project licence authority in breach of section 3(b); and in three cases without either authority. One case involved a delay in applying specified endpoints; one involved a departure from best practice at the time of surgery; and one involved the movement of animals to a non-designated premises.

Action taken

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.

As a result of these infringements, 33 licence holders were admonished; 15 were required to attend relevant modules of an accredited training course; 1 was required to have a supervision order added to the licence; 12 holders of certificates of designation were required to review the systems of control at their establishments in order to prevent recurrence; and in nine cases no formal action was judged necessary against those involved.

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 and required to submit their licences for revised supervision orders. Some of the certificate of designation holders were written to on more than one occasion, about more than one infringement, but were only counted once.

Return of procedures by project for 2001

OFFICIAL USE ONLY

Serial
Number

Project licence
number

Establishment
code

Dear Project Licence Holder

This form sets out the arrangements for the 2001 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 2001.

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 using the enclosed label. 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 overcome avoidable queries at a later date. **PLEASE NOTE CAREFULLY THE CODING INSTRUCTIONS. THERE ARE SOME WORKED EXAMPLES ON PAGES 9 & 10.**
- Please 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 2002**, using the enclosed label to:-

Home Office
Room 451, Horseferry House
Dean Ryle Street
LONDON SW1P 2AW

- 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.
- please retain a copy of this return in case of queries.

Thank you in advance for your care and attention.

Yours faithfully
DAVID WOOD
Animal Procedures and Coroners Unit
Community Policy Directorate

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

1. Have any procedures under the Animals (Scientific Procedures) Act 1986 under the project shown above been started during 2001?
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

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

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 448
Home Office
Horseferry House
Dean Ryle Street
LONDON SW1P 2AW

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

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
L1 Rabbit
C1 Cat
C2 Dog - beagle
C3 - greyhound
C4 - other including cross-bred dogs
C5 Ferret
C9 Other carnivore
U1 Horse, donkey and cross-bred equids
U2 Pig
U3 Goat
U4 Sheep
U5 Cattle
U6 Deer
U7 Carmelid
U9 Other ungulate
Primate
P1 - prosimian
- new world monkey
- marmoset, tamarin
- squirrel, owl or spider monkey
- other new world monkey
- old world monkey
- macaque
- baboon
- other old world monkey
- ape
- gibbon
- great ape
J9 Other Mammal

BIRD
T1 Domestic fowl (*Gallus domesticus*)
T2 Turkey
T3 Quail (*Coturnix coturnix*)
T4 Quail (spp. other than *C. coturnix*)
T9 Other bird

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

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 (including 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)
- 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 non-lethal clinical sign toxicity test (e.g. OECD 420). Includes tests such as the Maximum Non-Lethal Dose, Acute Toxic Class, Maximum Tolerated Dose or the Fixed Dose Procedure, where lethality may occur, but is not required for the quantitative assessment of the data.
- 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)
- 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 Rep. of Macedonia
Cyprus	Moldova	Turkey
Czech Republic	Norway	
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).
- 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 was the purpose of the procedure
- 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 column 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.
- (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

APPENDIX D

COLLECTION, VERIFICATION AND PUBLICATION OF THESE STATISTICS

Completeness

1. A return of Scientific Procedures is required each year from every person who holds a project licence for part or all of the year. A list of these people is created at the end of the year just prior to the start of the collection process, which is undertaken by the licensing staff (see Appendix B).
2. Licence holders are required, as a condition of their licence, to submit a return even if no work has been undertaken (nil returns). A record is kept of all licensees from whom returns have been received 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.
3. 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.

Accuracy

4. Verification and subsequent publication of these statistics are done by the Research Development and Statistics Directorate (RDS) of the Home Office.
5. Licensees make returns by completing a form using specified codes. A copy of the form and a full list of the codes used can be found at Appendix C. 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).
6. 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 will contact licensees to discuss and confirm coding, and inform RDS of any amendments which may be necessary.

APPENDIX E

CORRIGENDA

Although great care is exercised in the collection and publication of these statistics, certain errors in previous years' publications have come to light. During the preparation of the 2000 statistics the following errors were discovered:

1. In Tables 6 and 7 of every issue from 1995 to 1999 inclusive, the numbers of procedures were incorrectly split between "Disciplines" and "Other". The tables for those years recorded "Disciplines" as codes B01 to B19 inclusive (omitting codes B10 and B17 which have their separate rows), and "Other" as codes B20 to B32 inclusive. The footnotes to those tables show the *correct* distribution, which has been followed this year.
2. In Table 22 (historic table of anaesthetic use) the figures for "Anaesthesia with recovery for part of the procedure" and "Terminal anaesthesia" were shown incorrectly for 1997, 1998 and 1999. In those years, the latter category incorrectly recorded only those procedures where anaesthesia was used throughout the procedure. (Terminal anaesthesia can be administered either at the end of the procedure only, or throughout. See Tables 7 and 17.) In this publication, the figures for 1997 to 1999 inclusive have been corrected.
3. In Table 1a in the 1999 publication (Cm 4841), the number of rats used for the first time for breeding purposes (29,862) was greater than the corresponding figure for breeding procedures (29,381) given in Table 1. The figure in Table 1a should have read 29,332.

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
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".

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