Instructions for completion of annual Returns of Procedures in the UK

These instructions have been adapted from the EU Commission Implementing Decision of 14 November 2012:

http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm

They apply to Returns of Procedures **completed in 2014.**

The Excel form should be completed (one form for each project licence held during the year), saved using the project licence number in the format 7001234 (i.e. replacing the '/' in 70/1234 with a zero) and sent to the Home Office at:

ROPReturns@homeoffice.gsi.gov.uk

Note: In contrast to earlier years, procedures will be counted when they end, not when they begin. **Procedures already begun in a previous year, and which have already been counted, but which end in 2014 or later, should be counted again when they end.**

Complete the preliminary questions on the first page.

Project details

Complete name, address and email as per project licence. Provide a telephone number where you can be contacted if we need to seek further information on this Return.

Complete the Establishment Licence number. This is shown on your project licence and can be obtained from the Home Office Liaison Contact or the Establishment Licence Holder.

Complete project licence number in the format 7001234 (i.e. replacing the '/' in 70/1234 with a zero).

The report year will already be completed. This return should contain details of all procedures **completed** during that year, regardless of when they started.

1. Were any procedures carried out and completed in the reported year?

   If 'No' then there is no need to complete the rest of this form.

   If 'Yes' then continue.

2. Were larval or embryonic forms only used?

   This refers to mammalian embryos between two-thirds of gestation and term (prior to birth), avian and reptile eggs from two-thirds of incubation

prior to hatching and larval forms of amphibia and fish fry prior to the free feeding stages.

If 'Yes' <u>only</u> these larval or embryonic forms were used (you did not use any postnatal forms or free feeding forms), there is no need to complete the rest of this form.

If 'No' and later stages were also used then continue to provide further details of those animals.

3. Were any animals used of species listed in Appendix 1 of CITES?

   If 'Yes' please provide details.

4. Were neuromuscular blocking agents used in any procedures during the previous year?

   If 'Yes' please answer the next question; if general anaesthesia was not used throughout the entire period of neuromuscular blockade then please provide details.

5. Rodenticide trials. Indicate if rodenticide trials were carried out under this project licence during the previous year. There is no need to provide further details of those trials.

<u>If you answered 'Yes' to question 1 above, then provide further details of procedures on the 'Procedure details' page.</u>

General

1. Data should be provided on each procedure, i.e. each use of an animal. If an animal has been used in more than one study or experiment, i.e. re-used, provide details on each use separately.
2. Choose only one option for each entry for each procedure. If necessary choose the 'best fit'. If you select one of the 'Other' options provide additional details.
3. Do not count animals unless used on ***regulated procedures*** (these are procedures authorised on a project licence). Animals killed by Schedule 1 (or other PEL-permitted) methods of killing, for example, for tissue collection, are not counted unless they were genetically altered and bred under project licence authorities.
4. Surplus animals that are killed are not included, unless they have been produced under project licence authority, for example, genetically altered animals.
5. Mammals, birds and reptiles are only counted if they are born alive (including by caesarean section) or hatch.
6. Larval forms are counted from the free feeding stage. Zebra fish fry kept under conventional conditions should be counted from five days post-fertilisation.

7. Cephalopods should be counted from the stage at which the animal becomes capable of independent feeding. This will be immediately post-hatching for octopus and squid, and from around seven days post-hatching for cuttlefish.
8. In the case of very small animals, such as fish fry, an estimate of total numbers used is acceptable.
9. In exceptional cases where a single study involving a large group of animals extends over two calendar years, and data collection is not complete until the end of the entire study (as opposed to at the time of death of each individual subject) it is acceptable to count all procedures in the year in which the last procedure ends, i.e. at the end of the study. This must be agreed with your Home Office Inspector in advance.

Data categories

Do not leave any relevant cells blank.

NB. Some cells will be necessarily blank depending on previous entries

Use the drop down lists. Only use free entry for the 'Other ...' columns if this is relevant.

A single row can be completed for any number of procedures if all the details are identical, for example:

- a single animal, one procedure;
- a single experiment, a number of procedures; or
- a group of studies, many procedures.

However, if the number is large (see below) for a single cell you may need to explain the reason in the 'Comments' column.

Column E
Animal species

Select the species from the drop down list.

All cephalopods, regardless of species, should be reported under the one heading 'Cephalopod'.

Column F
Other species

If you selected 'Other' in Column E then you must provide details of the actual species here, otherwise leave blank.

Column G
Number of animals

This is the number of procedures or uses, i.e. the number of animals used in a particular experiment or study.

Note: If an animal is used on a long study, extending over more than one calendar year, it will not be counted until that procedure ends.

If more than 99 non-human primates or 999 of any other species are entered in a single cell then you should add a note in the 'Comments' column.

If the large number applies to a single study then briefly explain why so many animals were used.

If multiple studies have been combined in one entry, and this is the reason for the large number, simply state e.g. 'Combination of studies'.

If a large number of animals used on the same breeding protocol has been entered on one line, simply state "breeding".

Column H
Re-use

Each animal should be reported at the end of each procedure for which it was used. Most animals are used only once, and 'No' should be entered in this column. If the animals have been used before (at any time, not just in the reported year) enter 'Yes' in this column.

Re-use must have been authorised in the project licence.

Note: For the purpose of statistical reporting a single procedure or use of an animal extends from the time when the first technique was applied to the animal until the completion of data collection, observations or achievement of educational objective.

In most cases this means a single protocol.

Note: '*Continued use*', when a single experiment or study extends over more than one licence or protocol, constitutes a single use; it *is not re-use*. In this case the end user should report the entire procedure, even if it began on another project licence, and the initiator of the study does not report such procedures.
This includes when genetically altered animals are bred under one licence then transferred to a second licence (possibly at a different establishment) for the remainder of the study; the breeder would not report these animals, they would be returned under the end user's project licence return.

If in any doubt as to which classification is correct consult your Home Office Inspector.

Column I
Place of birth: all species except non-human primates

Only provide details of the place of birth for the first use of an animal. If animals have been re-used, this column is disabled.

Note: The *place of birth, not the source* of the animal, is required. A registered breeder can be any breeder within the EU who is registered under Article 20 of Directive 2010/63 EU.

The 'Rest of Europe' means Council of Europe* countries and Israel.

Column J
Place of birth: Non-human primates only

Additional detail is required for non-human primates (NHPs). This column will be disabled for all other species.
Note: The *place of birth, not the source* of the animal, is required.

Asia includes China.
America includes North, Central and South America.
Africa includes Mauritius.
'Elsewhere' includes Australasia. Provide details of place of birth if this category is used.

For any species other than primates, leave this column blank.

Column K
Non-human primate generation

Leave blank for any species other than primates.

If sourced from a colony that is not self-sustaining then 'F0', 'F1' or 'F2 or greater' should be used.

If the colony has become self-sustaining then you should enter every animal from this colony as 'Self-sustaining colony' regardless of generation of the individual animal, and not as 'F0', 'F1' or 'F2 or greater'.

Column L
Genetic status

1 'Not genetically altered' includes all wild-type animals, including inbred strains.
This includes genetically normal parents of genetically altered offspring and genetically normal offspring.

Genetically altered animals (GAAs)' includes all genetically modified animals (transgenic, knock-out and other forms of genetic alteration) and mutations, whether naturally occurring or induced.

2 'GAAs without a harmful phenotype' includes all GAAs that do not show an overtly harmful phenotype, or individuals of strains on which a formal

welfare assessment has been carried out, which showed the strain to have either no phenotype or a phenotype of sub-threshold severity.

This category can apply to any purpose given in Column N. It includes animals used for the creation of new strains, animals used in further procedures and animals used for maintenance of established colonies.

3 'GAAs with a harmful phenotype' includes all GAAs that exhibit an overtly harmful phenotype. This category can apply to any purpose given in Column N. It includes animals used for the creation of new strains, animals used in further procedures and animals used for maintenance of established colonies, but only if a harmful phenotype manifests.
If the strain is known to have a harmful phenotype but some individuals do not exhibit that phenotype, then do not use this category, use 'Genetically altered animals without a harmful phenotype' for those individuals.

Column M
Creation of a new genetically altered animal line

This category includes all animals involved in creation of a novel line up to the point where a new line is considered 'established'. See separate Home Office *Advice on Regulation and Severity Assessment of GAA*:

This category includes the offspring from crossing of established lines of genetically altered animals; this is considered to lead to the creation of a new line. Crossing of a genetically altered animal with a wild type will not normally be considered to create a new line unless it is expected that the change of background will adversely affect the phenotype.

Wild-type offspring that are not subjected to regulated procedures (for example, regulated genotyping methods) should not be reported.

If 'Yes' is used in this column, the purpose given in Column N **should not** be 'Maintenance of established lines'. The purpose given in Column N should be the primary scientific purpose for which the new strain was being created.

It excludes animals of established strains on which formal welfare assessment has been carried out and excludes long-standing strains of GAAs even if no formal welfare assessment has been carried out.

Column N
Purpose

Choose the best fit for the purpose of the study. This will generally be the purpose given in the project licence.

1. Basic research includes studies of a fundamental nature, including physiology.

Studies that are designed to add knowledge about the normal and abnormal structure, functioning and behaviour of living organisms and the environment. These include fundamental studies in toxicology.

Investigation and analysis focused on a better or fuller understanding of a subject, phenomenon, or a basic law of nature instead of on a specific practical application of the results.

Any animals used for the creation of a new genetically altered animal (GAA) line (including the crossing of two established lines) intended to be used for the purposes of basic research should be recorded according to the purpose they are being created for and should be reported as 'Yes' in Column M 'Creation of a new genetic line'.

Basic research categories

i. 'Oncology'. Any research studying oncology regardless of target system.
ii. 'Nervous system'. Includes neuroscience, peripheral or central nervous system, psychology.
iii. 'Sensory organs' (skin, eyes, ears).
You should report studies on the nose under 'Respiratory system' and those on the tongue under 'Gastrointestinal system including liver'.
iv. 'Multisystemic'. Should only include research where more than one system is the primary interest, for example, some infectious disease, but excluding oncology.
v. 'Ethology/animal behaviour/animal biology' category covers both animals in the wild and in captivity with the primary goal of learning more about that specific species.
vi. 'Other'. Research not related to an organ/system listed above or is not organ/system specific.

Animals used for the production and maintenance of infectious agents, vectors and neoplasms or other biological material, and animals used for the production of antibodies, but excluding production of monoclonal antibodies by ascites method (which is covered under category 'Regulatory use and routine production by type'), should be reported in the appropriate fields of categories 'Basic research studies' or 'Translational and applied research'. Where the purpose could be reported under the two categories you should only report the main purpose.

2. Translational and applied research includes discovery toxicology, investigations prior to formal regulatory studies and method development. It includes efficacy testing during the development of new medicinal products. It **does not** include studies required for regulatory submissions.

Any animals used for the creation of a new genetically altered animal line (including the crossing of two established lines) intended to be used for the purposes of translational and applied research should be recorded according to the purpose they are being created for and should be reported as 'Yes' in Column L 'Creation of a new genetic line'.

Translational and applied research categories

i. 'Human cancer'. You should include any applied research studying human cancer, regardless of the target.
ii. 'Human infectious disorders'. You should include any applied research studying human infectious disorders, regardless of the target.
iii. Any regulatory use of animals is to be excluded, such as regulatory carcinogenicity studies.
iv. You should report studies on disorders of the nose under 'Human respiratory disorders' and those of the tongue under 'Human gastrointestinal disorders including liver'.
v. 'Diagnosis of diseases' includes animals used in direct diagnosis of diseases such as rabies, botulism, but excluding those covered under regulatory use.
vi. Non-regulatory toxicology' covers discovery toxicology and investigations prior to formal the regulatory studies and method development. This category does not include studies required for regulatory submissions (preliminary studies, maximum tolerated dose).
vii. Animal welfare should include studies as per Article 5(b)(iii) of Directive 2010/63 EU.

3. Protection of the natural environment in the interests of the health or welfare of human beings or animals

This includes studies aimed at investigating and understanding phenomena such as environmental pollution, loss of biodiversity and epidemiology studies in wild animals.

This excludes the regulatory use of animals for ecotoxicology purposes.

4. Preservation of species. This includes research where the primary purpose is preservation of a species.

5. Higher education or training for the acquisition, maintenance or improvement of vocational skills.

This includes training to acquire and maintain practical competence in techniques as required under Article 23(2) of Directive 2010/63 EU.

6. Forensic enquiries. This includes tests as part of forensic investigations and the production of materials, for example, antisera, for use in forensic investigations where this is not being carried out to meet a regulatory requirement.

7. Maintenance of colonies of established genetically altered animals not used in other procedures.

This includes the animals required for the maintenance of colonies of genetically altered animals (GAAs); the intended purpose for which the line is being bred is not recorded (in contrast to “creation of new lines of GAA”).

It includes genetically altered breeding stock and surplus animals.

This category should be used for established or long-standing strains of GAAs. You should report the creation of new strains under the purpose for which they are being created.

It excludes:

- Genetically altered animals bred under project authorisation but killed using Sch1 listed methods and their tissues are used for research, these should be reported under the purpose for which their tissues are used.
- Live animals that go on to be used in further regulated procedures.

8. Regulatory use and routine production.

Use of animals in procedures carried out with a view to satisfying legal requirements for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed.

This includes tests carried out on products/substances for which no regulatory submission is made, i.e. tests performed on those products/substances (for which a regulatory submission was foreseen) that are ultimately deemed unsuitable for the market by the developer, and thus fail to reach the end of the development process.

This category also includes animals used in the manufacturing process of products *if that manufacturing process requires regulatory approval* (for example, animals used in the manufacturing of serum-based medicinal products should be included within this category).

The efficacy testing during the development of new medicinal products is excluded and you should report this under ‘Translational and applied research’.

Categories of Regulated use and routine production

Routine production. Applies to manufacturing processes requiring regulatory approval.

PR51 Routine production/blood-based products: Blood products including serum and polyclonal antisera by established methods.

PR52 Routine production/monoclonal antibodies: Covers the production of monoclonal antibodies by ascites. This excludes immunisation of animals for hybridoma production, which should be captured under ‘Basic research’ or ‘Translational and applied research’ under the appropriate category.

PR53 Other forms of production of biological material to meet regulatory standards or requirements that use live animals.

Note that production of antibodies, antigens etc. using routine or standard methods but not to meet a regulatory requirement should be reported under ‘Basic research’, ‘Translational and applied research’ etc. as appropriate.

Quality control (including batch safety and potency testing)
Quality control includes animals used in the testing of purity, stability, efficacy, potency and other quality control parameters of the final product and its constituents, and any controls carried out during the manufacturing process for registration purposes, to satisfy any other national or international regulatory requirements or to satisfy the in-house policy of the manufacturer. This includes pyrogenicity testing.

PR61 (Quality control) Batch safety testing. Batch safety testing excludes pyrogenicity testing.
PR62 (Quality control) Pyrogenicity testing.
PR63 (Quality control) Batch potency testing.
PR64 (Quality control) Other quality controls.

PR71 (Regulatory use) Other efficacy and tolerance testing
Efficacy testing of biocides and pesticides is covered under this category as well as the tolerance testing of additives in animal nutrition.

Toxicity and other safety testing including pharmacology by test type
Includes safety evaluation of products and devices for human medicine and dentistry and veterinary medicine. Covers studies carried out on any product or substance to determine its potential to cause any dangerous or undesirable effects in humans or animals as a result of its intended or abnormal use, manufacture or as a potential or actual contaminant in the environment.

Choose the most appropriate test description.

Immunotoxicology studies should be covered under ‘Repeated dose toxicity’.

Kinetics (pharmacokinetics, toxicokinetics, residue depletion): If toxicokinetics is performed as part of the regulatory repeat dose toxicity study, you should report it under ‘Repeated dose toxicity’.

Safety testing in the food and feed area includes testing of drinking water (including target animal safety testing).

Target animal safety: This is testing to ensure that a product for a specific animal can be used safely on that species (excluding batch safety testing, which is covered under ‘Quality control’).

Column O Other

If you have chosen any of the ‘Other’ categories of testing you should provide details in this column.

Column P Testing by legislation

The legislative requirement should be entered as per the *intended primary* use.

For example, water quality: If concerning tap water for drinking you should report it under ‘Food legislation’.

Column Q

If you have chosen ‘Other’ in Column P provide details in this column.

Column R Legislative requirements (origin of the legislation)

This category allows identification of the level of harmonisation between different legislative requirements. The determining factor is not *who* requests the test to be carried out but which legislation is satisfied, giving priority to the widest level of harmonisation.

Where national legislation is derived from EU legislation, only legislation satisfying EU requirements is to be chosen. Legislation satisfying EU requirements also includes any international requirement that at the same time satisfies EU requirements (such as testing to the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), the Organisation for Economic Cooperation and Development (OECD), and European Pharmacopoeia monographs).

Legislation satisfying national requirements only (within the EU) is to be chosen only when the test is carried out to satisfy the requirements of one or more EU Member States; not necessarily the one in which the work is being carried out. However, there is no equivalent requirement in the EU.

Legislation satisfying non-EU requirements only is to be chosen when there is no equivalent requirement to carry out the test to satisfy EU requirements.

Column S Severity

You should give the actual severity that animals used on the procedure experienced, **not** the severity classification or limit of the protocol.

Refer to the Home Office *Advice note on actual severity assessment* for detailed guidance on this:

Assign the severity to one of the categories:

- sub-threshold;
- mild;
- moderate;
- severe; or
- non-recovery.

If different animals on a study suffered different levels of severity you should enter a separate line for each class of severity.

Sub-threshold severity is chosen when a procedure was regulated, and therefore it was considered that the procedure might have caused mild, moderate or severe suffering, but which in retrospect did not.

Whenever the severe classification is exceeded, whether pre-authorised or not, you should report these animals and their use normally like any other use, and under the severe category. You should add a commentary giving:

- the species;
- numbers;
- whether prior exemption was authorised;
- the details of the use; and
- the reasons why the severe classification was exceeded.

Column U Techniques of special interest

Household product testing. Choose this option only if the work involved safety testing of substances used in the household.

Use of ascites models for monoclonal antibody production. Choose this option only if monoclonal antibodies were harvested from ascites fluid. Do not use this option for immunisation of animals to generate monoclonal antibodies.

Tobacco. Choose this option only for the safety testing of products containing tobacco, not for use of nicotine or other compounds found in tobacco and not for use of tobacco in disease models.

Alcohol. Choose this option only for the safety testing of products containing alcohol, not for use of alcohol as a research tool or in disease models.

Version 3 Jan 2015

*Council of Europe Countries

Albania, Andorra, Armenia, Azerbaijan, Bosnia & Herzegovina, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Montenegro, Norway, Russian Federation, San Marino, Serbia, Switzerland, Montenegro, Turkey, Ukraine

Annex - Code lists

PLEASE NOTE: These lists are for information only. To ensure the data you provide is not incorrect, you should still only select the codes available to you in the drop-down lists in the form. What appears in the drop-down lists, in some instances, will depend on what you selected in the preceding columns.

Animal Species (Column E)

[A1] Mice (Mus musculus)

[A2] Rats (Rattus norvegicus)

[A3] Guinea-Pigs (Cavia porcellus)

[A4] Hamsters (Syrian) (Mesocricetus auratus)

[A5] Hamsters (chinese) (Cricetulus griseus)

[A6] Mongolian gerbil (Meriones unguiculatus)

[A7] Other Rodents (other Rodentia)

[A8] Rabbits (Oryctolagus cuniculus)

[A9] Cats (Felis catus)

[A10] Dogs (Canis familiaris)

[A11] Ferrets (Mustela putorius furo)

[A12] Other carnivores (other Carnivora)

[A13] Horses, donkeys & cross-breeds (Equidae)

[A14] Pigs (Sus scrofa domesticus)

[A15] Goats (Capra aegagrus hircus)

[A16] Sheep (Ovis aries)

[A17] Cattle (Bos primigenius)

[A18] Prosimians (Prosimia)

[A19] Marmoset and tamarins (eg. Callithrix jacchus)

[A20] Cynomolgus monkey (Macaca fascicularis)

[A21] Rhesus monkey (Macaca mulatta)

[A22] Vervets Chlorocebus spp. (usually either pygerythrus or sabaeus)

[A23] Baboons (Papio spp.)

[A24] Squirrel monkey (eg. Saimiri sciureus)

[A25] Other species of non-human primates (other species of Ceboidea and Cercopithecoidea)

[A26] Apes (Hominoidea)

[A27] Other Mammals (other Mammalia)

[A28] Domestic fowl (Gallus gallus domesticus)

[A29] Other birds (other Aves)

[A30] Reptiles (Reptilia)

[A31] Rana (Rana temporaria and Rana pipiens)

[A32] Xenopus (Xenopus laevis and Xenopus tropicalis)

[A33] Other Amphibians (other Amphibia)

[A34] Zebra fish (Danio rerio)

[A35] Other Fish (other Pisces)

[A36] Cephalopods (Cephalopoda)

Place of birth (Column I)

Animals born in the UK at a registered breeder

Animals born in the UK NOT at a registered breeder

[O1] Animals born in the EU at a registered breeder

[O2] Animals born in the EU but not at a registered breeder

[O3] Animals born in rest of Europe

[O4] Animals born in rest of world

Non-human Primate Source (Column J)

[NHPO1] Animals born at a registered breeder within EU

[NHPO2] Animals born in rest of Europe

[NHPO3] Animals born in Asia

[NHPO4] Animals born in America

[NHPO5] Animals born in Africa

[NHPO6] Animals born elsewhere

NHP Generation (Column K)

[NHPG1] F0

[NHPG2] F1

[NHPG3] F2 or greater

[NHPG4] Self-sustaining colony

Genetic status (Column L)

[GS1] Not genetically altered

[GS2] Genetically altered without a harmful phenotype

[GS3] Genetically altered with a harmful phenotype

Purpose (Column N)

[PB1] (Basic Research) Oncology

[PB2] (Basic Research) Cardiovascular Blood and Lymphatic System

[PB3] (Basic Research) Nervous System

[PB4] (Basic Research) Respiratory System

[PB5] (Basic Research) Gastrointestinal System including Liver

[PB6] (Basic Research) Musculoskeletal System

[PB7] (Basic Research) Immune System

[PB8] (Basic Research) Urogenital/Reproductive System

[PB9] (Basic Research) Sensory Organs (skin, eyes and ears)

[PB10] (Basic Research) Endocrine System/Metabolism

[PB11] (Basic Research) Multisystemic

[PB12] (Basic Research) Ethology / Animal Behaviour /Animal Biology

[PB13] (Basic Research) Other

[PT21] (Trans/Appl Research) Human Cancer

[PT22] (Trans/Appl Research) Human Infectious Disorders

[PT23] (Trans/Appl Research) Human Cardiovascular Disorders

[PT24] (Trans/Appl Research) Human Nervous and Mental Disorders

[PT25] (Trans/Appl Research) Human Respiratory Disorders
[PT26] (Trans/Appl Research) Human Gastrointestinal Disorders including Liver
[PT27] (Trans/Appl Research) Human Musculoskeletal Disorders
[PT28] (Trans/Appl Research) Human Immune Disorders
[PT29] (Trans/Appl Research) Human Urogenital/Reproductive Disorders
[PT30] (Trans/Appl Research) Human Sensory Organ Disorders (skin, eyes and ears)
[PT31] (Trans/Appl Research) Human Endocrine/Metabolism Disorders
[PT32] (Trans/Appl Research) Other Human Disorders
[PT33] (Trans/Appl Research) Animal Diseases and Disorders
[PT34] (Trans/Appl Research) Animal Welfare
[PT35] (Trans/Appl Research) Diagnosis of diseases
[PT36] (Trans/Appl Research) Plant diseases
[PT37] (Trans/Appl Research) Non-regulatory toxicology and ecotoxicology
[PE40] Protection of the natural environment in the interests of the health or welfare of human beings or animals
[PS41] Preservation of species
[PE42] Higher education or training for the acquisition, maintenance or improvement of vocational skills
[PF43] Forensic enquiries
[PG43] Maintenance of colonies of established genetically altered animals, not used in other procedures
[PR51] (Regulatory use/ Routine production) Blood based products
[PR52] (Regulatory use/ Routine production) Monoclonal antibodies
[PR53] (Regulatory use/ Routine production) Other
[PR61] (Regulatory use/ Quality control) Batch safety testing
[PR62] (Regulatory use/ Quality control) Pyrogenicity testing
[PR63] (Regulatory use/ Quality control) Batch potency testing
[PR64] (Regulatory use/ Quality control) Other quality controls
[PR71] (Regulatory use) Other efficacy and tolerance testing
[PR81] (Regulatory use/Toxicity and../Acute and sub-acute) LD50, LC50
[PR82] (Regulatory use/Toxicity and../Acute and sub-acute) Other lethal methods
[PR83] (Regulatory use/Toxicity and../Acute and sub-acute) Non lethal methods
[PR84] (Regulatory use/Toxicity and..) Skin irritation/corrosion

[PR85] (Regulatory use/Toxicity and..) Skin sensitisation
[PR86] (Regulatory use/Toxicity and..) Eye irritation/corrosion
[PR87] (Regulatory use/Toxicity and../Repeated dose toxicity) up to 28 days
[PR88] (Regulatory use/Toxicity and../Repeated dose toxicity) 29 - 90 days
[PR89] (Regulatory use/Toxicity and../Repeated dose toxicity) > 90 days
[PR90] (Regulatory use/Toxicity and..) Carcinogenicity
[PR91] (Regulatory use/Toxicity and..) Genotoxicity
[PR92] (Regulatory use/Toxicity and..) Reproductive toxicity
[PR93] (Regulatory use/Toxicity and..) Developmental toxicity
[PR94] (Regulatory use/Toxicity and..) Neurotoxicity
[PR95] (Regulatory use/Toxicity and..) Kinetics
[PR96] (Regulatory use/Toxicity and..) Pharmaco-dynamics (incl safety pharmacology)
[PR97] (Regulatory use/Toxicity and..) Phototoxicity
[PR98] (Regulatory use/Toxicity and../Ecotoxicity) Acute toxicity
[PR99] (Regulatory use/Toxicity and../Ecotoxicity) Chronic toxicity
[PR100] (Regulatory use/Toxicity and../Ecotoxicity) Reproductive toxicity
[PR101] (Regulatory use/Toxicity and../Ecotoxicity) Endocrine activity
[PR102] (Regulatory use/Toxicity and../Ecotoxicity) Bioaccumulation
[PR103] (Regulatory use/Toxicity and../Ecotoxicity) Other
[PR104] (Regulatory use/Toxicity and..) Safety testing in food and feed area
[PR105] (Regulatory use/Toxicity and..) Target animal safety
[PR106] (Regulatory use/Toxicity and..) Other

Testing by legislation (Column P)
[LT1] Legislation on medicinal products for human use
[LT2] Legislation on medicinal products for veterinary use and their residues
[LT3] Medical devices legislation
[LT4] Industrial chemicals legislation
[LT5] Plant protection product legislation
[LT6] Biocides legislation
[LT7] Food legislation including food contact material
[LT8] Feed legislation including legislation for the safety of target animals, workers and environment
[LT9] Cosmetics legislation
[LT10] Other

Legislative requirements (Column R)

[LO1] Legislation satisfying EU requirements

[LO2] Legislation satisfying national requirements only [within EU]

[LO3] Legislation satisfying Non-EU requirements only

Actual severity (Column S)

Sub-threshold

[SV1] Non-recovery

[SV2] Mild

[SV3] Moderate

[SV4] Severe

Techniques of Special Interest (Column U)

None

Household product testing

Use of ascites models for monoclonal antibody production

Tobacco

Alcohol