



Home Office

**Statistics of Scientific Procedures
on Living Animals
Great Britain
2005**

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HOME OFFICE

Statistics of Scientific Procedures on Living Animals

GREAT BRITAIN
2005

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Home Department
by Command of Her Majesty
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Changes to publication

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

Since the 2004 publication some changes have been made to improve the contents and layout of this publication. This was done with the intention of making the publication easier to comprehend and follow. The introduction has been reduced, and most of the information regarding the tables has been transferred to a new Appendix C, '*Explanation of published tables*'. Further to this; additional information regarding comparisons between the 2005 figures and the previous year have been added to tables 1, 5, and 10. As a result of this some of the commentary regarding this information has been removed to avoid unnecessary duplication. The commentary itself has been amended, with the addition of new graphs and bullet points to make the report more accessible to a wider audience. The tree tables 18.a to 18.h have been removed, as this information already exists in other areas of the report.

We hope these changes improve the report and if you wish to provide us with feedback please see Appendix D for contact details.

STATISTICS OF SCIENTIFIC PROCEDURES ON LIVING ANIMALS GREAT BRITAIN 2005

INTRODUCTORY NOTES

1. The statistics in this publication relate to experiments or other scientific procedures performed on living animals that were subject to the provisions of the Animals (Scientific Procedures) Act 1986 during the year from 1 January 2005 in accordance with section 21(7) of the Act. 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 by the Home Office. The system of control under the Act is explained in Appendix A. The statistics exceed European Union requirements.

Collection procedures

2. The statistics are compiled from a return, submitted by project licence holders at the end of each year, or on the termination of the licence when this occurs during the year. A simplified copy of the form and its instructions can be found in Appendix B. The form provides details of the species of animal used, the main purpose of the procedure and other details as described in Appendix C below. Each procedure (which may consist of several stages) for a given purpose on an animal is counted as one returnable procedure for the year in which it commenced. A study involving a procedure using a number of animals is counted once for each animal. Where an animal which has recovered fully from a completed procedure is used again for a further procedure it is counted as a separate procedure, but the animal itself is not re-counted. The circumstances in which this re-use of an animal is permitted are limited.

3. Licence holders are required, as a condition of their licence, to submit a return even if no work has been undertaken (nil returns). A 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 to do so.

4. To ensure that the published data are as complete as possible the Home Office will not publish the statistics unless the number of missing returns represents less than 0.5 per cent of all the returns expected. In 2005 all forms were returned.

5. Details of the work of individual project licence holders are not identifiable in this publication. Where a further breakdown of the 'other' species categories are not given in the commentary this is to ensure the confidentiality of the establishment and the licence holder.

Accuracy

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

7. Project licence holders classify their procedures according to a standard coding list, see Appendix B. The current classification system dates from 1995, and was modified in 1999 in those areas relating to source of animals, production and breeding, toxicology and legislation. During the collection and verification process, forms that have been incorrectly coded are referred back to the licensees for correction. Incorrect coding might be either codes which are wrong (i.e. outside the appropriate code range for the particular row) or which fail a cross-validation check (i.e. where two codes in different rows are incompatible).

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

Description of statistical tables

9. Project licence holders are asked to answer 15 questions about the procedures performed (see form at Appendix B), 12 of which identify individual characteristics explained more fully in Appendix C below. The flowchart on page 17 shows the relationship between the tables and the data in Part A.

PART A TABLES - PROCEDURES IN 2005

10. Additional information comparing the 2005 figures with the previous year has been provided on tables 1, 5 and 10. As a result, some of this information has been removed from the commentary to limit duplication in the report. For the purpose of the commentary most figures used have been rounded to the nearest 100 procedures (or animals), in order to simplify the explanation, as the figures referenced will not be identical to the figures in the tables.

As a result of a review of the published tables in 2001, Tables 6, 7, 14, and 17 no longer appear. Although this leaves gaps in the table numbering, the existing numbering has been retained to preserve the continuity from previous years. The sequence of tables published in this year's report is the same as that published in 2001. As a result of further reviews in 2006 the tree-tables 18.a – 18.h have also been removed from the publication.

PART B - PROJECT LICENCE HOLDERS AND DESIGNATED PLACES

Type of designated place (Table 19)

11. 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

12. 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.

13. Some of the historical tables which appeared in publications prior to 1995 have been discontinued because of the lack of comparability with data for 1995 onwards, when the present system for collecting and presenting data was introduced.

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

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

MAIN POINTS

1. The number of scientific procedures started in 2005 was just under 2.9 million, a rise of about 41,300 (1.4%) on 2004.
2. Mice, rats and other rodents were used in the majority of procedures, 85 per cent of the total. Most of the remaining procedures used fish (8%), and birds (4%).
3. Dogs, cats, horses and non-human primates, afforded special protection by the Act, were collectively used in under one per cent of all procedures. Since 1995 there has been a 27 per cent decrease in the combined use of these animals for regulated procedures.
4. The number of procedures using non-human primates was 4,650, up 440 (11%) from 2004. The number of animals used for these procedures was 3,120, up 320 (12%) on 2004. This was mainly due to using macaques for pharmaceutical safety and efficacy testing, mostly conforming to a regulatory purpose.
5. Breeding procedures accounted for over a third (35%) of all the procedures conducted in 2005.
6. Over 99 per cent of procedures carried out on animals listed in Schedule 2 of the Act used animals acquired from designated sources in the United Kingdom.
7. Genetically normal animals were used in 1.65 million regulated procedures, a decrease of 22,700 (1%) from 2004. Breeding accounted for 1.03 million (35%) of these procedures. Their use represents 57 per cent of all procedures for 2005, compared with 59 per cent in 2004 and 84 per cent in 1995.
8. Species with harmful, but naturally-occurring, genetic mutations were used in 288,100 regulated procedures, representing ten per cent of all procedures for 2005. The majority of these procedures used rodents (89%).
9. Genetically modified animals were used in 957,500 regulated procedures representing 33 per cent of all procedures for 2005, compared with 32 per cent in 2004 and eight per cent in 1995. The vast majority (96%) of these procedures used rodents. Over one third (39%) of the genetically modified animals were used in scientific procedures for fundamental and applied studies.
10. Around 40 per cent of all procedures used some form of anesthesia to alleviate the severity of the interventions. For many of the remaining procedures the use of anesthesia would have potentially increased the adverse effects of the procedure.
11. Non-toxicological procedures accounted for about 86 per cent of the procedures started in 2005. This contrasts with 75 per cent of procedures being for a non-toxicological purpose in 1995. The main areas of use were for immunological studies, pharmaceutical research and development, anatomy and cancer research.
12. Procedures for toxicological purposes accounted for 14 per cent of all procedures started in 2005; this contrasts with 25 per cent of procedures being for a toxicological purpose in 1995. Over the last ten years the number of toxicological procedures has fallen by over 40 per cent. In 2005 about 73 per cent of toxicological procedures were for pharmacological safety and efficacy evaluation. Around 80 per cent of toxicological procedures in 2005 used rodent species, while non-human primates were used in less than one per cent of the toxicological procedures. Of all the toxicological procedures conducted in 2005, 87 per cent were performed to conform to legal or regulatory requirements.

COMMENTARY

OVERALL PICTURE

Procedures started in 2005

The number of scientific procedures started in 2005 was just under 2.9 million (Table 1), a rise of about 41,300 (1.4%) on 2004. There has been a significant reduction in the annual number of scientific procedures since 1976, this trend levelled out in the 1990s and in recent years there has been an increase in the number of procedures. Since 2000 the number of procedures has risen by seven percent, with the rise in breeding procedures accounting for a significant part of this increase. The overall level of scientific procedures is determined by a number of factors, including the economic climate and global trends in scientific endeavour. In 2005 some 2.81 million animals were used for the first time in procedures (Table 1a), this was about 34,200 (1%) more than in 2004, broadly reflecting the trend in procedures started.

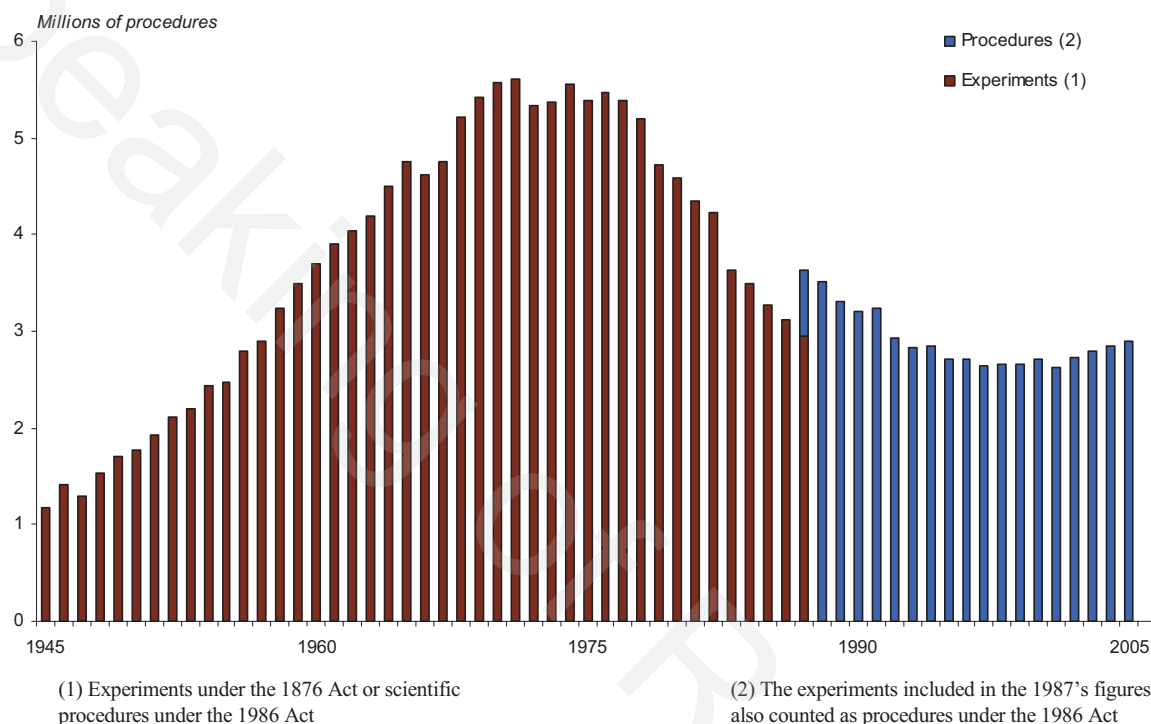


Figure 1: Experiments or procedures commenced each year, 1946-2005⁽¹⁾

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

For details of the changes in the number of species used for procedures reported since 2004 please see Table 1. Points of note are:

- The species of animals involved in the largest numbers of procedures in 2005 were mice (68%), rats (15%), fish (8%), and birds (4%), where domestic fowl accounted for nearly 88 per cent of all birds used. These proportions are all broadly similar to those in recent years.
- The proportion of dogs (0.26%), cats (0.02%) and non-human primates (0.16%) involved in procedures was very small, a combined total of 12,800 in 2005, less than half of one per cent of all procedures. The total use of these three groups fell by 200 procedures compared with the 2004 figure. A fall in the use of new-world primates, dogs and cats was largely offset by an increase in the use of macaques.
- The principal increase in 2005 was in procedures involving mice up 42,000 (2%) compared with 2004. Other species showing increases on the 2004 figures were fish up 38,300 (20%), birds up 7,900 (7%), cattle up 5,500 (40%) and amphibia up 2,800 (15%).
- The increased use of mice in 2005 was associated with breeding, and with fundamental biological research. The increased use of fish was attributed to fundamental biological research, applied studies and breeding. The use of amphibia has increased mainly for the conduct of breeding and

fundamental studies. The rise in bird use was due to increases in applied studies in veterinary medicine, which were slightly offset by a fall in the use of birds for fundamental biological research.

- There were decreases in procedures using some species, notably rats down 40,200 (9%), sheep down 12,000, (29%) and pigs down 7,600 (68%). There was also a decrease in the number of hamsters down 800 (16%), cats down 300 (40%) and Beagles down 400 (5%).
- There was a decrease in use of new world primates by over 100 (10%) procedures, as a continuation of the current downward trend. The number of procedures involving old-world primates increased by about 550 (17%). Although this was from a low base in 2004, the long-term trend in old-world primates has steadily been increasing since 2000, see Figure 2.
- Many primates are re-used, since many of the procedures in which they are involved are of only mild effect, for which anaesthesia is not required. The graph below shows the use of old-world and new-world primates over the last ten years. The rise in the use of old-world primates in recent years has been due to the increased use of these species for pharmaceutical safety testing

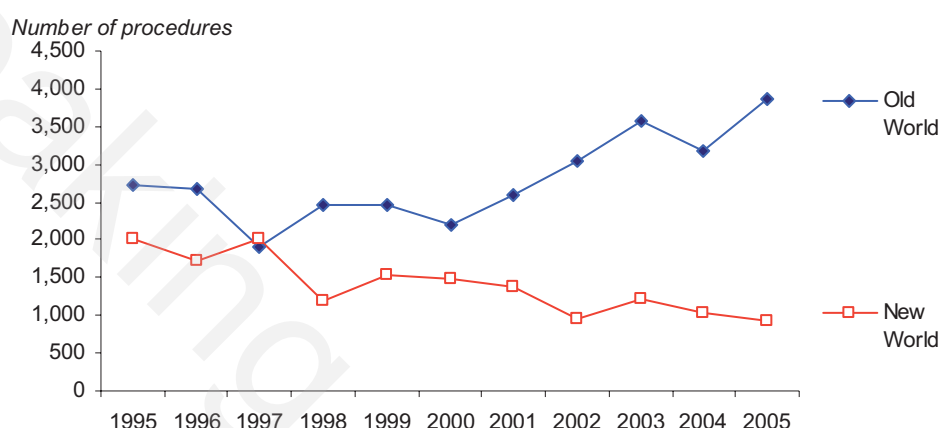


Figure 2: Procedures on non-human primates, 1995-2005

- In 2005 the 'other carnivore' category included red foxes, badgers, seals and several species of mustelids, used for research relevant to those species.
- The 'other ungulate' category, which appears only in some years, included only one species in 2005 used for a single programme of work.
- The 'other mammals' included species such as bats, and one type of shrew.
- No procedures were performed in 2005 on greyhounds, camelids, prosimians, baboons, great apes, gibbons, non-specified new-world primates and non-specified old-world primates, or the single cephalopod species protected by the Act (*Octopus vulgaris*).
- The government stated in November 1997 that it would no longer issue licences to use great apes in scientific procedures. No great apes have been used since the current legislation (the 1986 Act) was introduced in 1987. Where there was no use of a species, the species might not be listed in tables other than Tables 1, 1a, 5, 5a, 10 and 10a.

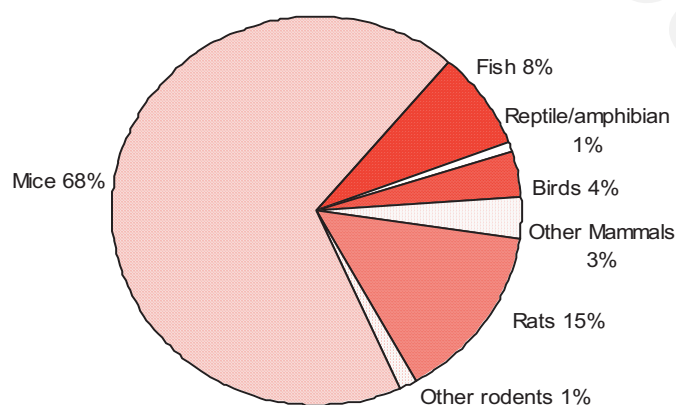


Figure 3: Procedures by species of animal, 2005 (Table 1)

Primary purpose (Tables 1 and 1a, Tables 26 and 27, Figure 4)

- In 2005 breeding accounted for 1.03 million procedures (35%), see figure 4. These procedures were up 44,500 (5%) from 2004 as part of a continuing trend.
- Fundamental biological research accounted for 939,800 (32%) procedures, up 58,900 (7%). Procedures for this purpose have typically been fluctuating for a number of years.
- Applied studies into human medicine or dentistry accounted for 625,000 (22%), however this was down 47,000 (7%) on 2004.
- There was also a decline in procedures for the protection of man, animals or the environment down 10,300 (9%). Procedures for this purpose are now under half the level reported in 1995.
- Procedures for applied studies for veterinary medicine were down 200 on the 2004 figure.
- Decreases were also reported for direct diagnosis of disease, down 3,600 (8%), the general trend for these procedures is downward.
- The other purposes reported in Tables 1 and 1a recorded small numbers in line with existing trends, with the exception of training which has increased by 34 procedures on 2004, but from a very low base.

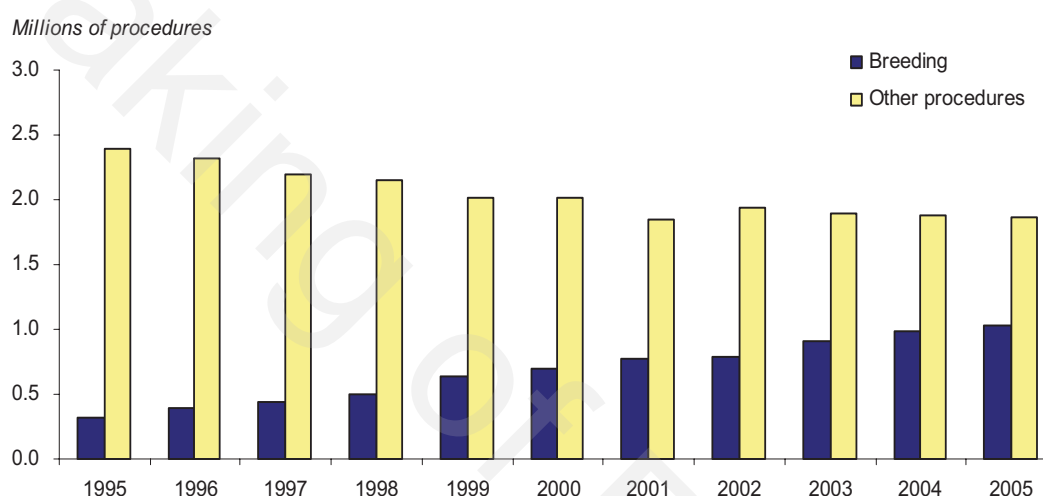


Figure 4: Comparison of breeding with all other procedures, 1995-2005

Source (Tables 2, 2.1 and 2.2)

In 2005 eighty-five per cent of all procedures were performed on animals listed in Schedule 2 to the Act. These animals are required to come from a designated source, unless a special exemption is granted. The animals in question are: mouse, rat, guinea pig, hamster, gerbil, rabbit, cat, dog, ferret, non-human primate, pigs (if genetically modified), sheep (if genetically modified), and quail (*Coturnix coturnix*).

- There was an increase in the number of these species used for procedures by 5,000 (less than 1%) on 2004, the remaining species rose 39,200 (9%) on 2004. These numbers have shown fluctuations in recent years.
- In total, 2.43 million (99%) of procedures carried out on animals listed in Schedule 2 used animals acquired from designated establishments in the United Kingdom (63 per cent from the user's own establishment, and 37 per cent from another designated establishment). There is an established trend towards using animals sourced from the licensee's own establishment, rather than obtaining them from a designated supplier, reflecting the rise in the use of genetically modified (GM) animals. Nearly 80 per cent of harmful mutant and 93 per cent of genetically modified animals were obtained from within the licensee's own designated establishment.
- The number of procedures involving Schedule 2 listed animals obtained from sources outside the EU in 2005 rose by 1,800 and of these 71 per cent used mice or rats.
- Twenty-seven per cent of all procedures performed on non-human primates used animals acquired from designated sources within the United Kingdom.
- Acquisition from abroad is often due to a lack of suitable animals.
- From Tables 2, 2.1 and 2.2, it can be seen that just under half of procedures on species listed in Schedule 2 obtained from sources outside the UK, were performed on either harmful mutant or

genetically modified animals. Most rodent imports are to obtain harmful mutant or genetically modified strains not available in the UK.

- The use of animals listed in Schedule 2 and acquired from non-designated sources in the UK was duly authorised as properly justified under Section 10(3) of The Act.
- The rodents from non-designated sources in the UK are mainly those involved in studies requiring animals from or in the wild.
- The dogs from non-designated sources within the UK were 'other dogs', i.e. neither beagles nor greyhounds. The research programmes required animals representative of the general pet population which are not available from the usual designated sources, and which were used for studies relevant to the specific breed or type of dog.

Genetic status (Tables 3, 3.1, 3.2, 3.3, Table 27, Figure 5)

Genetically normal animals (Tables 3, 3.1, Figure 5)

Of the procedures started in 2005 1.65 million (57%) involved normal animals, down 22,700 (1%) on 2004. In the longer term, the use of genetically normal animals has decreased from 2.27 million in 1995 to 1.65 million in 2005, down 27 per cent over this period. Table 3.1 shows normal animals used only in breeding programmes, nearly all these animals were mice (97%), the remainder being rats, other rodents, sheep, birds, reptile/amphibians and fish.

Animals with a naturally-occurring harmful genetic defect (Tables 3, 3.2, Figure 5)

Of all procedures started in 2005 some 288,100 (10%) involved animals with a naturally occurring harmful genetic defect, 20,500 (8%) more than in 2004.

- Use of such animals has risen from 8 per cent of all procedures in 1995 to just under 10 per cent now.
- The animals used in 2005 were mostly mice (82%), rats (7%), and fish (10%).
- Other than procedures associated with maintenance of breeding colonies, the work with mice and rats was mainly for fundamental biological research and applied studies (though mice were used more in each case).
- The fish and amphibians were used for breeding and for fundamental biological research.
- None were used in toxicology.

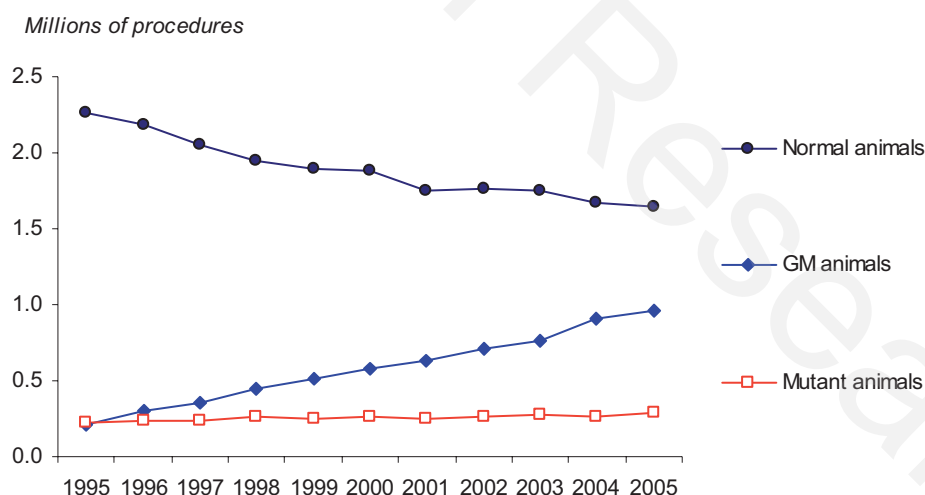


Figure 5: Procedures involving normal, mutant, and genetically modified animals, 1995-2005

Genetically modified animals (Tables 3, 3.3, Figure 5)

The use of genetically modified (GM) animals was identified as a separate category for the first time in 1990. This category accounted for some 957,500 (33%) procedures in 2005 some 43,400 (5%) more than in 2004.

- Mice accounted for 95 per cent of these procedures, most of the remainder being fish. Three GM sheep were used (for breeding) in 2005, but no GM pig use was reported.
- There was an increase in the number of procedures using GM birds (all domestic fowl) up 190 on

2004.

- Fish use rose by 6,600 on 2004 and there was also a marked rises in the use of reptiles/ amphibians, up around 1200.
- About 630,800 (66%) of GM animals were used solely to maintain breeding colonies, a similar proportion to last year. An additional 305,800 (32%) were used for further scientific purposes
- Less than a quarter of one per cent was used for fundamental research in toxicology.
- The regulated use of GM animals has more than quadrupled since 1995 and now represents about 33 per cent of all scientific procedures, compared with eight per cent in 1995. This increase has been offset by the decline in the use of genetically normal animals.

Target body system (Table 4a)

In 2005, about half of all procedures were prospectively directed towards one particular body system:

- The largest single category was the immune system, accounting for 475,300 (16%) procedures.
- The next largest was the nervous system 397,900 (14%) procedures. In both cases rodents were the main species used; in the former case mainly mice, but in the latter case both mice and rats were used.
- There were increases in use of procedures for special senses up 10,500 (67%), for research mainly into deafness and vision.
- Other increases targeted the respiratory system up 9,500 (12%) and the cardiovascular system up 1,000 (3%).
- All other singular body system categories saw decreases on 2004.

Use of anaesthesia (Table 4b, Table 22)

Procedures are permitted without anaesthesia or analgesic only when the administration of an anaesthetic or analgesic is judged to be more traumatic than the procedure itself, or when anaesthesia is incompatible with the object of the procedure.

- Just over 60 per cent of procedures did not use anaesthesia.
- Local anaesthesia was used in 301,000 (10%) procedures and mainly mice (96%) were used for these procedures.
- Anaesthesia without recovery was used in 275,400 (10%) procedures up 6,100 (2%) from 2004.
- The use of neuromuscular blocking agents (NMBA) in 2005 was reported to be 3,775 procedures, all of these being in conjunction with general anaesthesia. Just under eighty per cent (77%) of these procedures were carried out under general anaesthesia without recovery, almost all (95%) of these procedures were performed on rodents.

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

The attention of readers is drawn to paragraph four of Appendix C where the method of recording procedures for toxicology and regulatory purposes, against those for non-toxicology purposes, is explained.

- In 2005 some 2.5 million procedures were conducted for purposes of fundamental and applied studies other than toxicology, safety or other regulatory purposes.
- There was a rise of 83,700 (4%) in the number of such procedures.
- There was an increase of 76,000 (3%) in the number of animals used, broadly reflecting the rise in the overall number of procedures.
- Although the use of most species fell, this was more than offset by the increases in the use of mice up 76,400, mostly for breeding purposes and fish up 46,900.
- Of the procedures started in 2005, 1.79 million (72%) were performed on mice, 294,000 (12%) on rats 103,200 (4%) on birds (mainly domestic fowl) and 193,500 (8%) on fish.
- Just over 2,000 procedures used dogs, 500 used cats and 1,000 used non-human primates.

Field of research (Tables 5, 5a, 5.1 and 5.2, Table 24, Figure 4)

For details of the changes in the number of non-toxicology procedures reported for each field of research since 2004 please see Table 5. Points of note are:

- The largest single category was immunology (19%) which mainly used mice, although a wide range of other species were used.

- Anatomy, physiology, molecular biology, pharmaceutical R&D, cancer research and genetics were the only other fields of research where the number of procedures was greater than five per cent of all non-toxicology procedures.
- Dentistry showed a very large percentage increase (1005%). Although the actual use was only up around 200 procedures on 2004, this is still a very small section.
- No procedures were carried out for research on the effects of tobacco; there has been no research of this kind since 2001.
- Animals with harmful genetic defects (Table 5.1) were used across a wide range of disciplines, but none were used for clinical surgery, dentistry, zoology, botany, animal science, ecology, or research related to the use of tobacco or alcohol studies. The principal disciplines for which such animals were used were: Cancer research 91,100 procedures (32%), genetics 41,400 (14%), anatomy 32,300 (11%), immunology 28,200 (10%), and 'Other' use (i.e. disciplines not otherwise specified) accounted for 45,900 (16%). In all of the procedures mice, rats and fish were the main species used.
- There was a broadly similar spread of disciplines involving genetically modified animals (Table 5.2). No procedures using GM animals were performed for the disciplines of dentistry, botany, ecology, animal welfare or tobacco research. The principal disciplines for which such animals were used were: Immunology (26%), anatomy (14%), cancer research (12%) and physiology (10%).

Production of biological materials (Table 8)

In 2005 some 300,000 procedures, 13,600 (5%) more than in 2004, were performed for the purposes of production of biological materials.

- About 33 per cent were for the production of infectious agents, of this particular group the main species used were birds (65%) and mice (30%).
- Vectors, neoplasms and antibody production accounted for a further 14 per cent; in all cases a wide range of species was used.
- The remaining 53 per cent of production procedures were to obtain other biological material such as tissues or blood products, also using a wide range of species.

In November 1997, the Government confirmed that the production of monoclonal antibodies by the ascites method could only be considered if *in vitro* attempts at production had failed, or the use of animals was justified for specific diagnostic or therapeutic products. The coding of the returns form was changed in 1999 to distinguish between procedures for the immunisation of animals used in monoclonal antibody production, (for which there are no generally applicable replacement alternatives), and those where the ascites model has been used. The immunisation method to produce tissues for *in vitro* used for the produced for monoclonal antibodies showed a drop of 300 to 3,100. There were no procedures recorded as performed using the ascites model in 2005.

Techniques of particular interest (Table 9)

Among non-toxicological work, certain procedures have been identified as being of particular interest. (These have been described below in paragraph 8A (iii) of the Appendix C).

- About 145,700 (6%) non-toxicology procedures fell into this category in 2005, an increase of 900 on the number reported in 2004. The general trend is downwards since this category of procedure was separately identified in 1995, but the rate of decline has slowed in recent years.
- There were some increases; principally in procedures involving the use of physical trauma up 2,400 (15%); this included work for pain and other neuronal injury studies, tissue repair studies, and atherosclerosis. Inhalation was up 3,200 (8%) and aversive training procedures rose by 600 (7%).
- There were also decreases; including procedures involving interference with the brain, for neurological research, down 4,200 (17%), psychological stress down 3,300 (37%), while the thermal injury category fell by 300 (64%) and included mainly tissue repair studies.

TOXICOLOGY OR OTHER SAFETY OR EFFICACY EVALUATION

(Tables 10, 10a, 21, 25 and Figure 6)

Procedures for the purpose of toxicology or safety and efficacy evaluation accounted for 393,100 (14%) of the total number of procedures carried out in 2005, this was about 42,400 (10%) fewer than in 2004. The decrease was reflected in a similar fall (41,900) in the number of animals used for the first time in 2005

which was 383,300. Toxicology procedures continue to form an ever smaller proportion of scientific procedures overall; in 2005 they represented only 14 per cent, compared with 25 per cent in 1995, a fall of over 40 per cent (284,100 procedures) over the last ten years. As Figure 6 shows there has been a continuing divergence between toxicology and non-toxicology procedures since 1997.

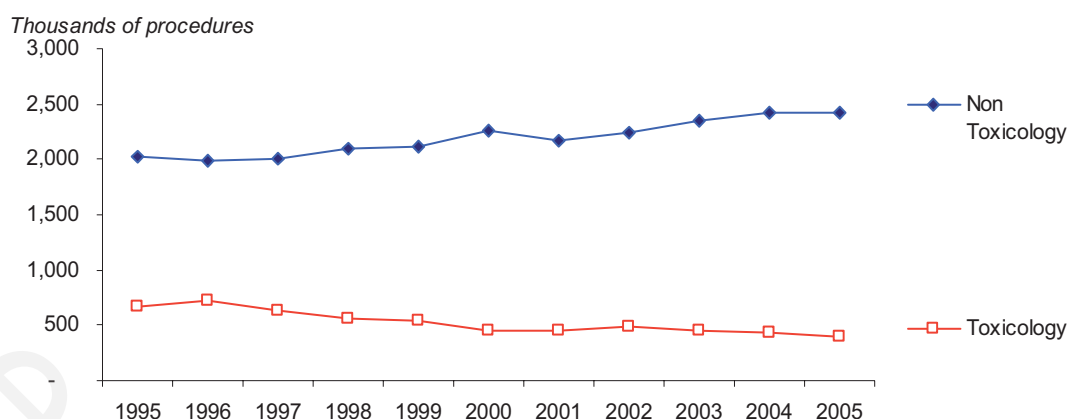


Figure 6: Toxicology and non-Toxicology procedures (Table 5)

Species (Figure 6)

For details of the changes in the number of toxicology or other safety or efficacy evaluation procedures reported for each field of research in 2005 please see Table 10. Points of note are:

- The majority of animals used were rodents, 313,900 procedures (79%). The other major use was fish accounting for some 39,000 procedures (10%)
- There were 3,600 procedures (less than 1%) that used non-human primates (principally old-world species), mainly for pharmaceutical safety testing
- Only 2,000 procedures involving genetically modified animals were carried out for toxicology, and all the animals so used were mice or rats (see Table 3.3). This represents around one in 500 of all genetically modified animals used, and is similar to the proportion reported a year ago.
- There were 680 procedures for toxicology involving animals with harmful genetic defects (all mice and rats); this represented about one procedure in every 435 involving these animals, again this is somewhat less than the number used last year (Table 3.2).
- The 'Other' species accounted for only four per cent of all toxicology procedures.

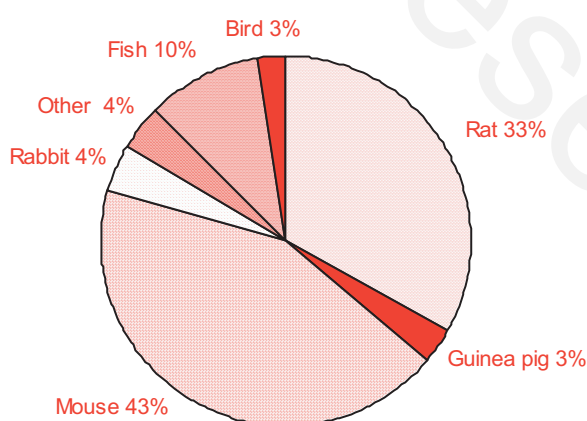


Figure 7: Procedures (toxicology) by species of animal, 2005

Purposes (Figure 8)

- Decreases were reported in some types of procedures, but particularly those concerned with the safety of substances used in evaluation of environmental pollution down 12,500 (43%), and substances used in industry down 9,800 (29%).
- Pharmaceutical quality control procedures were down 14,200 (15%) reversing the trend on 2004.
- Toxicology research down 3,800 (20%) following a slowly declining trend.
- A few categories showed a rise in the number of procedures; such as agriculture up 4,500 and foodstuffs up 5,500. The increased procedures reported under the 'foodstuffs' category is not a new program of work but represents a revision of the relevant coding from the previously used "other" category.
- 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 2005.

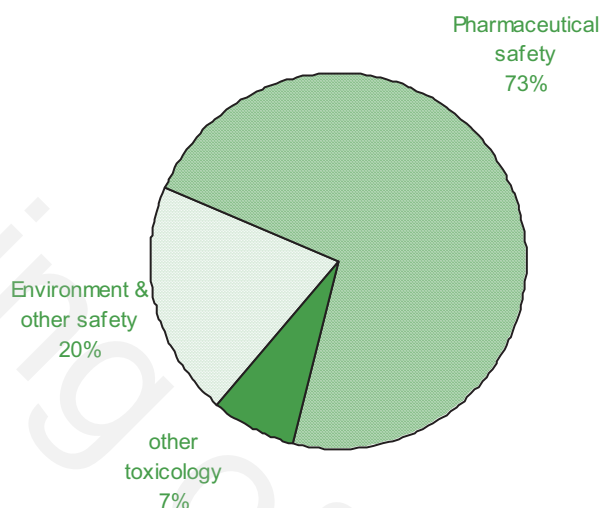


Figure 8: Procedures by purpose of test (toxicology), 2005 (Table 10)

Legislative requirements (Table 11, Table 21, Figure 9)

- Of the total of 393,100 toxicology or safety procedures in 2005 the majority of procedures were performed to fulfil legislative requirements (87%). Some 275,800 procedures (70%) were used to satisfy a combination of requirements i.e. avoiding duplication of animal use to fulfil more than one legislative requirement
- While some 52,500 procedures (13%) were performed for purposes other than direct legislative or regulatory requirements.

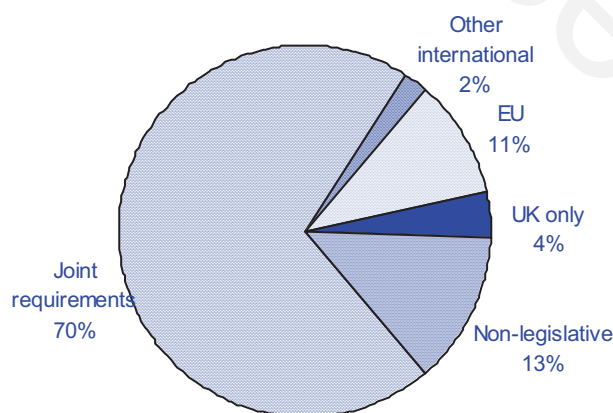


Figure 9: Procedures by legislative requirement (toxicology), 2005 (Table 11)

Type of test (Tables 12, 13, 15, 16, Figure 10)

See explanatory notes for List A, Row 11 in Appendix B 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.

- Tests were reported in fundamental research in toxicology, safety testing, efficacy testing and used in agriculture and foodstuffs other than additives.
- None of the acute lethal procedures were LD50 tests carried out according to the previous OECD Guideline 401.
- The acute lethal toxicity tests involved testing of biopharmaceuticals including veterinary biologicals, and food safety tests.
- Acute lethal concentration tests accounted for 14,200 (4%).
- There were 103,900 (26%) procedures for all categories of acute safety testing, a decrease of 34,300 on 2004.
- A further 47,700 (12%) procedure were carried out for subacute limit-setting or subacute toxicity tests, 4,300 more than in 2004.
- Of the remaining tests other non-specified toxicological tests (in which a wide range of species was used but the majority being mice, rats and other rodents) accounted for the greatest single proportion with 109,100 procedures (28% of the total), a fall of about 8,500 on 2004.
- The present 'other' category is comprised mostly of procedures concerning pharmaceutical safety testing not otherwise described, other fundamental or applied toxicology research, and the acquisition of tissues for further *in vitro* studies.
- Rabbits were used in about 8,800 procedures for pyrogenicity testing, which continues 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 845 procedures were carried out on rabbits to test for clinical signs in the eye. Both these figures are roughly the same number as in 2004.
- There were 34,500 procedures, of which 86 per cent were on rats, to test for teratogenicity and other reproductive toxicity.
- There were 2,800 procedures on rodents to test for skin sensitization, mainly on mice used for the safety testing of products used in agriculture and industry, as well as pharmaceutical safety testing and method development.

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 10 (general, pharmaceutical and other) and examines procedures for species by each of the types of test shown in the columns of Table 12.

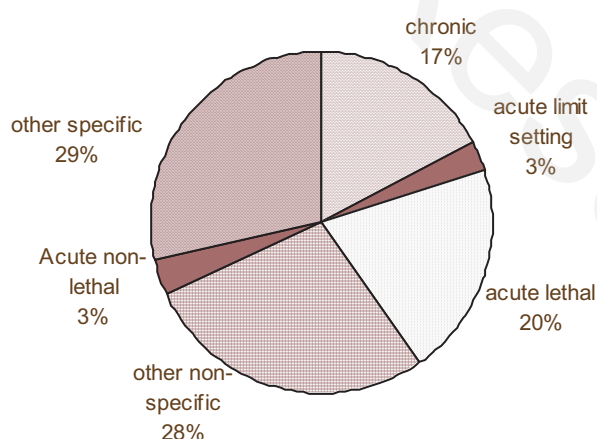


Figure 10: Type of test (toxicology), 2005 (Table 12)

Rodenticide trials

It is impracticable to collect accurate figures on the number of animals affected in field trials of rodenticidal substances. However, no field trials were reported to have been started in 2005.

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 B). There were 33 procedures performed in 2005 on animals in this category, all on wild birds.

RETURNS, PROJECT LICENSEES AND DESIGNATED PLACES

Returns (Table 19)

Returns were received in respect of 3,570 project licences in 2005. Just over 2,700 licensees reported starting procedures in 2005, similar to the number in 2004. Of these, about 1,950 (76%, similar to the proportion in 2004), reported starting more than 50 procedures. The holders of about 870 project licences (24% of all licensees) reported starting no procedures in 2005 (Table 19). This was also very similar to the position in 2004.

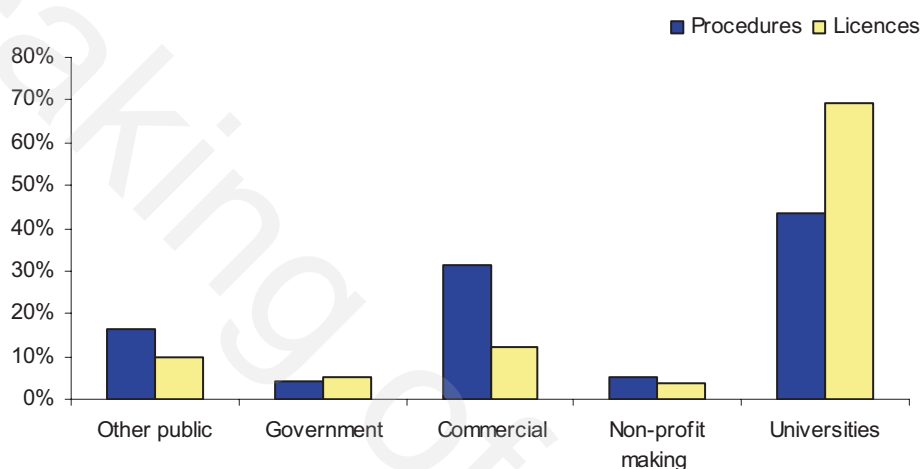


Figure 11: Project licence holders and procedures started in 2005, by type of designated place (Table 19) (note: only those project licence holders reporting procedures in 2005 are included)

Project licensees and designated places (Table 19, Table 23, Figures 11)

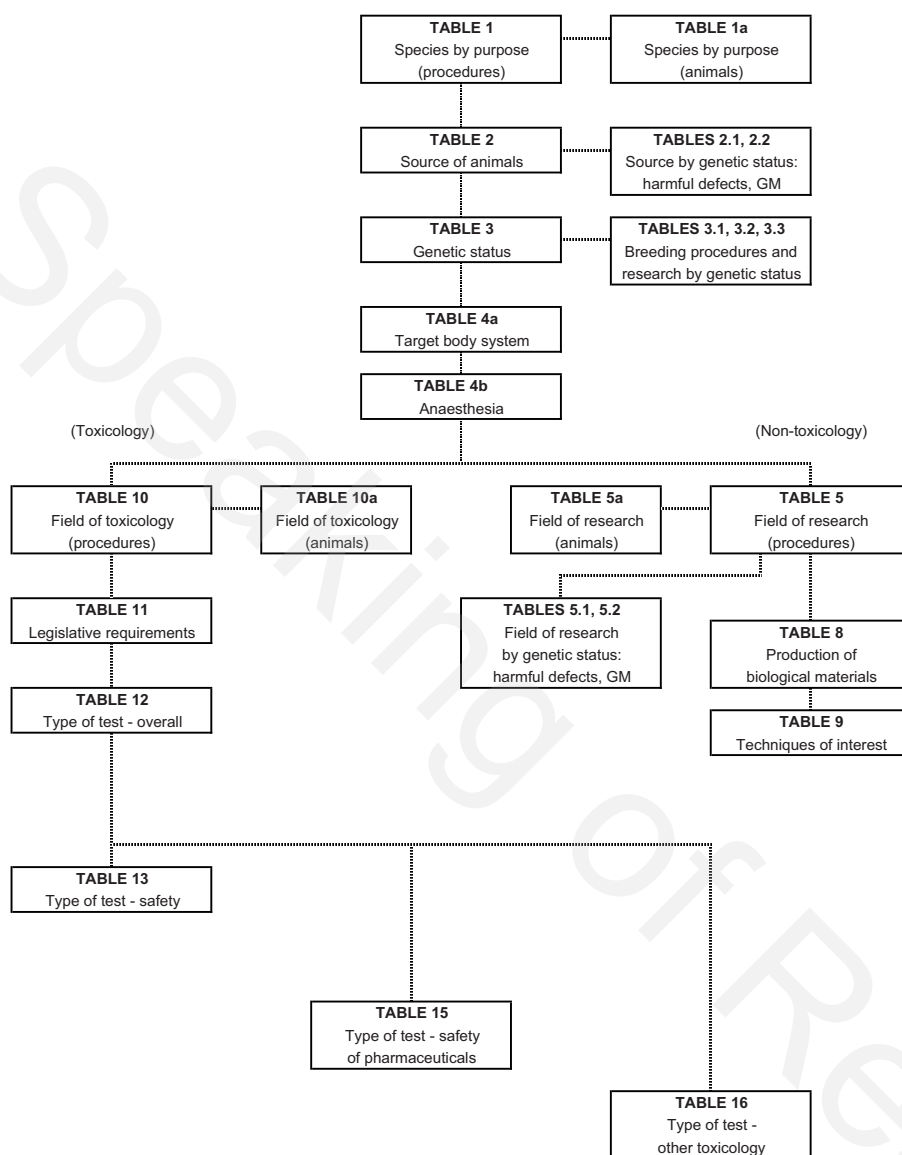
Throughout the period 1981 to 1992 university licensees performed between one-fifth and one-quarter of all experiments or procedures, but since 1992 this has slowly risen to over 43 per cent. The proportion of procedures carried out by commercial licensees has fallen from 60 per cent in 1987 to 31 per cent in 2005 (Table 23; see also Figure 11). The number of procedures reported by universities or other higher educational establishments overtook that reported by commercial organisations for the first time in 2000, and is now clearly ahead (see Table 23).

The fall in the number of procedures carried out by commercial licensees was largely responsible for the overall fall in the total number of procedures until a few years ago, but the rise in the number of procedures conducted in universities and non-governmental public bodies clearly contributed to the overall rise in the number of procedures in 2005 (see Table 23). The number of procedures started in public health laboratories has risen from the 2004 figure, as have those in NHS hospitals (many of the latter are classified as university departments for the purposes of these statistics). There is an overall rising trend in procedures conducted in non-governmental public bodies. There was also a rise in procedures reported by the not-for-profit sector, although this sector had declined in the last few years following a peak in 2001.

Historical tables

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

Organisation Chart: Relationship between the tables in part A, 2005



Notes

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

GM = genetically modified

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

Detailed descriptions of the terms used in the tables will be found in the Introductory Notes, at page 5 onwards.

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

Great Britain 2005		Number of procedures								
Species of animal	Primary purpose of the procedure								Total	
	Fundamental biological research	Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Protection of man, animals or environment	Education	Training	Forensic enquiries	Direct diagnosis		Breeding
Mammal										
Mouse	632,960	321,992	22,343	21,761	896	-	-	8,061	953,036	1,961,049
Rat	119,910	246,004	1,464	36,953	530	897	-	10	18,759	424,527
Guinea pig	3,464	22,959	1,564	414	118	-	-	500	-	29,019
Hamster	2,142	867	639	584	-	-	-	-	-	4,232
Gerbil	2,149	2,844	-	-	-	-	-	-	64	5,057
Other rodent	3,117	-	-	40	2	-	-	-	-	3,159
Rabbit	1,710	14,183	2,040	2,875	40	-	-	1,796	174	22,818
Cat	237	-	263	-	-	-	-	-	-	500
Dog										
Beagle	57	6,787	321	134	-	-	-	107	-	7,406
Greyhound	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	95	-	169	-	-	-	-	-	-	264
Ferret	144	778	-	-	13	-	-	35	-	970
Other carnivore	502	-	411	33	-	-	-	-	-	946
Horse, donkey and cross-bred equids	293	-	227	-	8	-	51	8,423	-	9,002
Pig	1,539	494	1,502	39	-	-	-	-	-	3,574
Goat	289	19	8	3	-	-	-	11	-	330
Sheep	5,650	472	3,719	10	5	-	3	19,411	59	29,329
Cattle	2,040	-	16,167	64	-	-	-	839	-	19,110
Deer	56	-	-	-	-	-	-	-	-	56
Camelid	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	7	-	-	-	-	-	7
Primate										
Prosimian	-	-	-	-	-	-	-	-	-	-
New World monkey										
marmoset, tamarin	147	726	-	21	-	-	-	16	-	910
Squirrel, owl, spider monkey	4	20	-	-	-	-	-	-	-	24
Other New World monkey	-	-	-	-	-	-	-	-	-	-

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

Species of animal	Primary purpose of the procedure								Number of procedures	
	Fundamental biological research	Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Protection of man, animals or environment	Education	Training	Forensic enquiries	Direct diagnosis	Breeding	Total
Old World monkey										
Macaque	96	3,226	-	396	-	-	-	-	-	3,718
Baboon	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-
Other mammal	1,921	182	15	215	-	-	-	-	-	2,333
Bird										
Domestic fowl (<i>Gallus domesticus</i>)	19,361	238	76,610	195	6	-	-	1,726	1,065	99,201
Turkey	1,102	59	1,102	-	-	-	-	114	-	2,377
Quail (<i>Coturnix coturnix</i>)	140	-	-	-	-	-	-	-	-	140
Quail (spp.other than <i>Coturnix coturnix</i>)	14	-	-	871	-	-	-	-	-	885
Other bird	7,492	-	1,973	571	-	-	-	517	-	10,553
Reptile										
Any reptilian species	50	826	-	2	-	-	-	-	-	878
Amphibian										
Any amphibian species	17,823	-	-	834	-	-	-	-	2,313	20,970
Fish										
Any fish species	115,262	2,275	25,674	37,800	-	-	-	163	51,680	232,854
Cephalopod										
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-	-
Total	939,766	624,951	156,211	103,822	1,618	897	54	41,729	1,027,150	2,896,198
Increase on 2004	58,869	-46,986	-177	-10,259	-1,130	34	11	-3,618	44,510	41,254
Percentage change from 2004	7%	-7%	*	-9%	-41%	4%	26%	-8%	5%	1%
Percent of total for 2005	32%	22%	5%	4%	*	*	*	1%	35%	100%

* Less than one percent.

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

Great Britain 2005		Primary purpose of the procedure								Number of animals	
Species of animal		Primary purpose of the procedure								Breeding	Total
		Fundamental biological research	Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Protection of man, animals or environment	Education	Training	Forensic enquiries	Direct diagnosis		
Mammal											
Mouse		628,654	320,820	22,343	21,761	896	-	-	8,061	952,500	1,955,035
Rat		116,757	238,965	1,464	36,953	530	897	-	10	18,759	414,335
Guinea pig		3,428	22,922	1,564	414	118	-	-	448	-	28,894
Hamster		1,656	867	639	584	-	-	-	-	-	3,746
Gerbil		2,149	2,844	-	-	-	-	-	-	64	5,057
Other rodent		3,117	-	-	40	2	-	-	-	-	3,159
Rabbit		1,510	7,774	1,252	2,869	32	-	-	1,737	174	15,348
Cat		237	-	71	-	-	-	-	-	-	308
Dog											
Beagle		38	4,833	280	112	-	-	-	15	-	5,278
Greyhound		-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs		95	-	-	-	-	-	-	-	-	95
Ferret		144	760	-	-	13	-	-	35	-	952
Other carnivore		502	-	403	33	-	-	-	-	-	938
Horse, donkey and cross-bred equids		38	-	178	-	8	-	2	68	-	294
Pig		1,517	455	1,491	39	-	-	-	-	-	3,502
Goat		233	19	8	3	-	-	-	11	-	274
Sheep		5,464	442	3,666	10	5	-	3	404	59	10,053
Cattle		1,857	-	1,652	64	-	-	-	9	-	3,582
Deer		56	-	-	-	-	-	-	-	-	56
Camelid		-	-	-	-	-	-	-	-	-	-
Other ungulate		-	-	-	7	-	-	-	-	-	7
Primate											
Prosimian		-	-	-	-	-	-	-	-	-	-
New World monkey											
marmoset, tamarin											
Squirrel, owl, spider monkey		114	500	-	13	-	-	-	16	-	643
Other New World monkey		-	-	-	-	-	-	-	-	-	-

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

Great Britain 2005		Primary purpose of the procedure							Number of animals	
Species of animal	Fundamental biological research	Applied studies - human medicine or dentistry	Applied studies - veterinary medicine	Protection of man, animals or environment	Education	Training	Forensic enquiries	Direct diagnosis	Breeding	Total
Old World monkey										
Macaque	89	2,125	-	258	-	-	-	-	-	2,472
Baboon	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-
Ape										
Gibbon	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-
Other mammal	1,921	182	15	215	-	-	-	-	-	2,333
Bird										
Domestic fowl (<i>Gallus domesticus</i>)	19,361	238	76,610	195	6	-	-	1,716	1,065	99,191
Turkey	1,102	8	1,102	-	-	-	-	8	-	2,220
Quail (<i>Coturnix coturnix</i>)	140	-	-	-	-	-	-	-	-	140
Quail (spp.other than <i>Coturnix coturnix</i>)	14	-	-	871	-	-	-	-	-	885
Other bird	7,366	-	1,903	571	-	-	-	516	-	10,356
Reptile										
Any reptilian species	50	12	-	2	-	-	-	-	-	64
Amphibian										
Any amphibian species	10,283	-	-	824	-	-	-	-	2,211	13,318
Fish										
Any fish species	114,009	2,275	25,538	37,800	-	-	-	163	50,530	230,315
Cephalopod										
<i>Octopus vulgaris</i>	-	-	-	-	-	-	-	-	-	-
Total	921,901	606,041	140,179	103,638	1,610	897	5	13,217	1,025,362	2,812,850

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

Species of animal	Number of procedures						
	Source						Total
	Animals acquired from within own designated establishment	Animals acquired from another designated breeding or supplying establishment in the UK	Animals acquired from non-designated sources in the UK	Animals acquired from sources within the EU (outside the UK)	Animals acquired from Council of Europe countries who are signatories to ETS123	Animals acquired from other sources	Animals not listed in schedule 2
Mouse	1,435,973	511,482	115	3,776	896	8,807	-
Rat	75,364	344,878	1,952	1,204	5	1,124	-
Guinea pig	632	28,387	-	-	-	-	-
Hamster	1,037	1,668	-	1,256	271	-	-
Gerbil	318	3,606	-	1,069	-	64	-
Rabbit	8,351	14,007	6	410	2	42	-
Cat	240	150	-	110	-	-	-
Dog	2,006	4,469	142	221	-	832	-
Ferret	53	911	-	-	-	6	-
Pig (genetically modified)	-	-	-	-	-	-	-
Sheep (genetically modified)	3	-	-	-	-	-	-
Primate	617	637	-	118	34	3,246	-
Quail (<i>Coturnix coturnix</i>)	-	140	-	-	-	-	-
Animals not listed	-	-	-	-	-	-	435,561
Total	1,524,594	910,335	2,215	8,164	1,208	14,121	435,561
							2,896,198

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

Species of animal	Number of procedures						
	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 ETS ¹²³	Animals acquired from other sources	Animals not listed in schedule 2 ⁽¹⁾
Mouse	211,622	22,425	-	485	-	744	-
Rat	18,376	1,153	-	221	-	478	-
Guinea pig	-	-	-	-	-	-	-
Hamster	-	-	-	-	-	-	-
Gerbil	-	-	-	-	-	-	-
Rabbit	180	79	-	-	-	-	259
Cat	-	-	-	-	-	-	-
Dog	-	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-
Primate	-	-	-	-	-	-	-
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-	-
Animals not listed	-	-	-	-	-	-	-
Total	230,178	23,657	-	706	-	1,222	32,338
							288,101

(1) The "animals not listed in Schedule 2" here were 681 domestic fowl, 1,637 amphibia and 30,020 fish.

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

Species of animal	Number of procedures						
	Animals acquired from within own designated establishment	Animals acquired from another designated breeding or supplying establishment in the UK	Animals acquired from non-designated sources in the UK	Animals acquired from sources within the EU (outside the UK)	Animals acquired from Council of Europe countries who are signatories to ETS123	Animals acquired from other sources	Animals not listed in schedule 2 ⁽¹⁾
Total							
Mouse	885,768	16,374	-	3,086	856	5,640	-
Rat	3,800	84	-	21	5	56	-
Guinea pig	-	-	-	-	-	-	-
Hamster	-	-	-	-	-	-	-
Gerbil	-	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-
Cat	-	-	-	-	-	-	-
Dog	-	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-
Pig (genetically modified)	-	-	-	-	-	-	-
Sheep (genetically modified)	3	-	-	-	-	-	3
Primate	-	-	-	-	-	-	-
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-	-
Animals not listed	-	-	-	-	-	-	-
Total	889,571	16,458	-	3,107	861	5,696	41,758
							41,758
							957,451

(1) The "animals not listed in Schedule 2" here were 300 domestic fowl, 3,067 amphibia and 38,391 fish.

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

Great Britain 2005		Number of procedures			
Species of animal	Primary purpose of procedure	Genetic status			Total
		Normal animal	Animal with harmful genetic defect	Genetically modified animal	
Mouse	Fundamental biological research	307,296	56,496	269,168	632,960
	Applied studies	282,274	37,014	25,047	344,335
	Safety	21,580	20	161	21,761
	Other uses	8,318	4	635	8,957
	Breeding	194,581	141,742	616,713	953,036
	Total	814,049	235,276	911,724	1,961,049
Rat	Fundamental biological research	115,387	2,998	1,525	119,910
	Applied studies	244,800	2,602	66	247,468
	Safety	36,953	-	-	36,953
	Other uses	1,437	-	-	1,437
	Breeding	1,756	14,628	2,375	18,759
	Total	400,333	20,228	3,966	424,527
Guinea pig	Fundamental biological research	3,464	-	-	3,464
	Applied studies	24,523	-	-	24,523
	Safety	414	-	-	414
	Other uses	618	-	-	618
	Breeding	-	-	-	-
	Total	29,019	-	-	29,019
Hamster	Fundamental biological research	2,142	-	-	2,142
	Applied studies	1,506	-	-	1,506
	Safety	584	-	-	584
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	4,232	-	-	4,232
Gerbil	Fundamental biological research	2,149	-	-	2,149
	Applied studies	2,844	-	-	2,844
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	64	-	-	64
	Total	5,057	-	-	5,057
Other rodent	Fundamental biological research	3,117	-	-	3,117
	Applied studies	-	-	-	-
	Safety	40	-	-	40
	Other uses	2	-	-	2
	Breeding	-	-	-	-
	Total	3,159	-	-	3,159
Rabbit	Fundamental biological research	1,704	6	-	1,710
	Applied studies	16,144	79	-	16,223
	Safety	2,875	-	-	2,875
	Other uses	1,836	-	-	1,836
	Breeding	-	174	-	174
	Total	22,559	259	-	22,818
Cat	Fundamental biological research	237	-	-	237
	Applied studies	263	-	-	263
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	500	-	-	500
Dog - Beagle	Fundamental biological research	57	-	-	57
	Applied studies	7,108	-	-	7,108
	Safety	134	-	-	134
	Other uses	107	-	-	107
	Breeding	-	-	-	-
	Total	7,406	-	-	7,406
Dog - Other	Fundamental biological research	95	-	-	95
	Applied studies	169	-	-	169
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	264	-	-	264
Ferret	Fundamental biological research	144	-	-	144
	Applied studies	778	-	-	778
	Safety	-	-	-	-
	Other uses	48	-	-	48
	Breeding	-	-	-	-
	Total	970	-	-	970

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

Great Britain 2005		Number of procedures			
Species of animal	Primary purpose of procedure	Genetic status			Total
		Normal animal	Animal with harmful genetic defect	Genetically modified animal	
Other carnivore	Fundamental biological research	502	-	-	502
	Applied studies	411	-	-	411
	Safety	33	-	-	33
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	946	-	-	946
Horse, Donkey etc	Fundamental biological research	293	-	-	293
	Applied studies	227	-	-	227
	Safety	-	-	-	-
	Other uses	8,482	-	-	8,482
	Breeding	-	-	-	-
	Total	9,002	-	-	9,002
Pig	Fundamental biological research	1,539	-	-	1,539
	Applied studies	1,996	-	-	1,996
	Safety	39	-	-	39
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	3,574	-	-	3,574
Goat	Fundamental biological research	289	-	-	289
	Applied studies	27	-	-	27
	Safety	3	-	-	3
	Other uses	11	-	-	11
	Breeding	-	-	-	-
	Total	330	-	-	330
Sheep	Fundamental biological research	5,650	-	-	5,650
	Applied studies	4,191	-	-	4,191
	Safety	10	-	-	10
	Other uses	19,419	-	-	19,419
	Breeding	56	-	3	59
	Total	29,326	-	3	29,329
Cattle	Fundamental biological research	2,040	-	-	2,040
	Applied studies	16,167	-	-	16,167
	Safety	64	-	-	64
	Other uses	839	-	-	839
	Breeding	-	-	-	-
	Total	19,110	-	-	19,110
Deer	Fundamental biological research	56	-	-	56
	Applied studies	-	-	-	-
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	56	-	-	56
Other ungulate	Fundamental biological research	-	-	-	-
	Applied studies	-	-	-	-
	Safety	7	-	-	7
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	7	-	-	7
Marmoset, Tamarin	Fundamental biological research	147	-	-	147
	Applied studies	726	-	-	726
	Safety	21	-	-	21
	Other uses	16	-	-	16
	Breeding	-	-	-	-
	Total	910	-	-	910
Squirrel, Owl or Spider monkey	Fundamental biological research	4	-	-	4
	Applied studies	20	-	-	20
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	24	-	-	24

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

Great Britain 2005		Number of procedures			
Species of animal	Primary purpose of procedure	Genetic status			Total
		Normal animal	Animal with harmful genetic defect	Genetically modified animal	
Macaque	Fundamental biological research	96	-	-	96
	Applied studies	3,226	-	-	3,226
	Safety	396	-	-	396
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	3,718	-	-	3,718
Other mammal	Fundamental biological research	1,921	-	-	1,921
	Applied studies	197	-	-	197
	Safety	215	-	-	215
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	2,333	-	-	2,333
Domestic fowl	Fundamental biological research	19,361	-	-	19,361
	Applied studies	76,848	-	-	76,848
	Safety	195	-	-	195
	Other uses	1,732	-	-	1,732
	Breeding	84	681	300	1,065
	Total	98,220	681	300	99,201
Turkey	Fundamental biological research	1,102	-	-	1,102
	Applied studies	1,161	-	-	1,161
	Safety	-	-	-	-
	Other uses	114	-	-	114
	Breeding	-	-	-	-
	Total	2,377	-	-	2,377
Quail (<i>Coturnix coturnix</i>)	Fundamental biological research	140	-	-	140
	Applied studies	-	-	-	-
	Safety	-	-	-	-
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	140	-	-	140
Quail (spp. other than <i>Coturnix coturnix</i>)	Fundamental biological research	14	-	-	14
	Applied studies	-	-	-	-
	Safety	871	-	-	871
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	885	-	-	885
Other bird	Fundamental biological research	7,492	-	-	7,492
	Applied studies	1,973	-	-	1,973
	Safety	571	-	-	571
	Other uses	517	-	-	517
	Breeding	-	-	-	-
	Total	10,553	-	-	10,553
Reptile	Fundamental biological research	50	-	-	50
	Applied studies	826	-	-	826
	Safety	2	-	-	2
	Other uses	-	-	-	-
	Breeding	-	-	-	-
	Total	878	-	-	878
Amphibian	Fundamental biological research	15,149	1,000	1,674	17,823
	Applied studies	-	-	-	-
	Safety	834	-	-	834
	Other uses	-	-	-	-
	Breeding	283	637	1,393	2,313
	Total	16,266	1,637	3,067	20,970
Fish	Fundamental biological research	94,162	13,579	7,521	115,262
	Applied studies	27,949	-	-	27,949
	Safety	37,800	-	-	37,800
	Other uses	163	-	-	163
	Breeding	4,369	16,441	30,870	51,680
	Total	164,443	30,020	38,391	232,854
All species	Fundamental biological research	585,799	74,079	279,888	939,766
	Applied studies	716,354	39,695	25,113	781,162
	Safety	103,641	20	161	103,822
	Other uses	43,659	4	635	44,298
	Breeding	201,193	174,303	651,654	1,027,150
	TOTAL	1,650,646	288,101	957,451	2,896,198

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

Great Britain 2005				Number of procedures
Species of animal	Generation of founder genetically modified animals	Normal animals within genetically modified breeding colonies	Normal animals within harmful mutant breeding colonies	Totals
Mouse	98,682	90,076	5,823	194,581
Rat	554	1,202	-	1,756
Other rodent	64	-	-	64
Rabbit	-	-	-	-
Cat	-	-	-	-
Dog	-	-	-	-
Ferret	-	-	-	-
Other carnivore	-	-	-	-
Horse and other equids	-	-	-	-
Pig	-	-	-	-
Sheep	56	-	-	56
Other ungulate	-	-	-	-
New World monkey	-	-	-	-
Old World monkey	-	-	-	-
Other mammal	-	-	-	-
Bird	84	-	-	84
Reptile / Amphibian	283	-	-	283
Fish	4,369	-	-	4,369
Total	104,092	91,278	5,823	201,193

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

Great Britain 2005 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	141,742	16,133	51,549	25,194	658	235,276
Rat	14,628	630	3,091	1,857	22	20,228
Other rodent	-	-	-	-	-	-
Rabbit	174	-	79	6	-	259
Cat	-	-	-	-	-	-
Dog	-	-	-	-	-	-
Ferret	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-
Old World monkey	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-
Bird	681	-	-	-	-	681
Reptile / Amphibian	637	965	-	35	-	1,637
Fish	16,441	2,885	10,694	-	-	30,020
Total	174,303	20,613	65,413	27,092	680	288,101

(1) See Annex A of Appendix B

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

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

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

Great Britain 2005		Number of procedures					
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⁾	Total
Mouse	19,376	597,428	115,033	118,148	59,808	1,931	911,724
Rat	92	2,283	715	618	210	48	3,966
Other rodent	-	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-
Cat	-	-	-	-	-	-	-
Dog	-	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-
Pig	-	-	-	-	-	-	-
Sheep	-	3	-	-	-	-	3
Other ungulate	-	-	-	-	-	-	-
New World monkey	-	-	-	-	-	-	-
Old World monkey	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-
Bird	14	286	-	-	-	-	300
Reptile / Amphibian	514	879	682	877	115	-	3,067
Fish	903	29,876	7,310	119	183	-	38,391
Total	20,899	630,755	123,740	119,762	60,316	1,979	957,451

(1) See Annex A of Appendix B

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

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

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

Great Britain 2005		Number of procedures											
Species of animal	Body systems											Total	
	Respiratory	Cardiovascular	Nervous	Senses	Alimentary	Skin	Musculo - skeletal	Reproductive	Immune and reticulo - endothelial	Other system	Multiple systems		System not relevant
Mammal													
Mouse	46,599	52,843	217,453	21,283	27,971	32,697	27,788	140,645	416,173	38,782	380,152	558,663	1,961,049
Rat	26,905	20,217	156,847	2,727	13,975	2,276	6,664	29,756	11,847	12,607	84,046	56,660	424,527
Other rodent	11,400	1,109	6,754	387	827	551	79	123	7,508	243	4,915	7,571	41,467
Rabbit	42	1,238	67	58	118	1,385	361	3,557	3,346	860	8,258	3,528	22,818
Cat	135	-	64	34	4	3	-	-	-	-	260	-	500
Dog	372	840	6	-	110	-	-	-	89	142	3,648	2,463	7,670
Ferret	201	115	87	59	-	-	-	-	66	6	432	4	970
Other carnivore	-	251	-	-	-	-	-	-	-	-	170	525	946
Horse, donkey and cross-bred equids	17	215	12	-	101	-	-	48	65	5,974	72	2,498	9,002
Other ungulate	654	1,321	640	13	2,097	260	383	1,184	17,849	18,152	5,896	3,957	52,406
Primate													
New World monkey	-	149	67	-	-	-	-	79	25	12	200	402	934
Old World monkey	33	84	81	14	8	-	-	1	28	3	1,393	2,073	3,718
Other mammal	-	240	182	-	20	1,421	-	-	-	240	-	230	2,333
Bird	1,189	1,202	5,459	740	8,811	368	742	292	3,842	66,026	10,360	14,125	113,156
Reptile, amphibian	-	472	34	50	79	333	888	12,906	-	826	3,995	2,265	21,848
Fish	-	1,969	10,193	846	1,584	6,001	2,963	17,311	14,505	413	88,549	88,520	232,854
Total	87,547	82,265	397,946	26,211	55,705	45,295	39,868	205,902	475,343	144,286	592,346	743,484	2,896,198

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

Species of animal	No anaesthesia	Type of anaesthesia			Number of procedures	
		General anaesthesia, with recovery	Local anaesthesia	General anaesthesia at end of procedure, without recovery	General anaesthesia throughout, without recovery	Total
Mouse	1,221,964	336,844	286,967	87,302	27,972	1,961,049
Rat	229,666	116,961	2,483	40,060	35,357	424,527
Other rodent	21,183	11,091	387	4,966	3,840	41,467
Rabbit	17,052	1,142	433	2,603	1,588	22,818
Cat	178	92	-	31	199	500
Dog	5,195	832	686	419	538	7,670
Ferret	116	745	-	10	99	970
Other carnivore	62	628	-	7	249	946
Horse and other equids	383	8	8,603	-	8	9,002
Other ungulates	49,453	1,940	411	96	506	52,406
New World monkey	748	122	16	38	10	934
Old World monkey	3,232	414	5	38	29	3,718
Other mammal	1,313	-	1,020	-	-	2,333
Bird	49,876	144	-	62,280	856	113,156
Reptile / Amphibian	15,432	5,388	-	-	1,028	21,848
Fish	131,706	95,859	-	3,378	1,911	232,854
Total	1,747,559	572,210	301,011	201,228	74,190	2,896,198

Neuromuscular blocking agents (NMBA) were used in 3,775 procedures in 2005. All of these procedures involved the use of general anaesthesia.

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

Great Britain 2005		Number of procedures												
Species of animal		Field of research								Number of procedures				
		Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Mammal														
Mouse	155,139	164,412	29,936	17,189	39,599	419,353	37,986	27,534	36,042	168,648	13,568	7,095	384	
Rat	9,177	40,177	5,194	13,185	3,416	9,062	692	1,891	29,675	151,891	2,969	4,201	1,246	
Guinea pig	4	692	4	-	69	394	802	20	3,193	12,321	-	-	-	
Hamster	64	329	5	-	-	-	296	1,211	-	30	-	-	-	
Gerbil	4	-	-	140	-	85	-	186	-	4,493	-	-	-	
Other rodent	-	3	-	-	-	-	-	6	-	-	-	-	-	
Rabbit	15	729	268	21	209	2,788	202	352	154	885	-	104	4	
Cat	-	209	-	-	-	-	-	7	10	89	-	-	-	
Dog														
Beagle	-	24	-	-	-	88	-	-	1	1,496	-	-	-	
Greyhound	-	-	-	-	-	-	-	-	-	-	-	-	-	
Other including cross-bred dogs	-	-	-	-	-	-	-	-	-	-	-	-	-	
Ferret	44	64	-	2	-	41	164	-	56	539	60	-	-	
Other carnivore	-	10	-	-	-	249	-	-	-	-	-	-	-	
Horse, donkey and cross-bred equids	8	76	-	12	5	54	8,468	-	203	17	9	24	-	
Pig	3	173	-	-	154	324	321	8	27	291	15	26	90	
Goat	-	100	-	-	8	19	2	130	-	1	-	4	15	
Sheep	90	1,010	379	17	702	529	19,466	358	19	164	194	1,599	254	
Cattle	-	262	-	-	12	15,673	319	116	11	318	-	769	-	
Deer	-	-	-	-	-	-	-	-	-	-	-	-	-	
Camelid	-	-	-	-	-	-	-	-	-	-	-	-	-	
Other ungulate	-	-	-	-	-	-	-	-	-	-	-	-	-	
Primate														
Prosimian	-	-	-	-	-	-	-	-	-	-	-	-	-	
New World monkey														
marmoset, tamarin	-	79	-	48	-	2	6	-	36	361	-	-	-	
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	24	-	-	-	
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											Number of procedures	
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Old World monkey													
Macaque	4	52	-	-	-	15	38	-	5	387	-	-	-
Baboon	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-
Ape	-	-	-	-	-	-	-	-	-	-	-	-	-
Gibbon	-	-	-	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-	-	-	-
Other mammal	-	20	-	-	-	-	-	-	182	-	-	-	-
Bird													
Domestic fowl (<i>Gallus domesticus</i>)	99	58	319	6,291	1,392	5,323	7,616	64,159	-	638	-	8	-
Turkey	-	-	-	-	195	-	249	884	-	47	-	-	-
Quail (<i>Coturnix coturnix</i>)	140	-	-	-	-	-	-	-	-	-	-	-	-
Quail (spp. other than <i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-
Other bird	5	99	-	480	90	793	-	217	-	-	-	-	-
Reptile													
Any reptilian species	-	50	-	-	-	-	-	-	-	-	-	-	-
Amphibian													
Any amphibian species	13,846	1,623	1,011	-	-	-	660	60	39	-	-	-	-
Fish													
Any fish species	63,017	6,627	1,086	7,862	1,237	18,297	6,536	2,883	-	4,424	-	-	-
Cephalopod													
Octopus vulgaris	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	241,659	216,878	38,202	45,247	47,088	473,089	83,823	100,022	69,653	347,064	16,815	13,830	1,993
Increase on 2004	-12,128	32,486	-15,607	10,564	2,292	-11,214	2,136	13,291	5,913	-45,941	1,563	-4,851	-578
Percentage change from 2004	-5%	18%	-29%	30%	5%	-2%	3%	15%	9%	-12%	10%	-26%	-22%
Percent of total for 2005	10%	9%	2%	2%	2%	19%	3%	4%	3%	14%	1%	1%	*

* Less than one percent.

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

Great Britain 2005	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	Total
	Mammal														
	Mouse	-	150,393	126,500	267,827	1,257	435	18	6,242	145	172	119,628	-	1,226	1,790,728
	Rat	-	1,208	2,818	7,772	3,597	-	4	-	-	29	5,661	-	112	293,977
	Guinea pig	173	-	-	-	-	-	-	-	159	-	-	-	-	17,831
	Hamster	-	-	59	76	97	249	-	-	32	-	-	-	-	2,448
	Gerbil	-	-	-	149	-	-	-	-	-	-	-	-	-	5,057
	Other rodent	-	-	-	-	-	302	-	-	2,808	-	-	-	-	3,119
	Rabbit	40	-	-	63	-	-	13	-	50	3	207	-	-	6,107
	Cat	-	-	-	-	185	-	-	-	-	-	-	-	-	500
	Dog	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Beagle	-	-	-	54	-	-	-	-	-	-	106	-	-	1,769
	Greyhound	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Other including cross-bred dogs	-	95	-	-	169	-	-	-	-	-	-	-	-	264
	Ferret	-	-	-	-	-	-	-	-	-	-	-	-	-	970
	Other carnivore	-	-	-	-	-	140	-	2	529	8	-	-	-	938
	Horse, donkey and cross-bred equids	-	-	-	-	-	-	-	-	-	51	-	-	-	8,927
	Pig	19	-	-	-	110	-	-	-	-	536	-	-	-	2,097
	Goat	-	-	-	-	42	-	-	-	-	-	-	-	-	321
	Sheep	-	-	-	-	895	-	-	-	-	21	-	-	-	28,891
	Cattle	-	442	-	-	110	-	-	2,752	-	165	-	-	-	17,981
	Deer	-	70	-	-	-	-	-	156	-	-	-	-	-	56
	Camelid	-	56	-	-	-	-	-	-	-	-	-	-	-	-
	Other ungulate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Primate	-	-	-	-	-	-	-	-	7	-	-	-	-	7
	Prosimian	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	marmoset, tamarin	-	-	-	-	-	-	-	-	-	-	-	-	-	532
	Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	24
	Other New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Great Britain 2005		Number of procedures													
Species of animal	Field of research													Total	
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol		
Old World monkey Macaque Baboon Other Old World monkey Ape Gibbon Great ape Other mammal Bird Domestic fowl (<i>Gallus domesticus</i>) Turkey Quail (<i>Coturnix coturnix</i>) Quail (spp. other than <i>Coturnix coturnix</i>) Other bird Reptile Any reptilian species Amphibian Any amphibian species Fish Any fish species Cephalopod Octopus vulgaris Total Increase on 2004 Percentage change from 2004 Percent of total for 2005	-	-	-	-	-	-	-	-	-	-	-	-	-	501	
	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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N/A = No comparable figures for 2004

* Less than one percent.

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

Great Britain 2005		Field of research											Number of animals	
Species of animal		Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Mammal	Mouse	155,005	163,834	29,809	17,189	39,430	417,673	37,986	27,530	35,590	167,741	13,559	7,052	384
	Rat	9,177	39,951	5,194	12,338	3,416	9,062	692	1,891	29,145	143,566	2,969	3,968	1,246
	Guinea pig	4	656	4	-	69	394	750	20	3,193	12,321	-	-	-
	Hamster	64	329	5	-	-	-	296	949	-	30	-	-	-
	Gerbil	4	-	-	140	-	85	-	186	-	4,493	-	-	-
	Other rodent	-	3	-	-	-	-	-	6	-	-	-	-	-
	Rabbit	15	729	73	21	209	2,784	154	25	154	852	-	71	4
	Cat	-	209	-	-	-	-	-	4	10	85	-	-	-
	Dog	-	-	-	-	-	88	-	-	1	647	-	-	-
	Beagle	-	24	-	-	-	-	-	-	-	-	-	-	-
	Greyhound	-	-	-	-	-	-	-	-	-	-	-	-	-
	Other including cross-bred dogs	-	-	-	-	-	-	-	-	-	-	-	-	-
	Ferret	44	64	-	2	-	41	164	-	56	533	48	-	-
	Other carnivore	-	10	-	-	-	249	-	-	-	-	-	-	-
	Horse, donkey and cross-bred equids	8	29	-	12	5	33	88	-	-	-	17	1	24
	Pig	3	173	-	-	150	324	321	8	10	277	15	25	90
	Goat	-	44	-	-	8	19	2	130	-	1	-	4	15
	Sheep	86	985	379	17	702	474	467	358	19	135	194	1,599	254
	Cattle	-	244	-	-	12	453	309	38	11	316	-	769	-
	Deer	-	-	-	-	-	-	-	-	-	-	-	-	-
	Camelid	-	-	-	-	-	-	-	-	-	-	-	-	-
	Other ungulate	-	-	-	-	-	-	-	-	-	-	-	-	-
	Primate	-	-	-	-	-	-	-	-	-	-	-	-	-
	Prosimian	-	-	-	-	-	-	-	-	-	-	-	-	-
	New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-
	marmoset, tamarin	-	46	-	48	-	-	2	6	-	36	147	-	-
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Species of animal	Field of research											Number of animals	
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Old World monkey													
Macaque	2	47	-	-	-	15	38	-	3	1	-	-	-
Baboon	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-
Ape													
Gibbon	-	-	-	-	-	-	-	-	-	-	-	-	-
Great ape	-	-	-	-	-	-	-	-	-	-	-	-	-
Other mammal	-	20	-	-	-	-	-	-	182	-	-	-	-
Bird													
Domestic fowl (<i>Gallus domesticus</i>)	99	58	319	6,291	1,392	5,323	7,606	64,159	-	638	-	8	-
Turkey	-	-	-	-	195	-	104	884	-	35	-	-	-
Quail (<i>Coturnix coturnix</i>)	140	-	-	-	-	-	-	-	-	-	-	-	-
Quail (spp.other than <i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-
Other bird	5	99	-	480	90	780	-	217	-	-	-	-	-
Reptile													
Any reptilian species	-	50	-	-	-	-	-	-	-	-	-	-	-
Amphibian													
Any amphibian species	8,431	1,066	87	-	-	-	660	60	39	-	-	-	-
Fish													
Any fish species	61,049	6,627	1,086	7,862	1,237	17,949	6,536	2,883	-	4,424	-	-	-
Cephalopod													
Octopus vulgaris	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	234,136	215,297	36,956	44,400	46,915	455,748	56,179	99,348	68,449	336,259	16,786	13,520	1,993

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

Great Britain 2005	Species of animal	Field of research										Number of animals			
		Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	Total
	Mammal														
	Mouse	-	150,065	125,973	266,783	1,257	435	18	6,242	145	172	119,628	-	1,226	1,784,726
	Rat	173	1,208	2,818	7,772	3,597	-	4	-	-	29	5,661	-	112	283,989
	Guinea pig	-	-	-	-	-	-	-	-	159	-	-	-	-	17,570
	Hamster	-	-	59	76	97	25	-	-	32	-	-	-	-	1,962
	Gerbil	-	-	-	149	-	-	-	-	-	-	-	-	-	5,057
	Other rodent	-	-	-	-	-	302	-	-	2,808	-	-	-	-	3,119
	Rabbit	40	-	-	63	-	-	13	-	50	3	199	-	-	5,459
	Cat	-	-	-	-	-	-	-	-	-	-	-	-	-	308
	Dog	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Beagle	-	-	-	10	-	-	-	-	-	-	14	-	-	784
	Greyhound	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Other including cross-bred dogs	-	95	-	-	-	-	-	-	-	-	-	-	-	95
	Ferret	-	-	-	-	-	-	-	-	-	-	-	-	-	952
	Other carnivore	-	-	-	-	-	-	-	2	529	8	-	-	-	938
	Horse, donkey and cross-bred equids	-	-	-	-	-	140	-	-	-	2	-	-	-	219
	Pig	19	-	-	-	-	-	-	-	-	536	-	-	-	2,061
	Goat	-	-	-	-	110	-	-	-	-	-	-	-	-	265
	Sheep	-	442	-	-	42	-	-	-	-	-	-	-	-	9,615
	Cattle	-	70	-	-	816	-	-	2,670	-	18	-	-	-	2,514
	Deer	-	56	-	-	37	-	-	131	-	124	-	-	-	56
	Camelid	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Other ungulate	-	-	-	-	-	-	-	-	7	-	-	-	-	7
	Primate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Prosimian	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	marmoset, tamarin	-	-	-	-	-	-	-	-	-	-	-	-	-	285
	Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Other New World monkey	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Great Britain 2005 Species of animal	Field of research										Number of animals			
	Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other	Tobacco	Alcohol	Total
Old World monkey Macaque Baboon Other Old World monkey Ape Gibbon Great ape Other mammal Bird Domestic fowl (<i>Gallus domesticus</i>) Turkey Quail (<i>Coturnix coturnix</i>) Quail (spp.other than <i>Coturnix coturnix</i>) Other bird Reptile Any reptilian species Amphibian Any amphibian species Fish Any fish species Cephalopod Octopus vulgaris	-	-	-	-	-	-	-	-	-	-	-	-	-	106
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	232	169,653	130,180	275,956	15,533	8,106	35	10,526	54,012	12,512	125,502	-	1,338	2,429,571

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

Great Britain 2005 Species of animal	Field of research											Number of procedures	
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Mammal													
Mouse	7,478	20,640	1,259	384	3,639	27,154	741	395	140	7,475	460	78	-
Rat	237	1,472	1,716	327	43	856	-	8	15	4,290	-	1,409	-
Other rodent	-	-	-	-	-	-	-	-	-	-	-	-	-
Rabbit	-	-	6	-	-	-	-	-	-	79	-	-	-
Cat	-	-	-	-	-	-	-	-	-	-	-	-	-
Dog	-	-	-	-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	-	-	-	-	-	-	-	-
Other mammal	-	-	-	-	-	-	-	-	-	-	-	-	-
Bird	-	-	-	-	-	-	-	-	-	-	-	-	-
Domestic fowl (<i>Gallus domesticus</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-
Amphibian	1,000	-	-	-	-	-	-	-	-	-	-	-	-
Any amphibian species	-	-	-	-	-	-	-	-	-	-	-	-	-
Fish	23,588	-	-	-	-	222	-	-	-	-	-	-	-
Any fish species	-	-	-	-	-	-	-	-	-	226	-	-	-
Total	32,303	22,112	2,981	711	3,682	28,232	741	403	155	12,070	460	1,487	-

Table 5.1 (Continued)

Great Britain 2005 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	Total
Mammal															
Mouse	-	32,975	3,155	87,546	229	-	-	-	-	34	40,836	-	-	234,618	
Rat	-	1,150	-	3,548	208	-	-	-	-	-	4,927	-	-	20,206	
Other rodent	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Rabbit	-	-	-	-	-	-	-	-	-	-	174	-	-	259	
Cat	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Dog															
Other including cross-bred dogs	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Other mammal	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Bird															
Domestic fowl (<i>Gallus domesticus</i>)	-	681	-	-	-	-	-	-	-	-	-	-	-	681	
Amphibian															
Any amphibian species	-	637	-	-	-	-	-	-	-	-	-	-	-	1,637	
Fish															
Any fish species	-	5,984	-	-	-	-	-	-	-	-	-	-	-	30,020	
Total	-	41,427	3,155	91,094	437	-	-	-	-	34	45,937	-	-	287,421	

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

Great Britain 2005		Number of procedures											
Species of animal	Field of research												
	Anatomy	Physiology	Biochemistry	Psychology	Pathology	Immunology	Microbiology	Parasitology	Pharmacology	Pharmaceutical R&D	Therapeutics	Clinical medicine	Clinical surgery
Mammal													
Mouse	92,790	100,083	21,646	9,177	23,194	249,251	10,626	663	17,351	48,570	1,523	3,063	148
Rat	658	1,419	-	16	205	92	-	5	24	-	152	8	-
Other rodent	-	-	-	-	-	-	-	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-	-	-	-	-	-	-
Pig	-	-	-	-	-	-	-	-	-	-	-	-	-
Sheep	3	-	-	-	-	-	-	-	-	-	-	-	-
Bird													
Domestic fowl (<i>Gallus domesticus</i>)	-	-	-	-	-	-	-	-	-	-	-	-	-
Amphibian													
Any amphibian species	2,790	-	-	-	-	-	-	-	-	-	-	-	-
Fish													
Any fish species	32,815	25	-	-	112	309	-	-	-	639	-	-	-
Total	129,056	101,527	21,646	9,193	23,511	249,652	10,626	668	17,375	49,209	1,675	3,061	148

Table 5.2 (Continued)

Great Britain 2005		Number of procedures												
Species of animal		Field of research											Total	
		Dentistry	Genetics	Molecular biology	Cancer research	Nutrition	Zoology	Botany	Animal science	Ecology	Animal welfare	Other		Tobacco
Mammal														
Mouse	-	54,620	87,444	112,420	489	64	-	5,669	-	-	70,984	-	28	909,793
Rat	-	-	1,223	-	-	-	-	-	-	-	116	-	-	3,918
Other rodent	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pig	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Sheep	-	-	-	-	-	-	-	-	-	-	-	-	-	3
Bird														
Domestic fowl (<i>Gallus domesticus</i>)	-	300	-	-	-	-	-	-	-	-	-	-	-	300
Amphibian														
Any amphibian species	-	264	13	-	-	-	-	-	-	-	-	-	-	3,067
Fish														
Any fish species	-	2,666	-	358	-	-	-	1,467	-	-	-	-	-	38,391
Total	-	57,850	88,680	112,778	489	64	-	7,136	-	-	71,100	-	28	955,472

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

Great Britain 2005		Number of procedures						
Species of animal	Infectious agents	Vectors	Neoplasms	Production			Other ⁽¹⁾	Total
				Monoclonal antibodies (ascites model)	Monoclonal antibodies (initial immunisation)	Polyclonal antibodies		
Mouse	29,538	5,626	10,304	-	2,736	16,616	1,640,356	1,790,728
Rat	2,655	6	446	-	266	282	272,197	294,150
Other rodent	1,231	634	19	-	32	513	25,282	28,282
Rabbit	17	349	-	-	28	3,277	2,151	6,107
Cat	4	3	-	-	-	-	493	500
Dog	-	-	-	-	-	1	1,484	2,033
Ferret	-	-	-	-	-	41	337	970
Other carnivore	-	-	-	-	-	-	938	938
Horse and other equids	-	-	-	-	-	-	2,858	8,927
Other ungulate	416	2	-	-	60	473	14,358	49,353
New World monkey	-	-	-	-	-	-	475	556
Old World monkey	-	-	-	-	-	-	500	501
Other mammal	-	-	-	-	-	-	2,318	2,318
Bird	64,196	-	-	-	-	60	35,891	103,236
Reptile / Amphibian	-	-	-	-	-	-	13,178	21,022
Fish	1,343	-	92	-	-	1,500	190,194	193,463
Total	99,400	6,620	10,861	-	3,122	22,763	2,203,010	2,503,084

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

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

Species of animal	Techniques of particular interest										Number of procedures	
	Interference with organs of special sense	Injection into brain	Interference with brain	Psychological stress	Aversive training	Radiation	Inhalation	Thermal injury	Physical trauma	All other techniques	Total	
Mouse	10,945	13,270	4,639	2,157	2,781	8,286	23,206	125	4,037	1,721,282	1,790,728	
Rat	11,147	136	15,359	1,769	2,463	913	14,076	-	14,786	233,501	294,150	
Other rodent	476	60	96	59	-	-	6,330	-	56	21,205	28,282	
Rabbit	-	-	33	-	-	-	30	-	49	5,995	6,107	
Cat	44	-	36	-	-	-	-	-	-	420	500	
Dog	-	-	-	-	-	-	32	-	-	2,001	2,033	
Ferret	70	-	-	-	-	-	41	-	-	859	970	
Other carnivore	-	-	-	-	-	-	-	-	8	930	938	
Horse and other equids	-	-	-	-	-	-	6	-	-	8,921	8,927	
Other ungulate	3	82	206	-	-	-	-	53	53	48,956	49,353	
New World monkey	-	-	81	-	-	-	-	-	-	475	556	
Old World monkey	8	-	27	1	-	-	-	-	-	465	501	
Other mammal	-	-	-	-	-	-	-	-	-	2,318	2,318	
Bird	95	430	21	500	5,171	-	-	-	-	97,019	103,236	
Reptile / Amphibian	50	-	-	-	-	-	-	-	30	20,942	21,022	
Fish	100	-	44	1,251	-	-	-	-	1	192,067	193,463	
Total	22,938	13,978	20,542	5,737	10,415	9,199	43,721	178	19,020	2,357,356	2,503,084	

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

Species of animal	Toxicology or other safety/efficacy evaluation							Number of procedures	
	Toxicology or other safety/efficacy evaluation								
	Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	Finished cosmetics	Cosmetics ingredients	
Mammal	3	3,345	6,955	21	-	5,732	-	-	-
Mouse	324	18,134	10,621	-	758	10	-	-	-
Rat	-	120	128	-	-	-	-	-	-
Guinea pig	-	551	16	-	-	-	-	-	-
Hamster	-	-	-	-	-	-	-	-	-
Gerbil	-	40	-	-	-	-	-	-	-
Other rodent	-	1,122	1,746	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-	-	-
Cat	-	103	-	-	-	-	-	-	-
Dog	-	-	-	-	-	-	-	-	-
Beagle	-	-	-	-	-	-	-	-	-
Greyhound	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs	-	-	-	-	-	-	-	-	-
Ferret	-	-	-	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids	-	-	-	-	-	-	-	-	-
Pig	-	90	-	-	-	-	-	-	-
Goat	-	3	-	-	-	-	-	-	-
Sheep	-	10	-	-	-	-	-	-	-
Cattle	-	48	-	-	-	-	-	-	-
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)

Great Britain 2005 Species of animal		Toxicology or other safety/efficacy evaluation						Number of procedures	
		General safety/efficacy evaluation						Finished cosmetics	Cosmetics ingredients
		Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs		
Old World monkey Macaque Baboon Other Old World monkey Ape Gibbon Great Ape Other mammal Bird Domestic fowl (<i>Gallus domesticus</i>) Turkey Quail (<i>Coturnix coturnix</i>) Quail (spp,other than <i>Coturnix coturnix</i>) Other bird Reptile Any reptilian species Amphibian Any amphibian species Fish Any fish species Cephalopod Octopus vulgaris Total Increase on 2004 Percentage change from 2004 Percent of total for 2005	-	-	-	-	-	-	-	-	-
	-	-	-	-	-	-	-	-	-
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N/A = No comparable figures for 2004

* Less than one percent.

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	
		Pharmaceutical safety/efficacy evaluation				Other purposes				Total	
		Safety testing	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development		
Mammal	Mouse	49,877	14,341	66,107	9,877	9,858	-	534	2,192	1,479	170,321
	Rat	70,895	73	2,414	17,814	2,145	-	53	3,589	3,547	130,377
	Guinea pig	2,403	2,116	6,263	55	217	-	-	59	-	11,361
	Hamster	721	480	-	-	-	-	-	16	-	1,784
	Gerbil	-	-	-	-	-	-	-	-	-	-
	Other rodent	-	-	-	-	-	-	-	-	-	40
	Rabbit	9,028	1,020	3,129	115	121	-	335	80	15	16,711
	Cat	-	-	-	-	-	-	-	-	-	-
	Dog	-	-	-	-	-	-	-	-	-	-
	Beagle	4,329	-	5	996	53	-	-	121	27	5,637
	Greyhound	-	-	-	-	-	-	-	-	-	-
	Other including cross-bred dogs	-	-	-	-	-	-	-	-	-	-
	Ferret	-	-	-	-	-	-	-	-	-	-
	Other carnivore	8	-	-	-	-	-	-	-	-	8
	Horse, donkey and cross-bred equids	25	50	-	-	-	-	-	-	-	75
	Pig	416	752	4	165	36	-	2	12	-	1,477
	Goat	-	-	-	6	-	-	-	-	-	9
	Sheep	213	169	12	34	-	-	-	-	-	438
	Cattle	346	584	53	98	-	-	-	-	-	1,129
	Deer	-	-	-	-	-	-	-	-	-	-
	Camelid	-	-	-	-	-	-	-	-	-	-
	Other ungulate	-	-	-	-	-	-	-	-	-	-
	Primate	-	-	-	-	-	-	-	-	-	-
Prosimian	-	-	-	-	-	-	-	-	-	-	
New World monkey	-	-	-	-	-	-	-	-	-	-	
marmoset, tamarin	297	14	-	18	-	-	-	-	49	378	
Squirrel, owl, spider monkey	-	-	-	-	-	-	-	-	-	-	
Other New World monkey	-	-	-	-	-	-	-	-	-	-	

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

Great Britain 2005		Toxicology or other safety/efficacy evaluation										Number of procedures	
Species of animal		Pharmaceutical safety/efficacy evaluation					Other purposes					Total	
		Safety testing	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other			
Old World monkey Macaque Baboon Other Old World monkey Ape Gibbon Great Ape Other mammal Bird Domestic fowl (<i>Gallus domesticus</i>) Turkey Quail (<i>Coturnix coturnix</i>) Quail (spp,other than <i>Coturnix coturnix</i>) Other bird Reptile Any reptilian species Amphibian Any amphibian species Fish Any fish species Cephalopod Octopus vulgaris Total	2,382	-	-	388	-	-	-	-	412	35	3,217		
	-	-	-	-	-	-	-	-	-	-	-		
	-	-	-	-	-	-	-	-	-	-	-		
	-	-	-	-	-	-	-	-	-	-	-		
	-	-	-	-	-	-	-	-	-	-	-		
	15	-	-	-	-	-	-	-	-	-	15		
	1,240	4,238	68	126	8	-	-	1	-	-	7,026		
	-	-	-	-	-	-	-	-	-	-	-		
	-	-	-	-	-	-	-	-	-	-	-		
	-	-	-	-	-	-	-	-	-	-	871		
	-	1,440	-	48	-	-	-	-	-	-	2,023		
	-	-	-	-	-	-	-	-	-	-	-		
	-	-	-	-	826	-	-	-	-	-	826		
	-	-	-	-	-	-	-	-	-	-	-		
	-	-	-	-	-	-	-	-	-	-	-		
	3,326	6,592	-	-	2,141	-	-	50	92	-	39,391		
	-	-	-	-	-	-	-	-	-	-	-		
	145,521	31,869	78,055	29,740	15,405	-	924	6,532	5,244	-	393,114		
	464	- 1,980	- 14,209	- 3,193	- 3,804	N/A	- 457	- 1,658	- 5,276	-	42,407		
	*	-6%	-15%	-10%	-20%	N/A	-33%	-20%	-50%	-	-10%		
37%	8%	20%	8%	4%	*	*	2%	1%	-	100%			

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

Great Britain 2005		Number of animals							
Species of animal		Toxicology or other safety/efficacy evaluation							
		General safety/efficacy evaluation							
		Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	Finished cosmetics	Cosmetics ingredients
Mammal		3	3,345	6,955	21	-	5,732	-	-
Mouse		324	18,134	10,531	90	758	10	-	-
Rat		-	120	128	-	-	-	-	-
Guinea pig		-	551	16	-	-	-	-	-
Hamster		-	-	-	-	-	-	-	-
Gerbil		-	-	-	-	-	-	-	-
Other rodent		-	40	-	-	-	-	-	-
Rabbit		-	1,120	1,742	-	-	-	-	-
Cat		-	-	-	-	-	-	-	-
Dog		-	-	-	-	-	-	-	-
Beagle		-	91	3	-	-	-	-	-
Greyhound		-	-	-	-	-	-	-	-
Other including cross-bred dogs		-	-	-	-	-	-	-	-
Ferret		-	-	-	-	-	-	-	-
Other carnivore		-	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids		-	-	-	-	-	-	-	-
Pig		-	90	-	-	-	-	-	-
Goat		-	3	-	-	-	-	-	-
Sheep		-	10	-	-	-	-	-	-
Cattle		-	48	-	-	-	-	-	-
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)

Great Britain 2005		Toxicology or other safety/efficacy evaluation							Number of animals
Species of animal		General safety/efficacy evaluation							
		Pollution	Agriculture	Industry	Household	Food additives	Other foodstuffs	Finished cosmetics	Cosmetics ingredients
Old World monkey Macaque Baboon Other Old World monkey Ape Gibbon Great Ape Other mammal Bird Domestic fowl (<i>Gallus domesticus</i>) Turkey Quail (<i>Coturnix coturnix</i>) Quail (spp,other than <i>Coturnix coturnix</i>) Other bird Reptile Any reptilian species Amphibian Any amphibian species Fish Any fish species Cephalopod Octopus vulgaris Total		-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-
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		-	-	-	-	-	-	-	-
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Table 10a Animals (toxicology) by species of animal and toxicological purpose (Continued)

Great Britain 2005		Number of animals									
Species of animal		Toxicology or other safety/efficacy evaluation								Total	
		Pharmaceutical safety/efficacy evaluation				Other purposes					
		Safety testing	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other	
Mammal											
Mouse		49,877	14,341	66,107	9,877	9,858	-	534	2,180	1,479	170,309
Rat		70,885	73	2,414	17,806	2,145	-	53	3,578	3,545	130,346
Guinea pig		2,366	2,116	6,263	55	217	-	-	59	-	11,324
Hamster		721	480	-	-	-	-	-	16	-	1,784
Gerbil		-	-	-	-	-	-	-	-	-	-
Other rodent		-	-	-	-	-	-	-	-	-	40
Rabbit		5,234	1,020	298	115	121	-	144	80	15	9,889
Cat		-	-	-	-	-	-	-	-	-	-
Dog											
Beagle		4,012	-	4	242	34	-	-	86	22	4,494
Greyhound		-	-	-	-	-	-	-	-	-	-
Other including cross-bred dogs		-	-	-	-	-	-	-	-	-	-
Ferret		-	-	-	-	-	-	-	-	-	-
Other carnivore		-	-	-	-	-	-	-	-	-	-
Horse, donkey and cross-bred equids		25	50	-	-	-	-	-	-	-	75
Pig		407	752	-	148	36	-	2	6	-	1,441
Goat		-	-	-	6	-	-	-	-	-	9
Sheep		213	169	12	34	-	-	-	-	-	438
Cattle		297	572	53	98	-	-	-	-	-	1,068
Deer		-	-	-	-	-	-	-	-	-	-
Camelid		-	-	-	-	-	-	-	-	-	-
Other ungulate		-	-	-	-	-	-	-	-	-	-
Primate											
Prosimian		-	-	-	-	-	-	-	-	-	-
New World monkey		-	-	-	-	-	-	-	-	-	-
marmoset, tamarin		297	8	-	16	-	-	-	-	37	358
Squirrel, owl, spider monkey		-	-	-	-	-	-	-	-	-	-
Other New World monkey		-	-	-	-	-	-	-	-	-	-

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

Great Britain 2005		Number of animals									
Species of animal	Toxicology or other safety/efficacy evaluation										
	Pharmaceutical safety/efficacy evaluation					Other purposes					
	Safety testing	Efficacy testing	Quality control	ADME and residue	Toxicology research	Tobacco safety	Medical device safety	Method development	Other	Total	
Old World monkey											
Macaque	1,961	-	-	109	-	-	-	267	29	2,366	
Baboon	-	-	-	-	-	-	-	-	-	-	
Other Old World monkey	-	-	-	-	-	-	-	-	-	-	
Ape											
Gibbon	-	-	-	-	-	-	-	-	-	-	
Great Ape	-	-	-	-	-	-	-	-	-	-	
Other mammal	15	-	-	-	-	-	-	-	-	15	
Bird											
Domestic fowl (<i>Gallus domesticus</i>)	1,240	4,238	68	126	8	-	-	1	-	7,026	
Turkey	-	-	-	-	-	-	-	-	-	-	
Quail (<i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-	-	
Quail (spp.other than <i>Coturnix coturnix</i>)	-	-	-	-	-	-	-	-	-	871	
Other bird	-	1,440	-	48	-	-	-	-	-	2,023	
Reptile											
Any reptilian species	-	-	-	-	12	-	-	-	-	12	
Amphibian											
Any amphibian species	-	-	-	-	-	-	-	-	-	-	
Fish											
Any fish species	3,326	6,592	-	-	2,141	-	-	50	92	39,391	
Cephalopod	-	-	-	-	-	-	-	-	-	-	
Octopus vulgaris	-	-	-	-	-	-	-	-	-	-	
Total	140,876	31,851	75,219	28,680	14,572	-	733	6,323	5,219	383,279	

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

Species	Legislative requirements	Toxicological purpose			Number of procedures	
		Safety testing other than cosmetics	Pharmaceutical safety	Other safety / Toxicology	Total	
Mouse	UK requirements only	60	2,155	348	2,563	
	One EU country only (not UK)	17	-	-	17	
	EU requirements, incl. European Pharmacopoeia	6,364	8,231	135	14,730	
	Requirements of (non-EU) Council of Europe	-	-	-	-	
	Requirements of other countries	1,570	282	205	2,057	
	Any combination of above	7,608	116,835	1,625	126,068	
Rat	Non-legislative purposes	437	12,699	11,750	24,886	
	Total	16,056	140,202	14,063	170,321	
	UK requirements only	360	652	-	1,012	
	One EU country only (not UK)	-	-	-	-	
	EU requirements, incl. European Pharmacopoeia	3,746	2,004	32	5,782	
	Requirements of (non-EU) Council of Europe	-	-	-	-	
Other rodent	Requirements of other countries	3,401	15	468	3,884	
	Any combination of above	20,290	75,569	4,661	100,520	
	Non-legislative purposes	2,050	12,956	4,173	19,179	
	Total	29,847	91,196	9,334	130,377	
	UK requirements only	-	5,715	-	5,715	
	One EU country only (not UK)	-	-	-	-	
Rabbit	EU requirements, incl. European Pharmacopoeia	34	1,965	45	2,044	
	Requirements of (non-EU) Council of Europe	-	-	-	-	
	Requirements of other countries	108	270	-	378	
	Any combination of above	307	3,940	16	4,263	
	Non-legislative purposes	406	148	231	785	
	Total	855	12,038	292	13,185	
Rabbit	UK requirements only	3	1,082	121	1,206	
	One EU country only (not UK)	6	-	-	6	
	EU requirements, incl. European Pharmacopoeia	288	5,755	23	6,066	
	Requirements of (non-EU) Council of Europe	-	-	-	-	
	Requirements of other countries	507	29	32	568	
	Any combination of above	2,064	6,417	263	8,744	
Rabbit	Non-legislative purposes	-	9	112	121	
	Total	2,868	13,292	551	16,711	

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	Total
			Pharmaceutical safety	Other safety / Toxicology
Dog	UK requirements only	-	-	-
	One EU country only (not UK)	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	40	40
	Requirements of (non-EU) Council of Europe	-	-	-
	Requirements of other countries	-	-	-
	Any combination of above	96	4,658	88
Other carnivore	Non-legislative purposes	10	632	113
	Total	106	5,330	201
	UK requirements only	-	8	8
	One EU country only (not UK)	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	-	-
	Requirements of (non-EU) Council of Europe	-	-	-
Horse and other equids	Requirements of other countries	-	-	-
	Any combination of above	-	-	-
	Non-legislative purposes	-	-	-
	Total	-	8	8
	UK requirements only	-	-	-
	One EU country only (not UK)	-	-	-
Other ungulate	EU requirements, incl. European Pharmacopoeia	-	-	-
	Requirements of (non-EU) Council of Europe	-	-	-
	Requirements of other countries	-	-	-
	Any combination of above	-	75	75
	Non-legislative purposes	-	-	-
	Total	-	75	75
Other ungulate	UK requirements only	-	93	93
	One EU country only (not UK)	-	-	-
	EU requirements, incl. European Pharmacopoeia	53	1,590	1,643
	Requirements of (non-EU) Council of Europe	-	-	-
	Requirements of other countries	-	-	-
	Any combination of above	98	1,017	1,115
Total	Non-legislative purposes	-	152	202
	Total	151	2,852	3,053

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

Species	Legislative requirements	Toxicological purpose			Number of procedures	
		Safety testing other than cosmetics	Pharmaceutical safety	Other safety / Toxicology	Total	
New World monkey	UK requirements only	-	-	-	-	-
	One EU country only (not UK)	-	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	-	-	-	-
	Requirements of (non-EU) Council of Europe	-	-	-	-	-
	Requirements of other countries	-	-	-	-	-
	Any combination of above	-	315	-	315	315
Old World monkey	Non-legislative purposes	-	14	49	63	63
	Total	-	329	49	378	378
Other mammal	UK requirements only	-	-	-	-	-
	One EU country only (not UK)	-	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	-	-	-	-
	Requirements of (non-EU) Council of Europe	-	-	-	-	-
	Requirements of other countries	-	-	-	-	-
	Any combination of above	-	2,711	442	3,153	3,153
Bird	Non-legislative purposes	-	59	-	64	64
	Total	-	2,770	447	3,217	3,217
Reptile / Amphibian	UK requirements only	-	-	-	-	-
	One EU country only (not UK)	-	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	-	15	-	15	15
	Requirements of (non-EU) Council of Europe	-	-	-	-	-
	Requirements of other countries	-	-	-	-	-
	Any combination of above	-	-	-	-	-
Great Britain 2005	Non-legislative purposes	-	-	-	-	-
	Total	-	15	-	15	15
Total	UK requirements only	50	-	-	50	50
	One EU country only (not UK)	-	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	110	928	-	1,038	1,038
	Requirements of (non-EU) Council of Europe	-	-	-	-	-
	Requirements of other countries	522	56	-	578	578
	Any combination of above	1,906	5,671	-	7,577	7,577
Total	Non-legislative purposes	163	505	9	677	677
	Total	2,751	7,160	9	9,920	9,920
Total	UK requirements only	-	-	826	826	826
	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	-	-	-	-	-
Total	Non-legislative purposes	-	-	-	-	-
	Total	-	-	826	826	826

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

Great Britain 2005		Number of procedures			
Species	Legislative requirements	Toxicological purpose			Total
		Safety testing other than cosmetics	Pharmaceutical safety	Other safety / Toxicology	
Fish	UK requirements only	3,581	-	-	3,581
	One EU country only (not UK)	-	-	-	-
	EU requirements, incl. European Pharmacopoeia	3,997	5,772	-	9,769
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	1,144	-	-	1,144
	Any combination of above	15,025	4,006	50	19,081
	Non-legislative purposes	3,443	140	2,233	5,816
All species	Total	27,190	9,918	2,283	39,391
	UK requirements only	4,054	9,705	1,295	15,054
	One EU country only (not UK)	23	-	-	23
	EU requirements, incl. European Pharmacopoeia	14,592	26,300	235	41,127
	Requirements of (non-EU) Council of Europe	-	-	-	-
	Requirements of other countries	7,252	652	705	8,609
	Any combination of above	47,394	221,214	7,145	275,753
TOTAL	Non-legislative purposes	6,509	27,314	18,725	52,548
		79,824	285,185	28,105	393,114

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

Species of animal	Type of toxicological test or procedure							Number of procedures		
	Acute lethal toxicity	Acute lethal concentration	Acute limit setting	Acute non - lethal clinical sign	Subacute limit-setting or dose ranging	Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Teratogenicity
Mouse	64,458	985	1,175	3,824	3,965	5,564	4,424	7,700	3,247	769
Rat	118	3,518	2,309	8,276	8,106	14,407	11,778	8,654	5,568	4,556
Other rodent	435	-	795	176	392	90	-	-	-	-
Rabbit	-	-	12	127	491	-	244	-	-	3,141
Cat	-	-	-	-	-	-	-	-	-	-
Dog	-	-	-	223	464	1,672	1,541	-	-	-
Ferret	-	-	-	-	-	-	-	-	-	-
Other carnivore	-	-	-	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	28	4	87	-	-	-	-
New World monkey	-	-	35	5	55	52	155	-	-	-
Old World monkey	-	-	-	8	375	975	886	-	-	-
Other mammal	-	-	-	-	-	-	-	-	-	-
Bird	380	540	140	-	-	400	-	-	-	-
Reptile / Amphibian	-	-	-	-	-	-	-	-	-	-
Fish	-	9,192	7,157	-	3,838	6,736	752	-	226	-
Total	65,391	14,235	11,623	12,667	17,690	29,983	19,780	16,354	9,041	8,466

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

Species of animal	Type of toxicological test or procedure										Number of procedures	
	Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	Toxicokinetics	Pyrogenicity	Biocompatibility	Enzyme induction for <i>in vitro</i> tests	Immunotoxicology	Other toxicology	Total	
Mouse	-	-	6	2,496	14,125	-	532	-	5,972	51,079	170,321	
Rat	25,216	-	-	-	15,546	-	53	208	126	21,938	130,377	
Other rodent	-	-	12	278	367	-	-	16	-	10,624	13,185	
Rabbit	123	845	1,307	-	158	8,769	115	-	9	1,370	16,711	
Cat	-	-	-	-	-	-	-	-	-	-	-	
Dog	-	-	-	-	702	-	-	-	-	1,035	5,637	
Ferret	-	-	-	-	-	-	-	-	-	-	-	
Other carnivore	-	-	-	-	-	-	-	-	-	8	8	
Horse and other Equids	-	-	-	-	-	-	-	-	-	75	75	
Other ungulate	-	-	-	-	243	-	2	-	248	2,441	3,053	
New World Monkey	-	-	-	-	30	-	-	-	-	46	378	
Old World Monkey	-	-	-	-	316	-	-	-	-	657	3,217	
Other mammal	-	-	-	-	-	-	-	-	-	15	15	
Bird	-	-	-	-	110	-	-	-	-	8,350	9,920	
Reptile / Amphibian	-	-	-	-	-	-	-	-	-	826	826	
Fish	710	-	-	-	156	-	-	27	-	10,597	39,391	
Total	26,049	845	1,325	2,774	31,753	8,769	702	251	6,355	109,061	393,114	

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	Acute lethal concentration	Acute limit setting	Acute non - lethal clinical sign	Subacute limit-setting or dose ranging	Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Teratogenicity	
Mouse	5,732	-	17	289	258	48	-	460	1,766	-	-
Rat	20	706	2,228	5,004	2,263	2,222	2,410	977	811	374	-
Other rodent	-	-	-	86	280	-	-	-	-	-	-
Rabbit	-	-	-	-	-	-	-	-	-	832	-
Dog	-	-	-	2	30	24	33	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	-	-	-	-	-
Bird	380	540	140	-	-	-	-	-	-	-	-
Reptile / Amphibian	-	-	-	-	-	-	-	-	-	-	-
Fish	-	8,123	6,079	-	87	6,736	752	-	226	-	-
Total	6,132	9,369	8,464	5,381	2,918	9,030	3,195	1,437	2,803	1,206	-

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	Pyrogenicity	Biocompatibility	Enzyme induction for <i>in vitro</i> tests	Immunotoxicology	Other toxicology	
Mouse	-	-	-	2,005	596	-	-	-	4,619	266	16,056
Rat	10,542	-	-	-	516	-	-	120	-	1,654	29,847
Other rodent	-	-	6	156	271	-	-	16	-	40	855
Rabbit	-	824	1,212	-	-	-	-	-	-	-	2,868
Dog	-	-	-	-	4	-	-	-	-	13	106
Horse and other equids	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	31	-	-	-	-	120	151
Bird	-	-	-	-	12	-	-	-	-	1,679	2,751
Reptile / Amphibian	-	-	-	-	-	-	-	-	-	-	-
Fish	710	-	-	-	156	-	-	27	-	4,294	27,190
Total	11,252	824	1,218	2,161	1,586	-	-	163	4,619	8,066	79,824

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

Species of animal	Type of toxicological test or procedure										Number of procedures	
	Great Britain 2005	Acute lethal toxicity	Acute lethal concentration	Acute limit setting	Acute non-lethal clinical sign	Subacute limit-setting or dose ranging	Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Teratogenicity	
Mouse		58,659	-	1,033	3,535	3,707	5,516	4,424	7,089	1,391	769	
Rat		-	-	81	2,930	5,783	12,169	8,876	7,573	4,168	4,182	
Other rodent		218	-	795	90	112	90	-	-	-	-	
Rabbit		-	-	12	127	491	-	244	-	-	2,309	
Cat		-	-	-	-	-	-	-	-	-	-	
Dog		-	-	-	221	434	1,628	1,508	-	-	-	
Ferret		-	-	-	-	-	-	-	-	-	-	
Other carnivore		-	-	-	-	-	-	-	-	-	-	
Horse and other equids		-	-	-	-	-	-	-	-	-	-	
Other ungulate		-	-	-	28	4	87	-	-	-	-	
New World monkey		-	-	14	5	55	52	155	-	-	-	
Old World monkey		-	-	-	8	375	975	886	-	-	-	
Other Mammal		-	-	-	-	-	-	-	-	-	-	
Bird		-	-	-	-	-	400	-	-	-	-	
Fish		-	-	35	-	3,751	-	-	-	-	-	
Total		58,877	-	1,970	6,944	14,712	20,917	16,083	14,662	5,559	7,260	

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

Species of animal	Type of toxicological test or procedure										Number of procedures	
	Great Britain 2005	Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	Toxicokinetics	Pyrogenicity	Biocompatibility	Enzyme induction for <i>in vitro</i> tests	Immunotoxicology	Other toxicology	Total
Mouse		-	-	6	336	12,654	-	-	-	218	40,865	140,202
Rat		14,674	-	-	-	14,644	-	-	48	126	15,942	91,196
Other rodent		-	-	6	77	96	-	-	-	-	10,554	12,038
Rabbit		123	9	29	-	46	8,551	49	-	-	1,302	13,292
Cat		-	-	-	-	-	-	-	-	-	-	-
Dog		-	-	-	-	645	-	-	-	-	894	5,330
Ferret		-	-	-	-	-	-	-	-	-	-	-
Other carnivore		-	-	-	-	-	-	-	-	-	8	8
Horse and other equids		-	-	-	-	-	-	-	-	-	75	75
Other ungulate		-	-	-	-	212	-	-	-	248	2,273	2,852
New World Monkey		-	-	-	-	30	-	-	-	-	18	329
Old World Monkey		-	-	-	-	316	-	-	-	-	210	2,770
Other Mammal		-	-	-	-	-	-	-	-	-	15	15
Bird		-	-	-	-	98	-	-	-	-	6,662	7,160
Fish		-	-	-	-	-	-	-	-	-	6,132	9,918
Total		14,797	9	41	413	28,741	8,551	49	48	592	84,950	285,185

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

Species of animal	Type of toxicological test or procedure										Number of procedures
	Acute lethal toxicity	Acute lethal concentration	Acute limit setting	Acute non - lethal clinical sign	Subacute limit-setting or dose ranging	Subacute toxicity	Subchronic and chronic	Carcinogenicity	Genetic toxicology (includes mutagenicity)	Teratogenicity	
Mouse	67	985	125	-	-	-	-	151	90	-	
Rat	98	2,812	-	342	60	16	492	104	589	-	
Other rodent	217	-	-	-	-	-	-	-	-	-	
Rabbit	-	-	-	-	-	-	-	-	-	-	
Cat	-	-	-	-	-	-	-	-	-	-	
Dog	-	-	-	-	-	20	-	-	-	-	
Other carnivore	-	-	-	-	-	-	-	-	-	-	
Horse and other equids	-	-	-	-	-	-	-	-	-	-	
Other ungulate	-	-	-	-	-	-	-	-	-	-	
New World monkey	-	-	21	-	-	-	-	-	-	-	
Old World monkey	-	-	-	-	-	-	-	-	-	-	
Bird	-	-	-	-	-	-	-	-	-	-	
Reptile / Amphibian	-	-	-	-	-	-	-	-	-	-	
Fish	-	1,069	1,043	-	-	-	-	-	-	-	
Total	382	4,866	1,189	342	60	36	492	255	679	-	

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

Species of animal	Type of toxicological test or procedure										Number of procedures
	Other reproductive toxicity	In eyes	For skin irritation	For skin sensitisation	Toxicokinetics	Pyrogenicity	Biocompatibility	Enzyme induction for <i>in vitro</i> tests	Immunotoxicology	Other toxicology	Total
Mouse	-	-	-	155	875	-	532	-	1,135	9,948	14,063
Rat	-	-	-	-	386	-	53	40	-	4,342	9,334
Other rodent	-	-	-	45	-	-	-	-	-	30	292
Rabbit	-	12	66	-	112	218	66	-	9	68	551
Cat	-	-	-	-	-	-	-	-	-	-	-
Dog	-	-	-	-	53	-	-	-	-	128	201
Ferret	-	-	-	-	-	-	-	-	-	-	-
Horse and other equids	-	-	-	-	-	-	-	-	-	-	-
Other ungulate	-	-	-	-	-	-	2	-	-	48	50
New World Monkey	-	-	-	-	-	-	-	-	-	28	49
Old World Monkey	-	-	-	-	-	-	-	-	-	447	447
Bird	-	-	-	-	-	-	-	-	-	9	9
Reptile / Amphibian	-	-	-	-	-	-	-	-	-	826	826
Fish	-	-	-	-	-	-	-	-	-	171	2,283
Total	-	12	66	200	1,426	218	653	40	1,144	16,045	28,105

Part B

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

Great Britain 2005

Type of designated establishment	Number of licence holders ⁽¹⁾ reporting countable ⁽²⁾ procedures								Licensees reporting non-countable ⁽²⁾ procedures only	Number of licence holders ⁽¹⁾ reporting no procedures	Total licensees	Procedures		
	Total											Total	Percentage	
	1 to 50	51 to 100	101 to 200	201 to 400	401 to 600	601 to 800	801 to 1,000	More than 1,000						
Public health laboratories	4	-	2	3	-	1	2	3	15	1	9	25	18,053	0.6
Universities, medical schools	432	207	210	263	148	95	72	313	1,740	98	632	2,470	1,256,452	43.4
NHS hospitals	6	2	4	5	1	2	-	10	30	-	5	35	32,354	1.1
Government departments	26	12	12	10	6	4	2	17	89	2	43	134	75,670	2.6
Other public bodies	46	24	26	28	22	9	8	78	241	31	57	329	462,539	16.0
Non-profit-making organisations	19	11	12	15	10	5	6	30	108	7	25	140	142,975	4.9
Commercial organisations	68	22	33	27	20	11	14	137	332	11	95	438	908,155	31.4
Total	601	278	299	351	207	127	104	588	2,555	150	866	3,571	2,896,198	100

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

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

Details of procedures on immature forms (e.g. larvae, embryos, fish fry) are collected but not counted (see introductory notes, paragraph 12)
Animals in the wild involved in rodenticide trials are also not counted. Details (if applicable) are given in the commentary.

Table 20 Scientific procedures by species of animal, 1988-2005

Great Britain		Thousands of procedures																
Species of animal		Scientific procedures																
1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	
1850.5	1744.9	1,636.3	1,698.9	1,449.0	1,457.3	1,475.0	1,454.9	1,502.1	1,517.9	1,590.8	1,641.9	1,607.0	1,657.7	1,720.3	1,816.9	1,919.1	1,961.0	
860.4	882.3	891.5	881.7	833	819.7	755.9	694.4	688.8	636.7	575.9	567.0	535.0	500.2	509.6	496.4	464.7	424.5	
184.1	171.8	162.5	152	131.5	138.2	141.1	134.2	125.2	103.3	93.1	81.4	71.5	61.6	60.0	48.1	37.5	41.5	
131.8	113.4	89.8	81.5	79.5	70.5	68.8	61.2	53.6	45.0	37.5	41.4	39.7	33.7	30.3	25.3	21.7	22.8	
20.5	21.4	19.3	17.6	17.1	15.3	14.1	15.1	15	12.7	11.9	13.9	11.6	11.6	12.1	10.9	10.7	10.1	
38.1	34.8	34.8	31.1	34.4	33	32.2	55.3	60.3	60.0	68.0	63.6	63.0	37.4	57.3	75.5	75.1	61.4	
6.3	5.3	5.3	4.5	5	5	5.2	4.7	4.4	3.9	3.7	4.0	3.7	4.0	4.0	4.8	4.2	4.7	
0.4	0.2	0.8	1.3	1.3	2.5	3.2	1	0.8	0.8	0.9	0.5	0.5	0.8	1.3	1.7	2.4	2.3	
269.5	252	245.6	226.7	220.3	116.4	189.6	140.4	113.9	120.8	141.2	106.0	124.2	126.9	138.3	121.6	105.3	113.2	
11.3	11.6	13.1	15	19	17.7	17.2	17.2	17.3	15.3	14.4	14.6	15.6	17.5	17.6	16.6	19.5	21.8	
107.5	77.5	108	132	138.3	152.1	139.9	131.1	135.2	119.6	122.3	122.4	243.0	171.1	182.0	174.0	194.6	232.9	
..	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
3,480.3	3,315.1	3,207.1	3,242.4	2,928.3	2,827.7	2,842.4	2,709.6	2,716.6	2,636.0	2,659.7	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9	2,896.2	

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

Table 21 Scientific procedures (toxicology) by type of legislation, 1995-2005

Great Britain		Thousands of procedures											
Legislative requirements		1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	
UK requirements only		42.3	25.4	21.9	39.2	37.3	26.2	24.5	23.2	19.8	18.0	15.1	
Requirements of one EU country only (1999 onwards)						5.8	2.9	1.3	1.0	0.7	0.3	0.0	
EU requirements		69.6	60.5	54.1	49.3	118.7	69.8	73.6	68.2	45.0	43.4	41.1	
Requirements of non-EU Council of Europe country/ies						25.2	10.6	4.6	3.7	0.6	0.6	0.0	
Other international requirements		48.0	38.2	24.5	25.7	33.9	29.2	30.6	30.5	22.6	14.0	8.6	
Joint requirements (any combination of above)		399.9	441.1	415.0	355.5	247.5	242.1	255.1	295.0	284.8	300.1	275.8	
Non-legislative purposes		117.5	155.0	109.6	94.8	74.7	74.1	65.7	64.2	74.3	59.1	52.5	
Total		677.2	720.2	625.1	564.4	543.2	454.9	455.5	485.8	447.7	435.5	393.1	

Table 22 Scientific procedures by use of anaesthesia, 1988-2005

Great Britain		Scientific Procedures																		Thousands of procedures			
		Level of anaesthesia																					
1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005						
No anaesthesia throughout the procedure ⁽¹⁾		2213.1	2094.9	2,205.4	2,223.7	1,960.0	1,792.5	1,796.6	1,751.4	1767.1	1690.8	1723.6	1683.9	1636.3	1551.1	1634.8	1691.9	1710.8	1747.6				
Anaesthesia, with recovery, for part of procedure ⁽²⁾		604.5	568.7	529.8	566.9	579.3	627	632.5	658.2	694.1	698.8	702.1	759.5	873.9	802.4	810.8	833.7	874.9	873.2				
Terminal Anaesthesia ⁽³⁾		662.7	651.5	472	451.9	388.9	408.2	413.3	300	255.4	246.4	233.9	213.3	204.5	268.9	287.2	266.1	269.3	275.4				
Total		3480.3	3,315.1	3,207.1	3,242.4	2,928.3	2,827.7	2,842.4	2,709.6	2,716.6	2,636.0	2,659.4	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9	2,896.2				

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

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

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

Table 23 Scientific procedures by type of designated establishment, 1988-2005

Great Britain	Type of designated establishment ⁽¹⁾	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
		Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures	Thousands of procedures
	Public health laboratories	56.4	58.4	73.2	60.2	63.1	51.5	49.2	45.1	35.1	20.0	19.7	25.2	18.4	15.7	16.6	16.3	16.3	#REF!
	Universities, medical schools	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	1,079.8	1,130.1	1,202.0	#REF!
	Polytechnics etc ⁽²⁾	36.0	29.0	38.1	26.3	32.8	-	-	-	-	-	-	-	-	-	-	-	-	-
	NHS hospitals	89.6	92.7	89.6	76.5	80.1	75.8	83.3	94.4	94.3	71.1	75.0	70.1	40.1	28.3	23.1	24.0	26.8	#REF!
	Government departments	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	94.1	72.0	69.8	#REF!
	Other public bodies	231.6	217.5	229.2	244.0	217.8	240.5	259.9	235.5	248.4	259.2	287.9	312.6	338.2	309.2	353.5	407.7	449.9	#REF!
	Non-profit making organisations	115.7	103.8	132.1	124.0	104.7	91.4	85.8	102.6	118.9	117.7	119.4	119.5	115.0	161.4	152.3	136.3	138.8	#REF!
	Commercial organisations	2,107.4	2,007.3	1,866.2	1,910.9	1,627.7	1,449.9	1,469.1	1,329.4	1,281.8	1,204.3	1,136.6	1,101.6	1,032.8	1,017.7	1,013.4	1,005.4	951.3	#REF!
	Total	3,480.3	3,315.1	3,207.1	3,242.4	2,928.3	2,827.7	2,842.4	2,709.6	2,716.6	2,636.0	2,659.4	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9	#REF!

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

A licensee may have commenced procedures at more than one registered or designated place during the year. For 1989 onwards, recorded on the basis of the designated place of the project licence holder at the time the returns were issued.

(2) Polytechnics all became universities during 1992. From 1993 onwards combined figures are given.

Table 24 Scientific procedures (non-toxicology) by field of research, 1995-2005

Great Britain											
											Thousands of procedures
Field of research	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Psychology	28.4	31.0	38.8	33.1	33.9	106.9	37.9	39.6	38.2	34.7	45.2
Pharmaceutical R&D	567.6	504.2	501.5	470.1	481.9	446.7	408.9	365.7	400.4	393.0	347.1
Cancer research	262.6	257.8	300.9	293.3	267.0	258.4	268.8	258.1	277.4	275.2	277.6
Ecology	14.5	15.2	11.9	13.7	9.1	12.6	19.8	22.1	32.0	35.8	54.0
Tobacco	.. ⁽¹⁾	0.0	0.0	0.0	0.0	0.1	.. ⁽¹⁾	0.0	0.0	0.0	0.0
Alcohol	3.2	2.2	1.9	0.4	1.2	3.1	3.1	2.3	1.5	0.9	1.3
Other	1,156.0	1,185.8	1,155.8	1,284.7	1,320.5	1,432.0	1,428.4	1,559.0	1,594.6	1,679.8	1,777.8
Total	2,032.4	1,996.4	2,010.8	2,095.3	2,113.6	2,259.8	2,167.0	2,246.9	2,344.1	2,419.4	2,503.1

(1) Fewer than 50 procedures

Table 25 Scientific procedures (toxicology) for safety evaluation, 1992-2005

Great Britain	Thousands of procedures													
	1992	1993	1994	1995 ⁽¹⁾	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Protection of man, animal or the environment by toxicology or other safety evaluation:														
Environmental pollution	59.2	62.9	51.8	35.7	35.7	27.6	34.0	32.3	35.0	38.2	38.2	32.8	29.1	16.6
Substances used in agriculture	77	67.3	68.6	65.6	68.8	53.8	55.8	48.1	35.3	41.0	57.8	40.1	28.3	32.8
Substances used in industry	91.8	80.2	65.9	85.1	80.4	76.2	58.8	57.6	53.9	52.7	42.3	36.1	33.7	23.9
Substances used in the household	2.1	2.2	1.4	1.7	2.6	2.0	1.5	0.3	1.2	0.6	1.0	0.2	0.3	- ⁽³⁾
Foodstuffs and food additives	6.1	7.6	8.2	7.4	3.8	7.5	4.0	4.9	6.0	3.5	5.4	8.1	0.9	6.6
Cosmetics and toiletries	2.2	3.8	3.5	1.9	2.8	1.3	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Tobacco	0.2	0	0.03	- ⁽²⁾	-
Alcohol research	1.1	7.3	9.1	- ⁽²⁾
Other safety evaluation	19	10.6	8.7
Pharmaceutical - safety, efficacy, ADME and residue	333.2	365.8	311.2	284.4	269.6	203.8	204.8	220.1	202.3	211.8	207.1
Pharmaceutical - quality control	83.8	84.3	77.8	74.0	85.6	70.9	72.2	74.5	78.3	92.3	78.1
Other purposes	62.7	76	67.7	51.4	44.7	48.8	42.5	46.4	49.8	39.3	28.1
Total	258.6	242.0	217.2	677.2	720.2	625.1	564.4	543.2	454.9	455.5	485.8	447.7	435.5	393.1

.. 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.

(3) Fewer than 50 procedures

Table 26 Scientific procedures by primary purpose, 1995-2005

Great Britain										Thousands of procedures	
Primary purpose of the procedure	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Fundamental biological research	841.2	884.8	829.4	894.9	803.8	872.8	778.7	864.3	832.9	880.9	939.8
Applied studies -											
human medicine or dentistry	1,073.3	1,012.2	945.4	847.3	836.2	739.0	689.9	669.9	693.7	671.9	625.0
veterinary medicine	199.2	144.1	160.1	181.3	169.6	190.7	182.2	175.0	150.7	156.4	156.2
Protection of man, animals or the environment	209.2	219.7	201.0	170.4	153.3	161.2	153.6	185.6	151.4	114.1	103.8
Education	7.1	6.7	5.9	6.3	5.5	4.7	4.6	4.3	3.7	2.7	1.6
Training	1.7	1.7	1.6	1.6	1.4	1.3	1.2	1.0	0.9	0.9	0.9
Forensic enquiries	0.1	0.1	0.1	0.1	0.1	_(1)	_(1)	_(1)	_(1)	_(1)	0.1
Direct diagnosis	65.0	55.8	55.5	52.0	47.8	45.3	34.5	41.3	55.8	45.3	41.7
Breeding	312.7	391.5	437.0	505.8	639.1	699.6	777.8	791.2	902.6	982.6	1,027.2
Total	2,709.6	2,716.6	2,636.0	2,659.7	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9	2,896.2

(1) Fewer than 50 procedures

Table 27 Scientific procedures by primary purpose and genetic status, 1995-2005

Great Britain									Thousands of procedures		
Primary purpose of procedure	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Normal animal											
Fundamental biological research	713.1	724.8	656.2	664.1	621.5	653.2	560.9	584.7	563.4	560.2	585.8
Applied studies	1,219.2	1,101.1	1,043.8	969.4	937.9	857.7	810.5	780.6	779.7	756.4	716.4
Safety	208.9	219.0	200.8	170.1	153.3	161.1	153.5	185.4	151.3	114.0	103.6
Other uses	73.0	64.2	62.8	59.9	54.7	51.3	40.1	46.7	59.6	48.3	43.7
Breeding	53.5	72.2	83.0	89.2	126.7	152.8	179.8	165.5	194.9	194.5	201.2
Total	2,267.7	2,181.3	2,046.6	1,952.7	1,894.1	1,876.1	1,744.8	1,762.8	1,748.9	1,673.4	1,650.6
Animal with harmful genetic defect											
Fundamental biological research	53.8	43.9	43.3	57.5	55.1	54.5	46.8	63.8	47.7	68.7	74.1
Applied studies	40.7	41.0	50.1	42.7	42.9	50.8	44.6	37.7	40.7	46.6	39.7
Safety	0.2	0.7	0.3	-	-	-	(1)	-	0.1	(1)	0.0
Other uses	(1)	(1)	0.2	(1)	0.1	0.1	0.1	(1)	0.4	0.1	0.0
Breeding	131.9	148.0	142.8	159.1	152.9	151.5	155.3	158.4	190.0	152.2	174.3
Total	226.6	233.7	236.6	259.3	251.0	256.9	246.8	259.9	278.8	267.6	288.1
Genetically modified animal											
Fundamental biological research	74.3	116.2	129.9	173.2	127.2	165.1	171.0	215.8	221.9	252.0	279.9
Applied studies	12.7	14.2	11.7	16.5	24.9	21.2	17.0	26.6	24.0	25.4	25.1
Safety	0.1	-	-	0.3	-	0.1	0.1	0.2	0.1	0.1	0.2
Other uses	1.0	-	(1)	(1)	(1)	(1)	(1)	(1)	0.4	0.6	0.6
Breeding	127.2	171.2	211.1	257.6	359.5	395.4	442.7	467.3	517.7	635.9	651.7
Total	215.3	301.6	352.8	447.6	511.6	581.8	630.8	710.0	764.1	914.0	957.5
All animals											
Fundamental biological research	841.2	884.8	829.4	894.9	803.8	872.8	778.7	864.3	832.9	880.9	939.8
Applied studies	1,272.6	1,156.3	1,105.6	1,028.7	1,005.7	929.7	872.1	844.9	844.4	828.3	781.2
Safety	209.2	219.7	201.0	170.1	153.3	161.2	153.6	185.6	151.4	114.1	103.8
Other uses	74.0	64.2	63.0	59.9	54.9	51.4	40.3	46.7	60.4	49.0	44.3
Breeding	312.6	391.5	437.0	505.8	639.1	699.6	777.8	791.2	902.6	982.6	1,027.2
Total	2,709.6	2,716.6	2,636.0	2,659.7	2,656.8	2,714.7	2,622.4	2,732.7	2,791.8	2,854.9	2,896.2

(1) Fewer than 50 procedures

APPENDIX A

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

Introduction

1. The Animals (Scientific Procedures) Act 1986 put in place a rigorous system of controls on scientific work on living animals, including the need for both the researcher and the project to be separately licensed; stringent safeguards on animal pain and suffering; and general requirements to ensure the care and welfare of animals.
2. Operation of the Act is not a devolved responsibility in Great Britain, the Home Office administering the legislation in England, Scotland and Wales. The Act is separately administered in Northern Ireland.

Scope of the Act

3. The Act controls any experimental or other scientific procedure applied to a 'protected animal' which may have the effect of causing that animal pain, suffering, distress or lasting harm. Such work is referred to in the Act as a 'regulated procedure'. 'Protected animals' are defined as all living vertebrate animals, except man, plus one invertebrate species, *Octopus vulgaris*. The definition extends to foetal, larval or embryonic forms that have reached specified stages in their development. Under the Act an animal is regarded as 'living' until "the permanent cessation of circulation or complete destruction of its brain". Procedures carried out on decerebrate animals are also subject to the controls of the Act.
4. The definition of a regulated procedure encompasses most breeding of animals with genetic defects; production of antisera and other blood products; the maintenance and passage of tumours and parasites; and the administration for a scientific purpose of an anaesthetic, analgesic, tranquilliser or other drug to dull perception. Killing an animal requires licence authority in certain circumstances.
5. The controls of the 1986 Act do not extend to procedures applied to animals in the course of recognised veterinary, agricultural or animal husbandry practice; procedures for the identification of animals for scientific purposes, if this causes no more than momentary pain or distress and no lasting harm; or the administration of a novel veterinary product under authority of an Animal Test Exemption Certificate (issued under the Medicines Act 1968).
6. Two kinds of licence are required for all work controlled by the Act. The procedures must be part of a programme of work authorised by a project licence and the person applying the regulated procedures must hold a personal licence. No work may be done unless the procedure, the animals used and the place where the work is to be done are specifically authorised in both project and personal licences.

Personal Licences

7. A personal licence is the Home Secretary's endorsement that the holder is a suitable and competent person to carry out specified procedures on specified animals, under supervision where necessary. Applicants must be over 18 and are required to give details of their qualifications, training and experience. Those who have not previously held a Home Office licence need the endorsement of a sponsor (normally a personal licence holder in a senior position at the applicant's place of work). Satisfactory completion of an accredited training course is also required before a personal licence is issued.
8. During 2005, 2119 personal licences were granted and 2,209 were revoked. On 31 December 2005 there were 14,188 active licences. Personal licences continue to be in force until revoked, but they must be reviewed at least every five years.

Project Licences

9. A project licence is granted when the Home Secretary considers that the use of living animals in a programme of work, for a purpose permitted by the Act, is justified and the methods proposed appropriate. In deciding whether and on what terms to authorise the project, the likely adverse effects on the animals used must be weighed against the potential benefits (to humans, other animals or the environment) which are expected to accrue from the work. Adequate consideration must also have been given to the feasibility of using alternative methods not involving living animals. The holder of a project licence undertakes overall responsibility for the scientific direction and control of the work and is responsible for making the statistical returns on which this publication is based. New project licence applicants are required to complete an accredited training course before the licence is granted.
10. When making an application for a project licence the applicant nominates, and the Home Office assigns, an overall severity banding for the project. There are three main severity bandings: mild, moderate and substantial. A fourth band, unclassified, is used for procedures where the animals are decerebrate or used under terminal anaesthesia – i.e. the animal is anaesthetised before the procedure starts, is kept anaesthetised throughout the course of the procedure and is killed without recovering consciousness.

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

12. The following table details the number of project licences which were active on 31 December 2005, the number granted during 2005 and the number revoked during 2005 (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

Severity band	In force on 31 December 2005		Granted during 2005		Revoked during 2005	
	Number	%	Number	%	Number	%
Mild	1,095	38	206	39	227	41
Moderate	1,658	57	296	56	290	53
Substantial	50	2	9	2	15	3
Unclassified	83	3	17	3	17	3
Total	2,886		528		549	

Designation of premises

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

14. The following table details the number of certificates of designation that were in force on 31 December 2005, the number granted during 2005 and the number revoked during 2005. The figures are subdivided for different types of establishment.

Certificates of Designation

Establishment type	In force on 31/12/2005	Granted during 2005	Revoked during 2005
Commercial concern	78	1	5
Higher education	81	1	2
Quango	27	0	3
Government	10	0	0
Non-profit	14	1	0
NHS hospital	5	0	0
Public health	3	0	0
Total	218	3	10

15. Of the 218 certificates of designation active on 31 December 2005, 215 were registered as user establishments, 137 as breeding establishments and 68 as supplying establishments. These figures add up to more than the total number of establishments because a single establishment may be represented in more than one of the categories: for example, an establishment may be registered as both a breeder and user of animals.

Guidance and Codes of Practice

16. In addition to these annual statistics, the Act requires the Home Secretary to publish and lay before Parliament guidance on the operation of the controls of the Act and codes of practice on the care and accommodation of animals and their use in regulated procedures. These and other documents have been published and can also be found at the Home Office website <http://scienceandresearch.homeoffice.gov.uk/animal-research/publications/>. These documents include:

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

Education and training

17. The Animals (Scientific Procedures) Act 1986 imposes clear responsibilities on persons with specific roles in relation to the care and use of animals in scientific procedures. These are elaborated further in the Home Office guidance on the operation of the Act (HC 321, The Stationery Office, 2000) as mentioned above. As the roles differ, it follows that the education and training required before assuming these responsibilities will differ:

- personal licence holders are responsible for the welfare of animals on which they carry out regulated procedures; applicants will be granted licences only if adequately trained to take on this responsibility and they will usually be required to work under supervision initially;
- project licences will be issued only to persons with appropriate qualifications to direct a programme of work which is well-justified and takes account of all reasonable possibilities for reducing the number of animals used, refining the procedures to reduce suffering and replacing animal procedures with alternatives which do not involve protected animals;
- holders of certificates of designation have responsibility not only for ensuring that the fabric and staffing of designated places are maintained to appropriate standards but also for ensuring that reasonable steps are taken to prevent unauthorised procedures being carried out and that adequate training facilities are available for all animal users.

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

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

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

The acquisition and use of primates

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

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

Animals Scientific Procedures Division

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

23. The Licensing Section operate the licensing system on behalf of the Secretary of State. They process applications for new licences and certificates; process amendments to existing authorities; and revoke or vary licences and certificates as necessary. They (not Inspectors nor the Animal Procedures Committee) grant, refuse, vary, revoke and suspend licences and certificates for the Secretary of State. They also administer the collection of annual fees from designated establishments and of annual statistical returns of procedures from project licence holders.

24. On 31 December 2005, the Licensing Section had a total complement of 23 staff and managers. The licensing work was carried out at five regional offices: Cambridge, Dundee, London, Shrewsbury and Swindon.

25. The Policy Section is the primary source of advice to Ministers on issues relating to the Act, including the preparation of responses to Parliamentary Questions and correspondence from MPs and the public about the use of animals in scientific procedures.

The Inspectorate

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

27. Inspectors assess all applications for new licences or amendments to existing licences in detail and advise the Home Secretary on whether and on what terms to grant the licences or accept the amendments. When assessing scientific proposals the Inspector checks that full consideration is given to alternatives, not only the **replacement** of procedures with others which do not use animals but, where animals have to be used, the **reduction** of the number of animals used and the **refinement** of procedures to minimise pain and suffering. These are known as the **3Rs**. Inspectors carry out visits, mainly without notice, to establishments designated under the Act to determine whether scientific work on animals is authorised, to inspect the premises and to check that the establishment's controls are adequate and that the terms and conditions of the licences issued under the Act are being observed.

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

29. At 31 December 2005, there were 28 inspectors in post. The distribution of inspectors was:

	Chief Inspector	Superintending Inspectors	Inspectors
London	1	1	7
Cambridge		1	4
Dundee		2	5
Shrewsbury			3
Swindon			4
Total	1	4	23

30. In 2005, the Inspectorate carried out 3,350 visits in addition to meeting demands for advice and assessment on the issue and amendment of licences and the formulation of policy. Of these visits 2,383 were for the purpose of inspection of designated establishments and work in progress. Well over fifty percent of the visits to designated departments were unannounced. The remaining 967 visits were for the purpose of maintaining scientific or professional skills, representing the Home Office or furthering Home Office policy.

Performance against published target

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

32. Data for 2005 indicate that 82 per cent of completed and signed project licence applications were processed within the 35 working days target, although many applications were actually turned around in significantly less time. The average processing time for all applications was 23 working days. It is expected that this performance will improve further once a new IT system currently under development is in place.

The Animal Procedures Committee

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

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

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

Recent developments

36. In January 2005 full public access rights were introduced under the Freedom of Information Act 2000. During 2005 the Home Office received 26 requests for information relating to the implementation of the Animals (Scientific Procedures) Act 1986. These requests focused mainly on who holds licences, specific projects, or types of work, infringements and inspection reports. In response, we released no information about individuals, or establishments, holding licences. We did, however, release some information about specific licences, after consulting with the relevant licensees.

37. Also in January 2005 a new project licence application form was launched. This included a section allowing applicants to provide a short description of the proposed project for publication as part of the Home Office publication scheme under the Freedom of Information Act. By the end of 2005, 195 'project licence abstracts' had been published on the Home Office website at <http://scienceandresearch.homeoffice.gov.uk/animal-research/publications/001-abstracts/>. This implemented a commitment given in the Government's reply to the report of the House of Lords Select Committee on Animals in Scientific Procedures to publish abridged details of project licences.

38. Work begun in 2003 on revising Directive 86/609/EEC, which the Animals (Scientific Procedures) Act 1986 transposes into UK legislation, and continued during 2005. In December 2005 the Animal Welfare Committee of the European Food Standards Agency (EFSA) published its opinion on four technical issues referred to it by the Commission for advice. The four issues related to the sentience and the capacity to feel pain, suffering or distress of some invertebrate species; the sentience and the capacity to feel pain, suffering or distress of foetal and embryonic forms; the criteria for requiring purpose-bred animals to be used in experiments and the list of those species falling within the criteria; and humane methods of euthanasia per type of species used in experiments. The opinion is available at http://www.efsa.eu.int/science/ahaw/ahaw_opinions/1286_en.html. The Commission is expected to publish a consultation document during 2006.

39. Work on the revision of the Appendix A to Council of Europe Convention ETS 123 for the protection of vertebrate animals used for experimental and other scientific purposes, relating to the accommodation and care of protected animals, was completed in 2005 and a revised proposal has been published and is available at http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Biological_safety_use_of_animals/Laboratory_animals/draft%20revision%20of%20Appendix%20A.asp. It was adopted at a multi-lateral consultation on 15 June 2006. Appendix A to the Convention is transformed into Annex 2 to Directive 86/609/EEC.

Summary of infringements

40. In the published statistics for 2000, details were given of new streamlined procedures for handling infringements. Action on 26 infringements was completed under these procedures in 2005.

Class One infringements

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

42. There were no Class One infringements dealt with in the reporting period.

Class Two infringements

43. 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.

44. Sixteen Class Two infringements were dealt with in the reporting period. Academic establishments and Quangos were involved in six each, and commercial establishments in four. Eleven were self-reported and five were discovered by the inspectorate.

Class Three infringements

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

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

47. Eight were reported by licensees to the Home Office, and two were discovered and reported by the Inspectorate.

48. A total of nine establishments had Class Three infringements reported. Academic establishments were involved in four, Quangos in three, and a commercial establishment and a non-profit making organisation in one each.

Nature of Class Three infringements

49. As in previous years, the nature of the infringements varied in severity. In four cases a regulated procedure was applied to animals without appropriate project licence authority in breach of section 3(b) of the 1986 Act, and in two cases without appropriate personal licence authority in breach of section 3(a) of the Act. In one case a regulated procedure was applied to animals without appropriate personal licence and project licence authority in breach of sections 3(a) and 3(b) of the Act. In one case an animal was discharged from the controls of the Act without appropriate authority in breach of section 15(1) of the Act. In two cases animals were not being maintained to the required standards as set out

in the Home Office Code of Practice for the Housing and Care of Animals used in Scientific Procedures.

Action taken

50. 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.

51. As a result of these infringements, 19 licence holders were admonished; 4 were required to attend relevant modules of an accredited training course; 2 holders of certificates of designation were required to review the systems of control at their establishments in order to prevent recurrence; and 1 non-licensee was sent a letter of censure.

52. 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.

NOTES FOR RETURN OF PROCEDURES

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

Home Office, ASPD (Mail Point 1B)
1st Floor Seacole Building
2 Marsham Street
LONDON SW1P 4DF

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.archive.official-documents.co.uk/document/hoc/321/321.htm> 6 December 2005.

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 6) 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 each of them.
11. Forms not completed in accordance with the guidance notes may be returned to the licence holder for clarification. Acceptance of the form in compliance with standard condition 10 of the licence will NOT be recorded until a properly completed form is received in the Home Office.
12. **Please consult your Inspector if you are uncertain how to complete the form correctly.**

CODE LISTS

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 under gone pain, suffering, distress or lasting harm during the field trials.
- R1 Mouse
R2 Rat
R3 Guinea-pig
R4 Hamster
R5 Gerbil
R9 Other rodent (*please append a note indicating species used*)
L1 Rabbit
C1 Cat
C2 Dog - beagle
C3 - greyhound
C4 - other including cross-bred dogs
C5 Ferret
C9 Other carnivore (*please append a note indicating species used*)
U1 Horse, donkey and cross-bred equids
U2 Pig
U3 Goat
U4 Sheep
U5 Cattle
U6 Deer
U7 Camelid
U9 Other ungulate (*please append a note indicating species used*)
- Primate**
P1 - prosimian
- new world monkey
P2 - marmoset, tamarin
P3 - squirrel, owl or spider monkey
P4 - other new world monkey
- old world monkey
P5 - macaque
P6 - baboon
P7 - other old world monkey
- ape
P8 - gibbon
P9 - great ape
J9 Other Mammal (*please append a note indicating species used*)

BIRD

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

REPTILE

- D1 Any reptilian species (*please indicate species used*)

AMPHIBIAN

- M1 Any amphibian species (*please indicate species used*)

FISH

- F1 Any fish species (*please indicate species used*)

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. (*please give both common and Latin name for species*)
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 LISTA, 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)

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. (*Associated codes for row 6 will usually be 1, 3 or 4.*)

ROW 8 : PRIMARY PURPOSE OF THE PROCEDURE

Select the appropriate code from the list below.

- 1 **Fundamental biological research:**
studies of normal or abnormal structure or function of living organisms, organs, tissues, cells or other systems (including fundamental studies in toxicology).
- 2 **Applied studies – human medicine or dentistry:**
research, development or quality control of products or appliances including toxicological evaluation and safety or efficacy testing.
- 3 **Applied studies – veterinary medicine:**
research, development or quality control of products or appliances including toxicological evaluation and safety or efficacy testing.
- 4 **Protection of man, animals or environment by**
toxicological or other safety or environmental evaluation (excluding medical or veterinary products or appliances). This category is intended to cater for toxicological work which is not related either to fundamental research or to the solution of medical or veterinary problems as such. Ecological studies may be included here with the appropriate codes in Rows 10-12: A codes for toxicological testing or B codes for other investigative studies.
- 5 **Education**
- 6 **Training:**
use of animals in acquisition of manual skills is permitted in microsurgery training only.
- 7 **Forensic enquiries:**
human or veterinary.
- 8 **Direct diagnosis:**
procedures for specific detection of human or veterinary pathogens or production of diagnostic reagents.
- 9 **Breeding**
of harmful mutants or genetically modified animals.
Before selecting this code please read the guidance in Annex A. If using this code row 11 must be B61, B62, or B64.

ROW 9 : BODY SYSTEM

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

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

ROW 10, 11 & 12

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

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

Use **list B** for any other primary purpose.

LIST A, ROW 10

TOXICOLOGY OR OTHER SAFETY OR EFFICACY EVALUATION

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

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

Pharmaceutical safety/efficacy evaluation

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

Other purpose

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

LIST A, ROW 11

TYPE OF TEST OR PROCEDURE

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

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

LIST A, ROW 12

LEGISLATIVE REQUIREMENTS

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

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

Dose-ranging or other types of preliminary studies should also be classified as having a legislative requirement, using the same code as for the related definitive study.

- 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	Malta
Belgium	Greece	Netherlands
Cyprus	Hungary	Poland
Czech Republic	Irish Republic	Portugal
Denmark	Italy	Slovakia
Estonia	Latvia	Slovenia
Finland	Lithuania	Spain
France	Luxembourg	Sweden

COUNTRY LIST FOR CODE A94 ABOVE (Council of Europe nations other than EU)

Albania	Georgia	San Marino
Andorra	Iceland	Serbia and Montenegro
Armenia	Liechtenstein	Switzerland
Azerbaijan	Moldova	Former Yugoslav
Bosnia and Herzegovina	Monaco	Rep. of Macedonia
Bulgaria	Norway	Turkey
Croatia	Romania	Ukraine
	Russian Federation	

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
 - B32 Alcohol research
- } Use these codes for research on 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 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 Annex A, paragraph 2, attached. Normal animals, which have not undergone any other regulated procedures, do not need to be accounted for – see Annex A, 1(i). Where harmful mutant animals have been crossbred with a GM line, the offspring should be reported as GM.
- B65 **Harmful mutant** animals used in research programmes, where they underwent regulated procedures other than those required for a breeding programme, i.e. where the primary purpose was NOT breeding, i.e. Row 8 = 1-8. Normal or wild-type animals used as controls in such research and also subject to regulated procedures should be coded as 1 in Row 4 and codes B50-B56, or B79 as appropriate, in this list.

Other

- B79 None of the above

LIST B, ROW 12

TECHNIQUES OF PARTICULAR INTEREST

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

- B91 Direct interference with any part of the organs of special sense including the brain centres
 - B92 Direct injection of micro-organisms or material suspected of containing micro-organisms into the brain
 - B93 Other direct physical interference with the brain
 - B94 Induction of psychological stress integral to the procedure
 - B95 Use of aversive training stimuli
 - B96 Exposure to ionising radiation at doses intended to produce a potentially adverse effect on the animal
 - B97 Inhalation – DO NOT USE FOR FISH
 - B98 Thermal injury
 - B99 Physical trauma
 - B00 None of the above
- } where the study of such injury or trauma
} was the purpose of the procedure

IMPORTANT NOTES ON RE-USE

ROWS 13 and 14

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

ROW 15

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

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

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

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

ROW 13 : NUMBER OF PROCEDURES CARRIED OUT ON ANIMALS

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

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

ROW 14 : NUMBER OF ANIMALS USED FOR THE FIRST TIME

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

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

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

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

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

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

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

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

If you have entered 0 in Row 13, then this row must also be 0.

The sum of the values in Rows 14 and 15 must not exceed the value in Row 13.

ANNEX A

Coding and counting of animals with abnormal genetic constitution

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

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

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

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

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

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

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

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

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

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

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

- (i) they died or were humanely killed as a result of the harmful genetic defect or the genetic manipulation;
- (ii) they died or were humanely killed as a result of other causes, e.g. disease;
- (iii) they were humanely killed 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.

Return of procedures by project for 2005

Name and address

OFFICIAL USE ONLY

Serial
Number

Project licence
number

Establishment
code (PCD code)

Dear Project Licence Holder,

This form sets out the arrangements for the 2005 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 2005. 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 contact details, and return it to the address below. However if the answer is YES, please read the rest of this letter, accompanying notes, and code lists carefully before completing the form in black ink.
- **complete the form with care; this is a computer input document. This should avoid queries at a later date. PLEASE NOTE CAREFULLY THE CODING INSTRUCTIONS. THERE ARE SOME WORKED EXAMPLES ON PAGES 7 & 8.**
- 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 2006** to:-

Home Office, ASPD (Mail Point 1B)
1st Floor Seacole Building
2 Marsham Street
LONDON SW1P 4DF

It is a requirement of the Animals (Scientific Procedures) Act 1986 that this return is completed, and it should be returned to us by 31 January 2006 at the latest. Failure to comply constitutes a breach of the Act and may be considered as a Class 2 infringement. This may affect other licences you hold and any future licence applications.

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

Thank you in advance for your care and attention.

Paul Vallender

Animal Scientific Procedures Division
Science and Research Group

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

- under normal circumstances the form will not be accepted unless you, the project licence holder, sign SECTION 1. If this is not possible due, for example, to sickness or other unavoidable leave of absence, a note from the signatory to explain the circumstances should be attached.
1. Have any procedures under the Animals (Scientific Procedures) Act 1986 under the project shown above been started during 2005?
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.		01	02	03	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					
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> TOXICOLOGY Purpose Use List A </div> <div style="width: 45%;"> ALL WORK OTHER THAN TOXICOLOGY Field of Research Use List B </div> </div>		Row 10					
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> Type of Test Use List A </div> <div style="width: 45%;"> Production Use List B </div> </div>		Row 11					
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> Legislative Requirements Use List A </div> <div style="width: 45%;"> Techniques Use List B </div> </div>		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 <u>Reused</u> for the first time this year Enter the total number of animals <u>reused</u> for the <u>first time this year</u> in regulated procedures (see Notes) If no animals were reused this should be set to zero		Row 15					

APPENDIX C

Explanation of published tables

Species of animal

1. All tables in Part A are classified by species of animal. The full classification is used in Tables 1, 1a, 5, 5a, 10 and 10a, but the other tables use a condensed classification. All the tables except 1a, 5a and 10a give the number of procedures. Tables 1a, 5a, and 10a give the actual number of animals used for the first, and usually only, time in 2005 classified according to their first use. The list of species or categories of animals is selective to avoid undue complications; when collective terms are used it is because previous experience suggests that the category will contain a relatively small number or because further breakdown is of little interest. In several of the tables, rows which are completely zero have been omitted and if a species is not mentioned it is because the row or rows pertaining to that species is blank.

Genetic status of animal

2. 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)

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

- (i) **fundamental biological research**; carried out with the primary intention of increasing knowledge of the structure, function and malfunction of man and other animals, or plants. Such studies may be aimed solely at an increase in knowledge, application of that knowledge being beyond the scope of the investigation, or with a view to providing a practical solution to a medical or veterinary problem once the issues are more clearly defined and understood. This category includes physiological, pathological, pharmacological, genetic and biochemical studies, including toxicological evaluation.
- (ii) **applied studies - human medicine or dentistry, and veterinary medicine**; consisting of research into, development of and quality control of products or devices, including toxicological evaluation and safety or efficacy testing.
- (iii) **protection of man, animals or the environment**; by toxicological or other safety or environmental evaluation. This category is intended to cater for toxicological work which is not related either to fundamental research or to the solution of medical and veterinary problems as such (see (i) and (ii) above), but also includes some non-toxicological procedures. This category is further divided into a number of subgroups (listed in Tables 10 and 10a). These are largely self-explanatory but the following notes may be helpful in understanding the figures:
 - (a) while any one substance may be used in industry or in the home, or may be an environmental pollutant, a herbicide or a pesticide, the project licence holder classifies the procedure in accordance with the particular context of the procedure and the expected primary use of the product;
 - (b) animal pesticides (distinct from plant pesticides) are not

included amongst the types of substances listed, because a substance intended to kill pests which infest or attack animals would be regarded as a veterinary product. These are included in the appropriate body-system group covered by primary purposes described in (ii) above;

- (c) many of the procedures recorded under this category are required by UK law or by the laws and regulations of countries in which it is intended to use the substance concerned;
- (d) the term 'food additives' covers substances deliberately added to food as preservatives, artificial colourants or flavouring agents but not studies on the nutritive value of food, accidental contamination or infection of food, or medicines administered to animals or humans in food.
- (iv) **education and training;** these categories include procedures carried out under project licences for the purposes of education or training under the 1986 Act. They also include killing of animals by methods not included in Schedule 1 to the 1986 Act, if the killing takes place for educational purposes at a designated establishment. Such killing may be authorised to provide, for example, tissues subsequently used for education or training. The use of animals for the acquisition of manual skills is currently permitted only for training in microvascular surgery, and at present this is always carried out under general anaesthesia, without recovery.
- (v) **forensic enquiries;** may refer to animal use in human or veterinary enquiries relevant to potential legal proceedings.
- (vi) **direct diagnosis;** investigation of disease including investigating suspected poisoning. This caters for procedures carried out under the 1986 Act for the purpose of diagnosing disease in an individual human or animal patient or a group of such patients. There is no research function: these are essentially applied studies, predominantly involving the production of biological reagents, for example antibodies and clotting factors.
- (vii) **breeding;** a category for recording the production and breeding of animals with harmful genetic defects, and genetically modified animals. The numbers recorded in this category include those animals which are identified as possessing a harmful mutation or are genetically modified, but not used subsequently on procedures which are recorded elsewhere in the tables. The numbers also include some genetically normal animals which were subjected to regulated procedures such as tissue sampling or hormonal administration for the purpose of regulated breeding programmes (see also Tables 3, 3.1, 3.2, 3.3).

Source of animals (Tables 2, 2.1, 2.2)

4. 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 2005 were: mouse, rat, guinea-pig, hamster, gerbil, rabbit, cat, dog, ferret, primate and quail (*Coturnix coturnix*); also pigs (if genetically modified), and sheep (if genetically modified). Normal pigs and normal sheep remain outside the scope of this schedule. The source of these species is tabulated according to whether it is within the UK, within the remainder of the EU, within certain Council of Europe (but non-EU) countries who are signatories to convention ETS 123, or elsewhere. Animals which originate from non-designated sources, such as overseas breeding centres, but which are acquired by the project licence holder from a designated supplying establishment in the UK, are reported under the heading "Animals acquired from other designated breeding or supplying establishments in the UK."

Table 2 lists numbers of procedures by source of animal, as described above; tables 2.1 and 2.2 list

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

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

5. Stage of development

Details of procedures on animals in foetal, larval or embryonic form are collected but not shown in any of the published tables because it may be impracticable in some cases to count such procedures, e.g. a foetus resorbed during gestation, or fish fry which are very small and fast-moving.

Genetic status

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

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

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

Breeding

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

The classifications of procedures concerned with breeding distinguish between:

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

- (e) for maintenance of breeding colonies;
animals with a harmful mutation used in research programmes not concerned with breeding.

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

Target body system (Table 4a)

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

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

Use of anaesthesia (Table 4b)

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

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

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

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

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

Type of procedure

8. 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 10–16).

If the purpose was non-toxicological, the licensee was asked to

specify the field of research, the nature of the procedure with regard to production and breeding and whether the technique was identified as being of particular interest.

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

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

A Fundamental and applied studies other than toxicology

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

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

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

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

(ii) Production of biological materials (Table 8)

Production:

- (a) procedures for production and maintenance of infectious agents (excluding those causing neoplasms);
- (b) procedures for production and maintenance of vectors, e.g. parasites;
- (c) procedures for production and maintenance of neoplasms;
- (d) the ascites model for the production of monoclonal antibodies;
- (e) initial immunisation for subsequent *in vitro* or *in vivo* production of monoclonal antibodies;
- (f) procedures for production of polyclonal antibodies;
- (g) 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:

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

(ii) **Legislative requirements (Table 11)**

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

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

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

Medicines Act 1968;
 Workplace safety, e.g. Health and Safety at Work Act 1974, COSHH Regulations;
 Substances used in agriculture, e.g. Control of Pesticides Regulations 1986; EU Pesticides Directives;
 Substances used in foodstuffs, e.g. Food Safety Act 1990.

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

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

(iv) **Tables showing some selected work in greater detail**

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

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

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

APPENDIX D

ERRATA IN 2004 PUBLISHED TABLES

Table 18.b

The information displayed in this table relates to procedures conducted in 2004 use species of dog, not rabbits as the title indicates. The title should read:

Table 18.b Tree table – scientific procedures involving dogs, 2004

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	Year	Command Paper
2004	Cm 6713	1995	Cm 3516
2003	Cm 6291	1994	Cm 3012
2002	Cm 5886	1993	Cm 2746
2001	Cm 5581	1992	Cm 2356
2000	Cm 5244	1991	Cm 2023
1999	Cm 4841	1990	Cm 1574
1998	Cm 4418	1989	Cm 1152
1997	Cm 4025	1988	Cm 743
1996	Cm 3722	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	Year	Command Paper
1986	Cm 187	1981	Cmnd 8657
1985	Cmnd 9839	1980	Cmnd 8301
1984	Cmnd 9574	1979	Cmnd 8069
1983	Cmnd 9311	1978	Cmnd 7628
1982	Cmnd 8986	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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The Home Office would welcome comments from users on how well this publication meets their needs, and will consider any suggestions for improving it in future years. Comments and suggestions must be sent to the address below by 31 March 2007 if they are to be taken into account in time for the next publication (covering procedures started in 2006).

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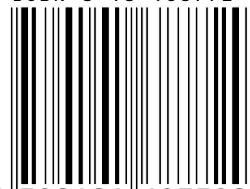
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