APPENDIX B

Animals (Scientific Procedures) Act 1986

NOTES FOR RETURN OF PROCEDURES

For each licence, project licence holders should complete a separate form by 31 January for all regulated procedures on living animals started in the year (including the work of all personal licensees performing regulated procedures on their project) as part of the conditions for the licence. NB Failure to provide a return 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.

NOTES ON COMPLETING THE FORM – a checklist

(i) discard any previous versions of these guidance notes or of the form.

(ii) make sure you are clear what is meant by a 'regulated procedure' see definition below.

(iii) if you have carried out any work using harmful mutant or genetically modified animals, please first read Annex B at pages 6-8 of these guidance notes.

(iv) if the procedures started included the re-use of animals (irrespective of whether the first use was in 2009 or earlier) please first read the definitions of re-use under ROW 15 at page 5 of these guidance notes.

(v) 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, using the code lists at pages 2-3 of these guidance notes, entering only one code in any one box. Complete as many columns as necessary to describe fully the use of different groups of animals in a particular procedure. If a mistake is made and alterations are necessary, strike out the whole column and complete a fresh one.

(vi) each completed column should record all the procedures for any animal or group of animals of the same species which are described by that particular combination of codes. 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.

(vii) where procedures are carried out on multiple sites under a licence, please check that all procedures have been included.

(viii) please carry out the following consistency checks:

- ROW 1 Entries of R9, C9, U9, J9, T9, D1, M1, F1 – have you indicated the species used?
- ROW 3 Entry of 2 – larval/embryonic/foetal animals – entries at ROW 13, ROW 14, ROW 15 must be zero.
- ROW 5 Species at ROW 1 must be R1, R2, R3, R4, R5, L1, C2, C3, C4, C1, C5, P1-P9, T3 or (if row 4 entry of 2 or 3) either U2 or U4, otherwise enter zero.
- ROW 8 Entry of 9 means that ROW 11 entry must be B61, B62, or B64 (check definitions of these codes under List B ROW 11 code list on page 5 of these notes).
- ROW 10 Entry of B24 have you provided a separate note describing the procedure?
- ROW 11 Entry of A43 have you indicated the test used? Entries of B62-B63, is the entry 3 at ROW 4? Entries of B64-B65, is the entry 2 at ROW 4?
- the sum of ROW 14 and ROW 15 must not be higher than the number of procedures reported in ROW 13.

(ix) complete the declaration in SECTION 1, take a copy in case of queries, and return the form asap.

Definition of a regulated procedure

A 'regulated procedure' is defined by Section 2 (1) of the Act as 'any experimental of 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 http://www.archive.official-documents.co.uk/document/hoc/321/321.htm) before completing this section.

Queries

If you have any queries about how to complete this form please consult your Inspector.

THANK YOU FOR YOUR ASSISTANCE. **Further guidance and code lists overleaf** 

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
P2 marmoset, tamarin
P3 squirrel, owl or spider monkey
P4 other new world monkey ***(please append a note indicating species used)***
P5 macaque
P6 baboon
P7 other old world monkey ***(please append a note indicating species used)***
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 append a note indicating species used)***

AMPHIBIAN

M1 Any amphibian species ***(please append a note indicating species used)***

FISH

F1 Any fish species ***(please append a note indicating species used)***

CEPHALOPOD

F5 Octopus vulgaris

ROW 2: CITES

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).
Use this code for Zebra fish fry from 6 days post hatching and amphibia from the stage when 4 limbs have developed, including Axolotls.
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 B.

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).
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 B. 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
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 - please describe the procedure and its purpose in a separate note

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. Please describe the procedure and its purpose in a separate note.

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 - please describe the procedure and its purpose in a separate note

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 Rep. of Macedonia**
Azerbaijan	**Monaco**	**Turkey**
Bosnia and Hetzegovina	**Montenegro**	**Ukraine**
Croatia	**Norway**	
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)

Use of Genetically Modified or Harmful Mutant Animals

Please read Annex B (pages 6-8), 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 B.

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 B. Normal animals, which have not undergone any other regulated procedures, do not need to be accounted for – see Annex B.

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.

B79 For all other types of animal use, i.e. where GM or HM animals are not involved and the purpose is not production of biological materials, use code B79.

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 } Only use these codes where the study
B99 Physical trauma } was the main purpose of the procedure
B00 None of the above

ROW 13 : NUMBER OF PROCEDURES STARTED IN 2009

Please read definition of Procedure on page 1 before completing this row. Each separate use of one animal counts as one procedure. Only procedures started during the year should be included, and not procedures reported in returns for previous years that have continued into 2009.

Do not include foetal, larval or embryonic animals: enter '0' in ROW 13 for these animals i.e. if you have entered '2' at ROW 3. Also enter '0' in ROW 13 if you have entered 'R0' in ROW 1.

ROW 14 : NUMBER OF ANIMALS USED FOR THE FIRST TIME EVER IN 2009 (NEVER USED IN A PREVIOUS YEAR)

Where animals are used in more than one separate procedure (i.e. re-use; 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.

ROW 15 : NUMBER OF ANIMALS RE-USED IN 2009

In ROW 15 count the number of animals that were re-used (not the number of times they were re-used) in 2009, even if they were re-used before in 2008.

If the figure in ROW 13 (Number of procedures) exceeds the figure in ROW 14 (Number of animals used for the first time in 2009) then some animals must have been re-used.

Definition "Re-use" is a term used where, after completion of one series of regulated procedures, an animal is used again in the same or a different protocol, where a previously unused animal would have equally sufficed to meet the objectives of the second and subsequent use.

(See the HO Website for further guidance on the definition of "Re-Use": http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/guidance/use-con-animals?view=Standard&pubID=606442)

Example of re-use An animal is bled three times per year for the collection of normal blood, starting in 2008 and continuing in 2009. For the return on 2008 procedures, the entries for ROW 13, ROW 14, and ROW 15 would be 3, 1, 1, respectively.

For the return of 2009 procedures the entries for ROW 13, ROW 14, and ROW 15 would be 3, 0, 1, respectively.

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 6.

CHECKS ON ROW 13, ROW 14, ROW 15

Please check as follows:

- ROW 3 entry is 2, entries at ROW 13, ROW 14, ROW 15 must be zero
- ROW 13 entry is zero, entries at ROW 14, ROW 15 must also be zero
- Sum of entries in ROW 14 and ROW 15 must not exceed the entry in ROW 13.

ANNEX A

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).

ANNEX B

Explanation of how to code Genetically Modified and Harmful Mutant animals

ROW 4 Overall principles and definition

Harmful Mutants (HM), whether deliberately generated or spontaneously arising, are coded as 2 and Genetically Modified animals (GM), i.e Transgenics, Knockouts etc. and combinations of GM and HM, are coded as 3.

- animals should be counted only once in their lifetime.
- animals should be counted when they are born (or develop to the appropriate stage -see ROW 3), unless they have continued use beyond the breeding protocol, in which case animals should be counted for the final use only on the Return of Procedures for the Project Licence covering the final use (this may mean they are not counted in the year in which they are born).

Exclusions

- Do not count the mating of 2 adults as a procedure, regardless of the genetic status of the adults.
- Animals subjected to somatic mutation, eg. by vector mediated gene delivery, should be coded as for the starting status in ROW 4, eg. code as '1' (Normal animal) if they are wild type at the start of the protocol.

ROW 8 How to Code the Primary Purpose for the use of GM and HM animals

Record the primary purpose as "Breeding" (Code 9 in ROW 8) only for

- animals used solely for generation or maintenance of a GM or HM breeding colony, or
- for any animals bred but never used on subsequent protocols, and in these circumstances, GM animals should be coded B61 or B62 in ROW 11 whilst HM animals should be coded B64 in ROW 11.

When not to code as 'Breeding'

The primary purpose recorded at ROW 8 should be coded according to the final protocol, and not coded as 9, in all other circumstances (i.e. where GM and HM animals are bred and then used in a subsequent experimental protocol, whether on the same or a different project licence) – and correspondingly, GM animals should then be coded as B63 in ROW 11, whilst HM should be coded B65 in ROW 11.

ROW 11 How to code Production and Breeding

Harmful mutant and Genetically modified animal use generally falls under B Codes; rarely are they used in safety evaluation work where A codes would be applicable.

Code B79 should be used if none of the previous codes are applicable, ie. animals not used for production of biological materials and neither GM nor HM animals.

How to Code Common Scenarios:

Scenario	How to code		
	ROW 4 Genetic Status	**ROW 8 Primary Purpose**	**ROW 11 Production and breeding**
Generation of founders			
1. Normal animals used to generate founder colony	1	9	B61
2. **GM or HM** animals used to generate founder colony	2 or 3	9	B61
Offspring that are Normal animals and			
3. Not Biopsied	Do not count		
4. Biopsied	1	9	B61 if from founders. B62 or B64 if from breeding colony.
5. Used in further procedures e.g. as controls for GM and HM animals	1	1-8 based on further procedures Do not code as 9	B79
Offspring that are GM or HM offspring and			
6. Used exclusively for maintenance of breeding colony	2 or 3	9	B62 or B64
7. Intercurrent deaths or animals , not used for breeding or anything else. Killed by a Schedule 1 listed method.	2 or 3	9	B62 or B64
8. Animals, whether used for breeding or not, but afterwards killed by a Schedule 1 listed method and tissues used post mortem ie. scientific use made of the animal but outside ASPA	2 or 3	1-8 based on further use Do not code as 9	B62 or B64
9. Continued use on another protocol	2 or 3	1-8 based on further procedures Do not code as 9	B63 or B65

Scenario	How to code		
	ROW 4 Genetic Status	**ROW 8 Primary Purpose**	**ROW 11 Production and breeding**
GM or HM animals generated on one project licence but transferred to another PPL:			
10. If used only for breeding on the second PPL, count only on the originators return when born.	2 or 3	9	B62 or B64
11. If used in an experiment, do not count at all on the originators return, count on the recipient's final use protocol as appropriate	2 or 3	1-8 based on further procedures Do not code as 9	B63 or B65
12. GM or HM animals generated on a PPL but then exported, (released from ASPA eg. by a transfer form). Count on the originator's return	2 or 3	9	B62 or B64
Imported GM or HM animals			
13. Imported and used solely for breeding. Count in the year when first obtained.	2 or 3	9	B62 or B64
14. Imported and used in a non-breeding procedure	2 or 3	1-8 based on procedures	B63 or B65
Other scenarios:			
15. Used for production of biological material	1 or 2 or 3	1-8 based on procedures	B50 to B56 as appropriate
16. Normal mice crossed with GM or HM mice in breeding protocol	Do not count		
17. All other animals i.e. neither GM or HM, not used for the generation of founders and not used for production of biological materials	1	1-8 Not 9	B79