

Animals (Scientific Procedures) Act 1986

NOTES FOR RETURN OF PROCEDURES

1. It is a condition of every project licence that the project licence holder must make a return by 31 January of all regulated procedures on living animals commenced during each year. **Note:** Failure to comply constitutes a breach of the Act and can be considered as an infringement. This can affect other licences you hold and any future licence applications.
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 should be completed on the front of the form. 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.

NOTES ON COMPLETING SECTION 2

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

A 'regulated procedure' is defined by Section 2 (1) of the Act as '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'. The 'use' of a protected animal under project licence authorities extends from the time the first regulated procedure is applied to the animal up to the time when the observations, or the collection of data (or other products) for a particular scientific purpose (usually a single experiment or test), are completed. This is the use which should be reported as a single procedure in Row 13 of the form. Continued use between more than one project licence protocol should be returned as a single procedure. Each re-use as identified in the project licence should be reported as additional procedure(s). 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.

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 one column at a time 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 will 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.

QUERIES

12. It is important that forms are completed as accurately as possible. 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.

- 0 the species is **not** so listed.
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*)

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 or commercial breeder).
3 If the animals were acquired from non-designated sources in the UK.
4 If the animals were acquired from other countries **within** the EU other than the UK (See list at LIST A, ROW 12 below).
5 If the animals were acquired from member countries of the Council of Europe which are parties to convention ETS 123 (excluding EU member states). See list below.
6 If the animals were acquired from other sources.

Non-EU ETS 123 countries (code 5 above)

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) e.g. respiratory and immune system
- 12 System not relevant (where the system or systems affected were not predictable or not relevant) e.g. safety studies

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 (including biological products, e.g. cells)

- 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).
- A31 Acute quantitative lethal concentration tests (LC50) (OECD 403 or 203).
- A32 Acute limit-setting, 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), usually 14 to 28 days duration.
- A36 Subchronic and chronic toxicity tests (e.g. OECD 408, 409, 411, 413, 452) 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 (OECD 406).**
- A44 Toxicokinetics (e.g. OECD 417)
- A45 Pyrogenicity tests
- A46 Biocompatibility tests
- A47 Enzyme induction for *in vitro* tests
- A48 Immunotoxicology tests
- A50 Other toxicology tests – these other tests may include collection of normal tissues such as blood for *in vitro* work, and investigative procedures not compatible with other codes.

LIST A, ROW 12

LEGISLATIVE REQUIREMENTS

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

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

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

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

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

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 & D, or 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 for 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

REMEMBER: Do not mix codes from lists A and B in the same column.

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 page 6, as well as the example on page 8 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, on page 6.
- 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 not 9. 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 not 9. 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 **codes B50-B65**

LIST B, ROW 12

PARTICULAR TECHNIQUES

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
- Only use these codes where the study was the main 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 7.

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 7 and 8.

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, 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 5).

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

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

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

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

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

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

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

Examples of counting, re-use and the use of some toxicology codes:

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

Column 1

The whole series of techniques were carried out for a particular purpose and were covered by the description in a single 19(b) protocol sheet of the project licence.

- Fifteen 8-week-old rats (Row 1 = R2 and Row 3 = 1)
- Not CITES listed (Row 2 = 0)
- Normal genetic status (Row 4 = 1)
- Purchased from a commercial breeder in the UK (Row 5 = 2)
- Surgical implantation of vascular cannulae with recovery from general anaesthesia (Row6 = 1), without the use of neuromuscular blocking agents (Row 7 = 0)
- Subsequently the animals were dosed with a potential drug for cancer therapy (Row8 = 2 and Row 9 = 11)
- Three timed blood samples are taken from the cannulae for a pharmacokinetic study (Row10 = A14)
- Finally the animals were killed by perfusion of fixative under general anaesthesia.

Column 2

- 40 genetically normal, six week old mice (Row1 = R1, Row 3 = 1 and Row 4 = 1)
- Purchased from a commercial breeder in the UK (Row 5 = 2)
- Used in a sub-acute quantitative toxicity test (28 days study) to provide data on a household product (Row 11 = A35)
- The study was needed to fulfil the requirements for safety evaluation of the product during the manufacturing process when material needs to be moved in bulk, i.e. the testing was required under the regulations relating to the safety of substances used in industry for production within the EU (Row 8 = 4, Row 9 = 12, Row 10 = A03 and Row 12 = A93).

Column 3

- 90 domestic cats used in feeding studies of feline nutrition (Row 1 = C1, Row 2 = 0, Row 3 = 1, Row 4 = 1 and Row 13 = 90)
- Last year 40 new cats were purchased from a designated source in the UK and used (Row 5 = 2).
- This year 50 more cats were purchased from the same source and used (Row 5 = 2).
- The regulated procedures do not involve general anaesthesia (Row 6 = 0).
- The project licence authorises re-use of the animals.
- The 50 cats purchased this year were used for the first time (Row 14 = 50).
- The 40 cats used last year were re-used in this experiment for the first time during this new calendar year (Row 15 = 40).

Further examples - breeding procedures

Columns 4 - 10

At the beginning of the calendar year, there were 10 pairs of genetically modified mice in a breeding colony for fundamental immunological research. The colony was maintained using heterozygous parents as homozygous offspring must be killed at five weeks of age due to an adverse phenotype. The breeding pairs had been included in the previous year's return for use in breeding procedures. During the course of the year 300 offspring were produced. All of these animals undergo local anaesthesia to remove the tip of the tail for genotyping. Row 6 = 2 (local anaesthesia) as code 3 (terminal anaesthesia) is only used where there was no prior use of an anaesthetic.

- 50 homozygous animals were killed before five weeks of age using a Schedule 1 method of killing and their tissues used for *in vitro* cell culture and further relevant research (Column 4). Note Row 8 = 1 to reflect their final use in accordance with paragraph 1(i) above.
- 25 homozygous animals were killed before five weeks of age using a Schedule 1 method of killing in accordance with the project licence end points (Column 5), and coded according to paragraph 2(i) above.
- 75 animals were found not to express the genotype of interest and were culled by a Schedule 1 method of killing (Column 6). Note the coding is the same as Column 5 except for Row 4 = 1 for normal genetic status.
- 30 heterozygous animals were retained as the future breeding nucleus (Column 7).
- 50 heterozygous animals were used in further procedures involving general anaesthesia with recovery but without neuromuscular blockade for dosing and sampling under procedures in the project licence under which they were bred (Column 8). Note Row 8 = 1 for fundamental research, Row 6 = 1 for recovery following general anaesthesia and Row 11 = B63 for genetically modified animals used in further regulated procedures, other than breeding.
- 50 heterozygous animals were killed by perfusion under terminal general anaesthesia in accordance with the project licence for further analysis (Column 9). Note Row 8 = 1 for fundamental research and Row 11 = B63.
- 10 heterozygous animals were moved to the project licence of a collaborator in the UK in order to set up their own breeding colony. In accordance with paragraph 1(iii) above, these 10 animals were not recorded by this licence, but would be reported by the licensee to whom they were sent.
- 10 heterozygous animals were exported, with appropriate Home Office authority, to a collaborator in another country. These were recorded in Column 10, in accordance with paragraph 2(v) above.

Note 1: The 20 animals of the original 10 pairs are not counted for the current calendar year, having been reported the previous year.

Note 2: The codes in Columns 5, 7 and 10 are identical. For the purpose of the returns the numbers could be added to give one column. However, this is not essential as they will be automatically totalled on the Home Office database.

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