

# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2020/569

of 16 April 2020

**establishing a common format and information content for the submission of the information to be reported by Member States pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes and repealing Commission Implementing Decision 2012/707/EU**

*(notified under document C(2020) 2179)*

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes <sup>(1)</sup>, and in particular Article 43(4) and Article 54(4) thereof,

Whereas:

- (1) Following the amendments provided for in Regulation (EU) 2019/1010 of the European Parliament and of the Council <sup>(2)</sup>, Directive 2010/63/EU now requires Member States to submit non-technical project summaries of authorised projects, and any updates thereto, by electronic transfer to the Commission. In order to enable the Commission to establish and maintain a central database for those summaries and updates and to ensure that meaningful searches can be carried out on that data, a uniform presentation of those summaries and updates is needed. Therefore, templates should be established for submitting the non-technical project summaries, and any updates thereto, and Member States should be required to upload such summaries and updates to the database established by the Commission.
- (2) Directive 2010/63/EU also requires Member States to submit information on the implementation of that Directive, as well as statistical information on the use of animals in procedures, by electronic transfer to the Commission.
- (3) On the basis of the information submitted by the Member States on the implementation of Directive 2010/63/EU, the Commission services are to publish and regularly update a Union overview. Directive 2010/63/EU also requires the Commission services to make the statistical data submitted by the Member States and a summary report thereof publicly available on an annual basis. To enable the Commission to satisfy both of those requirements, the content of that information should be established by laying down information categories.
- (4) As regards information on implementation, the information categories to be reported on should correlate with the relevant requirements of Directive 2010/63/EU. As regards statistical information, it is necessary to specify the statistical data input categories available in the searchable, open access database established by the Commission pursuant to Directive 2010/63/EU.
- (5) In order to improve transparency and to reduce the administrative burden, Member States should be required to use the database established by the Commission for the purposes of submitting the information on the implementation of Directive 2010/63/EU as well as the statistical information on the use of animals in procedures.

<sup>(1)</sup> OJ L 276, 20.10.2010, p. 33.

<sup>(2)</sup> Regulation (EU) 2019/1010 of the European Parliament and of the Council of 5 June 2019 on the alignment of reporting obligations in the field of legislation related to the environment, and amending Regulations (EC) No 166/2006 and (EU) No 995/2010 of the European Parliament and of the Council, Directives 2002/49/EC, 2004/35/EC, 2007/2/EC, 2009/147/EC and 2010/63/EU of the European Parliament and of the Council, Council Regulations (EC) No 338/97 and (EC) No 2173/2005, and Council Directive 86/278/EEC (OJ L 170, 25.6.2019, p. 115).

- (6) The content and format of the detailed information to be submitted by Member States on the methods considered to be at least as humane as those contained in Annex IV to Directive 2010/63/EU should be specified in a way that allows the list of methods for the killing of animals contained in that Annex to be kept up to date. Therefore, it is appropriate to lay down a template allowing for the submission of information on the type of method, the species concerned and the justification for granting an exemption, and to require Member States to use that template.
- (7) The empowerments on which this Decision is based are closely linked as they both deal with the reporting of information by Member States under Directive 2010/63/EU. Given this substantive link, and to ensure a consistent and coherent approach, it is appropriate to adopt a single Decision establishing all requirements falling within the scope of those empowerments. It is therefore necessary to replace Commission Implementing Decision 2012/707/EU <sup>(3)</sup>, in which the common format for the submission of the information referred to in Article 54 of Directive 2010/63/EU is laid down, by a new Implementing Decision based on both Article 43(4) and Article 54(4) of Directive 2010/63/EU. Implementing Decision 2012/707/EU should therefore be repealed.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Animals in Science Committee,

HAS ADOPTED THIS DECISION:

#### *Article 1*

For the purposes of the second sentence of Article 43(3) of Directive 2010/63/EU, Member States shall submit the information specified in Annex I to this Decision using the database established by the Commission in accordance with the third sentence of Article 43(4) of that Directive. The non-technical project summaries, and updates thereto, shall correspond to the templates laid down in Annex I to this Decision.

#### *Article 2*

For the purposes of Article 54(1) of Directive 2010/63/EU, Member States shall submit the information specified in Annex II to this Decision using the database established by the Commission in accordance with the first sentence of the third subparagraph of Article 54(2) of that Directive.

#### *Article 3*

For the purposes of Article 54(2) of Directive 2010/63/EU, Member States shall submit the information specified in Annex III to this Decision using the database established by the Commission in accordance with the first sentence of the third subparagraph of Article 54(2) of that Directive.

#### *Article 4*

For the purposes of Article 54(3) of Directive 2010/63/EU, Member States shall submit the information specified in Annex IV to this Decision using the template laid down in that Annex.

#### *Article 5*

Implementing Decision 2012/707/EU is repealed with effect from 17 April 2020. References to the repealed Decision shall be construed as references to this Decision and read in accordance with the correlation table in Annex V.

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<sup>(3)</sup> Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 320, 17.11.2012, p. 33).

*Article 6*

This Decision is addressed to the Member States.

Done at Brussels, 16 April 2020.

*For the Commission*  
Virginijus SINKEVIČIUS  
*Member of the Commission*

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## ANNEX I

## PART A

**Template for the submission of non-technical project summaries referred to in article 43(1) of directive 2010/63/EU**

|   |   |
|---|---|
| <b>Title of the project</b>   |   |
| <b>Duration of project</b><br>(in months)   |   |
| Key Words (maximum of 5) <sup>(1)</sup>   |   |
| <b>Purpose of project</b> <sup>(2)</sup><br>(multiple choices possible)   | <ul style="list-style-type: none"> <li>— Basic research <sup>(3)</sup></li> <li>— Translational and applied research <sup>(3)</sup></li> <li>— Regulatory use and routine production: <ul style="list-style-type: none"> <li>— Quality control (including batch safety and potency testing)</li> <li>— Other efficacy and tolerance testing</li> <li>— Toxicity and other safety testing including pharmacology</li> <li>— Routine production</li> </ul> </li> <li>— Protection of the natural environment in the interests of the health or welfare of human beings or animals</li> <li>— Preservation of species</li> <li>— Higher education</li> <li>— Training</li> <li>— Forensic enquiries</li> <li>— Maintenance of colonies of genetically altered animals, not used in other procedures</li> </ul> |
| <b>Objectives and predicted benefits of the project</b>   |   |
| Describe the objectives of the project (for example, addressing certain scientific unknowns, or scientific or clinical needs).  |   |
| What are the potential benefits likely to derive from this project? Explain how science could be advanced, or humans, animals or environment may ultimately benefit from the project. Where applicable, differentiate between short-term benefits (within the duration of the project) and long-term benefits (which may accrue after the project is finished). |   |
| <b>Predicted harms</b>  |   |
| In what procedures will the animals typically be used (for example, injections, surgical procedures)? Indicate the number and duration of these procedures.   |   |

|   |                                      |                                |   |             |                                       |               |
|---|--------------------------------------|--------------------------------|---|-------------|---------------------------------------|---------------|
| <p>What are the expected impacts/ adverse effects on the animals, for example pain, weight loss, inactivity/ reduced mobility, stress, abnormal behaviour, and the duration of those effects?</p>   |                                      |                                |   |             |                                       |               |
| <p>What species and numbers of animals are expected to be used? What are the expected severities and the numbers of animals in each severity category (per species)?</p>  | <p>Species <sup>(4)</sup></p>        | <p>Estimated total numbers</p> | <p>Estimated numbers per severity</p>                               |             |                                       |               |
|   |                                      |                                | <p>Non-recovery</p>   | <p>Mild</p> | <p>Moderate</p>                       | <p>Severe</p> |
|   |                                      |                                |   |             |                                       |               |
|   |                                      |                                |   |             |                                       |               |
|   |                                      |                                |   |             |                                       |               |
|   |                                      |                                |   |             |                                       |               |
| <p>What will happen to the animals kept alive at the end of the procedure? <sup>(5)</sup> <sup>(6)</sup></p>  | <p>Estimated number to be reused</p> |                                | <p>Estimated number to be returned to habitat/ husbandry system</p> |             | <p>Estimated number to be rehomed</p> |               |
| <p>Please provide reasons for the planned fate of the animals after the procedure.</p>  |                                      |                                |   |             |                                       |               |
| <p><b>Application of the Three Rs</b></p>   |                                      |                                |   |             |                                       |               |
| <p><b>1. Replacement</b><br/>State which non-animal alternatives are available in this field and why they cannot be used for the purposes of the project.</p>   |                                      |                                |   |             |                                       |               |
| <p><b>2. Reduction</b><br/>Explain how the numbers of animals for this project were determined. Describe steps that have been taken to reduce the number of animals to be used, and principles used to design studies. Where applicable, describe practices that will be used throughout the project to minimise the number of animals used consistent with scientific objectives. Those practices may include e.g. pilot studies, computer modelling, sharing of tissue and reuse.</p> |                                      |                                |   |             |                                       |               |

|  |                 |                                   |                                |                     |
|--|-----------------|-----------------------------------|--------------------------------|---------------------|
| <p><b>3. Refinement</b><br/>Give examples of the specific measures (e.g., increased monitoring, post-operative care, pain management, training of animals) to be taken, in relation to the procedures, to minimise welfare costs (harms) to the animals. Describe the mechanisms to take up emerging refinement techniques during the lifetime of the project.</p> |                 |                                   |                                |                     |
| <p>Explain the choice of species and the related life stages.</p>  |                 |                                   |                                |                     |
| <p><b>Project selected for Retrospective Assessment <sup>(7)</sup></b></p>   | <p>Deadline</p> | <p>Contains severe procedures</p> | <p>Uses non-human primates</p> | <p>Other reason</p> |

(<sup>1</sup>) Including scientific terms which may consist of more than 5 individual words and excluding species and purposes entered elsewhere in the document

(<sup>2</sup>) To be provided via a dropdown menu

(<sup>3</sup>) List of purposes in accordance with statistical reporting categories and sub-categories in Annex III to this Decision

(<sup>4</sup>) Species in accordance with statistical reporting categories in Annex III to this Decision, with an additional option of 'non-specified mammal' to safeguard anonymity in exceptional cases

(<sup>5</sup>) Species to be populated from the previous response to select from under the relevant category (proportions)

(<sup>6</sup>) Multiple choices per species possible

(<sup>7</sup>) Multiple choices possible; applicable to those MS where this information is required by the legislation

## PART B

**Template for the submission of an update to the non-technical project summary referred to in article 43(2) of directive 2010/63/EU**

| <b>Title (as per Non-technical Project Summary)</b>  |                                      |   |                                     |                     |               |
|--|--------------------------------------|---|-------------------------------------|---------------------|---------------|
| <b>Reason for Retrospective Assessment <sup>(1)</sup></b>  |                                      | <b>Using non-human primates</b>               | <b>Contains 'severe' procedures</b> | <b>Other reason</b> |               |
| <b>Explain 'Other reason'</b>  |                                      |   |                                     |                     |               |
| <b>Achievement of objectives</b>   |                                      |   |                                     |                     |               |
| <p>Explain briefly whether, and to what extent, the objectives set out in the authorised project have been achieved. Provide reasons if objectives have not been attained.<br/>         Have there been any other significant findings?<br/>         What benefits have resulted from the work to date, and are further benefits expected?<br/>         Have the results of this project been disseminated, including where hypotheses are not proven? If so, describe how. If not, indicate how and when results are expected to be publicised.</p> |                                      |   |                                     |                     |               |
| <b>Harms</b>   |                                      |   |                                     |                     |               |
| <b>Species <sup>(2)</sup></b>  | <b>Total numbers of animals used</b> | <b>Numbers of animals per actual severity</b> |                                     |                     |               |
|  |                                      | <b>Non-recovery</b>                           | <b>Mild</b>                         | <b>Moderate</b>     | <b>Severe</b> |
|  |                                      |   |                                     |                     |               |
|  |                                      |   |                                     |                     |               |
|  |                                      |   |                                     |                     |               |
|  |                                      |   |                                     |                     |               |
|  |                                      |   |                                     |                     |               |
| <p>How do numbers of animals used and actual severities compare with those estimated? Where the actual numbers are higher than the estimated numbers, please provide an explanation. Where the actual numbers are lower, please provide an explanation unless that difference is a result of Reduction or Refinement?</p>  |                                      |   |                                     |                     |               |
| <p>How does the fate of animals kept alive at the end of the study compare with the estimated fate? Please provide an explanation.</p>   |                                      |   |                                     |                     |               |
| <b>Any elements that may contribute to further implementation of the Three Rs:</b>   |                                      |   |                                     |                     |               |
| <b>1. Replacement</b>  |                                      |   |                                     |                     |               |
| <p>With the knowledge obtained from this project, have any new approaches that could replace some or all of the use of animals in similar projects been identified/developed (including the development/validation of new <i>in vitro</i> or <i>in silico</i> techniques)?</p>   |                                      |   |                                     |                     |               |

**2. Reduction**

With the knowledge obtained from this project, could the experimental design be improved to enable any further reduction of the use of animals, and if so, how?  
Provide an explanation where numbers of animals used were lower than those originally estimated.

**3. Refinement**

Provide an explanation where the actual severities were lower than those originally estimated.  
With the new knowledge obtained from this project, are the animal models used still the most appropriate? Please specify per species/model, where appropriate.  
List any novel refinements introduced during the project to reduce harm to the animals or to improve their welfare.  
What are the potential opportunities for further refinement in the future, for example, emerging technologies, techniques, improved welfare assessment methods, earlier endpoints, housing/husbandry measures?

**4. Other**

How are the findings for further implementation of the Three Rs disseminated?

Additional comments

(<sup>1</sup>) Multiple choices possible

(<sup>2</sup>) Species in accordance with statistical reporting categories in Annex III to this Decision, with an additional option of 'non-specified mammal' to safeguard anonymity in exceptional cases



## ANNEX II

## INFORMATION REFERRED TO IN ARTICLE 54(1) OF DIRECTIVE 2010/63/EU

- A. NATIONAL MEASURES ON THE IMPLEMENTATION OF DIRECTIVE 2010/63/EU
- Provide information on changes made to national measures regarding the implementation of Directive 2010/63/EU since the previous report.
- B. STRUCTURES AND FRAMEWORK
1. **Competent authorities (Article 59 of Directive 2010/63/EU)**
- Explain the framework for competent authorities, including the numbers and types of authorities as well as their respective tasks, and explain the measures taken to ensure compliance with the requirements of Article 59(1) of Directive 2010/63/EU.
2. **National committee (Article 49 of Directive 2010/63/EU)**
- Explain the structure and operation of the national committee, and the measures taken to ensure compliance with the requirements of Article 49 of Directive 2010/63/EU.
3. **Education and training of personnel (Article 23 of Directive 2010/63/EU)**
- Provide information on the minimum requirements referred to in Article 23(3) of Directive 2010/63/EU; describe any additional educational and training requirements for staff coming from another Member State.
4. **Project evaluation and authorisation (Articles 38 and 40 of Directive 2010/63/EU)**
- Explain the processes of project evaluation and authorisation, and the measures taken to ensure compliance with the requirements of Articles 38 and 40 of Directive 2010/63/EU.
- C. OPERATION
1. **Projects**
- 1.1. *Granting of project authorisation (Articles 40 and 41 of Directive 2010/63/EU)*
- 1.1.1. In respect of each year, provide numbers for the following:
- (a) all authorisation decisions and authorised projects;
  - (b) multiple generic projects, as provided for in Article 40(4) of Directive 2010/63/EU, categorised as one of the following types:
    - projects to satisfy regulatory requirements;
    - projects using animals for production purposes;
    - projects using animals for diagnostic purposes;
  - (c) the authorisation decisions where the deadline of 40 days has been extended in accordance with Article 41(2) of Directive 2010/63/EU.
- 1.1.2. For the purposes of point (c), provide summary information, covering the five-year reporting cycle, on the reasons where the deadline of 40 days has been extended.
- 1.2. *Retrospective assessment, non-technical project summaries (Article 38(2)(f), Articles 39 and 43 of Directive 2010/63/EU)*
- 1.2.1. Explain the measures taken to ensure compliance with the requirements of Article 43(1) of Directive 2010/63/EU and indicate whether there is a requirement for non-technical project summaries to specify that a project is to undergo retrospective assessment (Article 43(2) of Directive 2010/63/EU).

1.2.2. In respect of each year, provide the number of projects authorised that are to undergo a retrospective assessment in accordance with Article 39(2) of Directive 2010/63/EU and the number of projects authorised that are to undergo a retrospective assessment under Article 38(2)(f) of that Directive. Categorise each of those projects as one of the following types:

- (a) projects using non-human primates;
- (b) projects involving procedures classified as 'severe';
- (c) projects using non-human primates and involving procedures classified as 'severe';
- (d) other projects that are to undergo a retrospective assessment.

1.2.3. Provide summary information, covering the five-year reporting cycle, on the nature of projects selected for retrospective assessment in accordance with Article 38(2)(f) of Directive 2010/63/EU that are not automatically subject to retrospective assessment in accordance with Article 39(2).

## 2. **Animals bred for use in procedures (Articles 10, 28 and 30 of Directive 2010/63/EU)**

2.1. Provide the species and numbers of animals that were bred and born (including by Caesarean section) for use in procedures and, having never been used in any procedures, were killed during the calendar year immediately preceding that in which the five-year report is submitted.

2.1.1. Include animals killed for organs or tissues and animals from the creation and maintenance of genetically altered (GA) animal lines, which are not covered in the annual statistics pursuant to Article 54(2) of Directive 2010/63/EU.

2.1.2. Categorise these animals as one of the following types:

- (a) genetically normal animals not providing organs and/or tissues;
- (b) genetically normal animals providing organs and/or tissues;
- (c) GA animals providing organs and/or tissues;
- (d) genetically normal animals (wild type offspring) as a result of the creation of a new GA line;
- (e) animals from the maintenance of a GA line covering all GA and wild type offspring of both harmful and non-harmful phenotype.

2.1.3. The category referred to in point (a) excludes animals as a result of a creation of a new GA line and from the maintenance of a GA line, which are to be reported in the categories referred to in points (d) and (e) respectively;

2.1.4. The categories referred to in points (b) and (c) include animals as a result of creation of a new GA line and from maintenance of a GA line, when providing organs and/or tissues;

2.1.5. The categories referred to in points 2.1.2(d) and (e) exclude the following animals, which are to be reported in the annual statistics pursuant to Article 54(2) of Directive 2010/63/EU:

- (a) animals that were genotyped using invasive methods;
- (b) animals from a harmful phenotype line that experienced adverse effect.

2.2. Explain the measures taken to ensure compliance with the requirements of Articles 10 and 28 of Directive 2010/63/EU when sourcing non-human primates.

## 3. **Exemptions**

3.1. Provide summary information, covering the five-year reporting cycle, on circumstances under which exemptions were granted in accordance with Article 10(3), the second subparagraph of Article 12(1) and Article 33(3) of Directive 2010/63/EU.

- 3.2. Provide information for the same period on any exceptional circumstances as referred to in Article 16(2) of that Directive where the reuse of an animal was authorised after a procedure in which the suffering of that animal was assessed to have been severe.

4. **Animal welfare body (Articles 26 and 27 of Directive 2010/63/EU)**

Explain the measures taken to ensure compliance with the requirements regarding the structure and functioning of animal welfare bodies of Articles 26 and 27 of Directive 2010/63/EU.

- D. PRINCIPLES OF REPLACEMENT, REDUCTION AND REFINEMENT

1. **Principle of replacement, reduction and refinement (Articles 4 and 13 and Annex VI of Directive 2010/63/EU)**

- 1.1. Provide information on the measures taken to ensure that the principles of (a) replacement, (b) reduction and (c) refinement are satisfactorily addressed within authorised projects in accordance with Articles 4 and 13 of Directive 2010/63/EU.

- 1.2. Provide information on the measures taken to ensure that the principles of (a) reduction and (b) refinement are satisfactorily addressed during housing and care in breeding and supplying establishments in accordance with Article 4 of Directive 2010/63/EU.

2. **Avoidance of duplication (Article 46 of Directive 2010/63/EU)**

Explain how duplication of procedures is avoided to comply with Article 46 of Directive 2010/63/EU.

3. **Tissue sampling of genetically altered animals (Articles 4, 30 and 38 of Directive 2010/63/EU)**

- 3.1. In respect of tissue sampling for the purposes of genetic characterisation carried out with and without project authorisation, provide representative information and numbers regarding species, methods and their related actual severity. That information shall be provided only for the calendar year immediately preceding that in which the five-year report is submitted.

- 3.2. List the criteria used to ensure that the information in point 3.1 is representative.

- 3.3. Provide information on efforts made to refine tissue sampling methods.

- E. ENFORCEMENT

1. **Authorisation of breeders, suppliers and users (Articles 20 and 21 of Directive 2010/63/EU)**

- 1.1. In respect of each year, provide numbers for all active authorised breeders, suppliers and users separately.

- 1.2. Provide summary information, covering the five-year reporting cycle, on reasons for suspensions or withdrawals of authorisations of breeders, suppliers and users.

2. **Inspections (Article 34 of Directive 2010/63/EU)**

- 2.1. In respect of each year, provide numbers for inspections, broken down by announced and unannounced.

- 2.2. Provide summary information, covering the five-year reporting cycle, on main findings of inspections.

- 2.3. Explain the measures taken to ensure compliance with the requirements of Article 34(2) of Directive 2010/63/EU.

3. **Withdrawals of project authorisation (Article 44 of Directive 2010/63/EU)**

Provide summary information, covering the five-year reporting cycle, on reasons for the withdrawal of project authorisations.

4. **Penalties (Article 60 of Directive 2010/63/EU)**

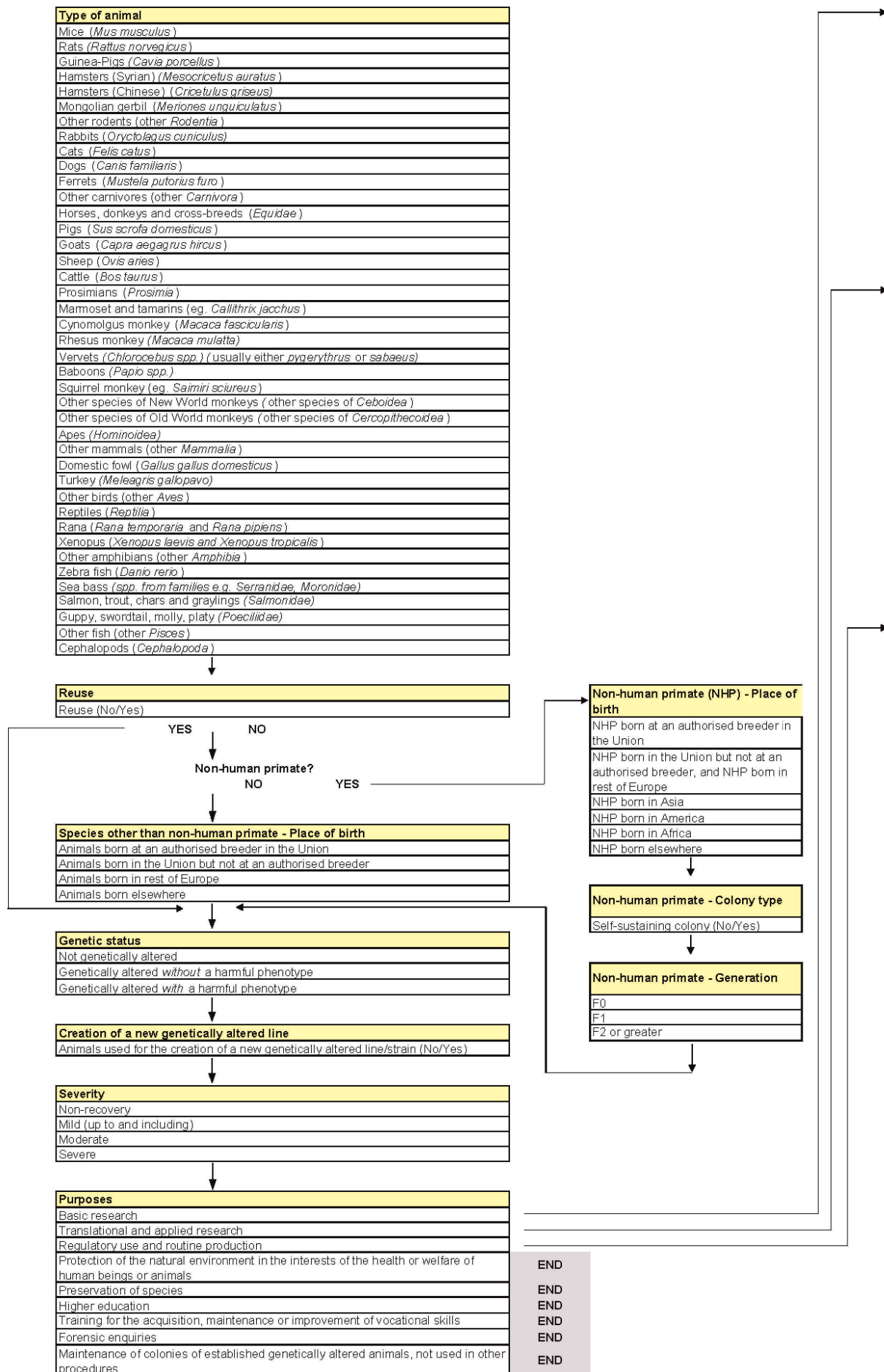
4.1. Provide summary information, covering the five-year reporting cycle, on the nature of the following:

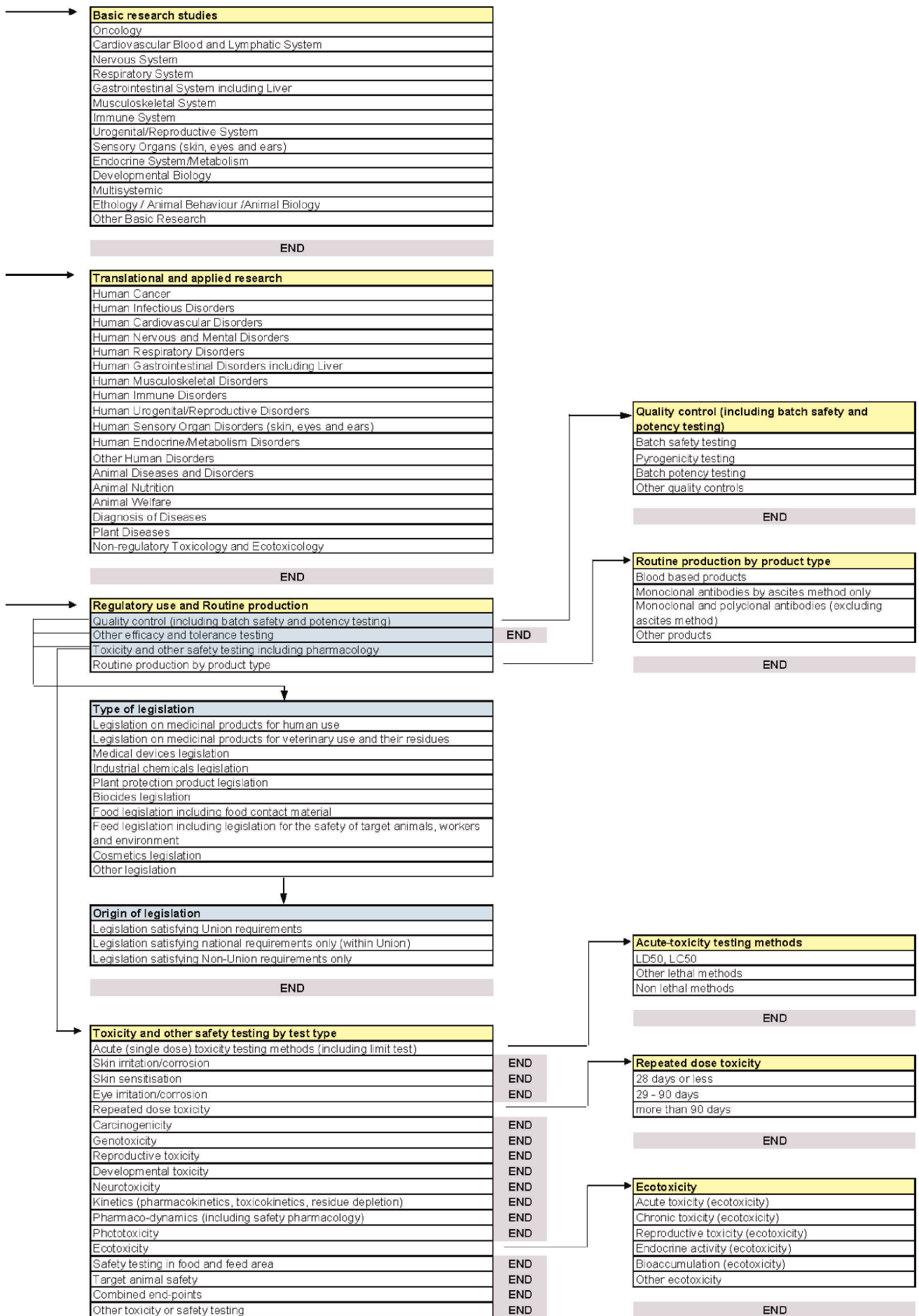
- (a) infringements;
  - (b) administrative actions in response to infringements;
  - (c) legal actions in response to infringements.
-

*ANNEX III*

PART A

**Flowchart of statistical data input categories under article 54(2) of directive 2010/63/EU**





## PART B

**Information referred to in article 54(2) of directive 2010/63/EU**

## A. GENERAL PROVISIONS

1. The data shall be reported on each use of an animal.
2. When reporting data for an animal, only one option within a category shall be selected.
3. Animals killed for organs and tissues
  - 3.1. Animals killed for organs and tissues, as well as sentinels, are excluded from the provision of annual statistical data, unless any of the following applies:
    - (a) the killing is performed under a project authorisation using a method not included in Annex IV to Directive 2010/63/EU;
    - (b) the animal has gone through a previous intervention, which has been above the threshold of minimum pain, suffering, distress and lasting harm prior to being killed;
    - (c) the animal is from a genetically altered animal line with an intended harmful phenotype and which has expressed the harmful phenotype before being killed for organs and tissues.
  - 3.2. Other animals killed for organs and tissues (those not reported in the annual statistics) are reported as part of the five-year implementation report in line with Annex II to this Decision.
4. Animals that are bred and killed without being used in a procedure
  - 4.1. Animals that are bred and killed without being used in a procedure shall not be included in the annual statistical data apart from the following animals:
    - (a) genetically altered animals with an intended and exhibited harmful phenotype;
    - (b) those animals that have been genotyped (genetic characterisation/tissue sampling) using an invasive method, which was not carried out for the purposes of identification/marketing of the animal.
  - 4.2. For the purposes of point 4.1(b), an invasive method shall be a method which may cause the animal pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.
  - 4.3. The animals that are bred and killed without being used in a procedure shall be reported in accordance with Annex II of this Decision as part of the five-year implementation report.
5. Genetically normal animals born during the creation of a new genetic line shall be excluded from the provision of annual statistical data and shall instead be reported as part of the five-year implementation report in line with Annex II of this Decision, unless such animals have been genotyped using an invasive method.
6. Larval forms of animals shall be included once they become capable of independent feeding.
7. Foetal and embryonic forms of mammalian species shall be excluded from the provision of annual statistical data. Only animals that are born, including by Caesarean section, and live are to be counted. When studies involve both mother and offspring, the mother shall be reported when she has been subject to a procedure above the threshold of minimum pain, suffering, distress and lasting harm. Offspring shall be reported when they are an integral part of the procedure.
8. Where the use of an animal in a procedure results in severe pain, suffering or distress that is long-lasting and cannot be ameliorated, whether pre-authorised or not, the animal shall be reported under the 'severe' category. Commentary shall be inserted in the Member State narrative pursuant to Section C of this Annex covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.
9. Data relating to animals used in a procedure shall be reported for the year in which that procedure ends. In the case of studies running across two calendar years, all of the animals may be accounted for together in the year in which the last procedure ends if this exemption to annual reporting is authorised by the competent authority. For projects running longer than two calendar years, data on animals shall be reported for the year the animal is killed or dies.



10. Where the 'Other' categories are used, an entry shall be made in the narratives to provide a further breakdown of the content of 'Other'.
11. Genetically altered animals
  - 11.1. For the purposes of statistical reporting, 'genetically altered animals' refer to either of the following:
    - (a) genetically modified (such as transgenic, knock-out and other forms of genetic alteration) and induced mutant animals (irrespective of the type of mutation);
    - (b) animals with spontaneous deleterious mutations maintained for research for that specific genotype.
  - 11.2. Genetically altered animals shall be reported in any of the following cases:
    - (a) when used for the creation of a new line;
    - (b) when used for the maintenance of an established line with an intended and exhibited harmful phenotype (see section B.10.7);
    - (c) when used in procedures other than maintenance of a line.
  - 11.3. All animals carrying the genetic alteration shall be reported during the creation of a new line. In addition, those used for superovulation, vasectomy, embryo implantation shall be reported (these may or may not be genetically altered themselves).
  - 11.4. Genetically normal animals (wild type offspring) produced as a result of creation of a new genetically altered line shall not be reported in annual statistics, unless the animal has been genotyped (genetic characterisation/tissue sampling) using an invasive method which was not carried out for the purposes of identification/marketing of the animal. Genetically normal animals (wild type offspring) not reported in annual statistics are covered in the five-year implementation report as described in Annex II.
  - 11.5. In the category 'Purposes' as set out in Part A of this Annex, the animals used for the creation of a new genetically altered line shall be reported in the respective category for which the line is being created (generally expected to be 'basic research' or 'translational and applied research').
  - 11.6. A new strain or line of genetically altered animals is considered to be 'established' where transmission of the genetic alteration is stable, which will be a minimum of two generations, and a welfare assessment has been completed.
  - 11.7. The welfare assessment will determine if the newly created line is expected to have an intended harmful phenotype and, if this is the case, the animals from this point onwards shall be reported under category 'Maintenance of colonies of established genetically altered animals, not used in other procedures' – or, if appropriate, in the other procedures they are being used for. Such animals include, amongst others, those that require a specific bio-secure environment (for example, special housing arrangements to protect animals that are particularly sensitive to infection as a consequence of the gene alteration) or additional care beyond that required for conventional animals to maintain their health and well-being.
  - 11.8. If the welfare assessment concludes that the line is not expected to have a harmful phenotype, its breeding falls outside the scope of a procedure and no longer needs to be reported. Such animals include, amongst others, inducible and cre-lox lines, which require an active intervention for the harmful phenotype to be expressed.
  - 11.9. 'Maintenance of colonies of established genetically altered animals, not used in other procedures'
    - 11.9.1. This category contains the animals required for the maintenance of colonies of genetically altered animals of established lines with an intended harmful phenotype and which have exhibited pain, suffering, distress or lasting harm as a consequence of the harmful genotype. The intended purpose for which the line is being maintained is not recorded.
    - 11.9.2. This category also includes genetically altered animals during maintenance of an established line, irrespective of whether the line is of intended non-harmful or harmful phenotype, that have been subject to invasive genotyping (genetic characterisation/tissue sampling). See section B.10.7.

- 11.10. All genetically altered animals which are used in other procedures (not for the creation or maintenance of a genetically altered line) shall be reported under their respective purposes (the same way as any non-genetically altered animal). These animals may or may not exhibit a harmful phenotype.
- 11.11. Genetically altered animals, expressing a harmful phenotype, and killed for their organs and tissues, shall be reported under the respective primary purposes for which the organs/tissues were used.

B. DATA INPUT CATEGORIES

The sections below follow the order of the categories and related headings in the flow chart laid down in Part A.

1. **Type of animal**

---

Mice (*Mus musculus*)

---

Rats (*Rattus norvegicus*)

---

Guinea-Pigs (*Cavia porcellus*)

---

Hamsters (Syrian) (*Mesocricetus auratus*)

---

Hamsters (Chinese) (*Cricetulus griseus*)

---

Mongolian gerbil (*Meriones unguiculatus*)

---

Other rodents (other *Rodentia*)

---

Rabbits (*Oryctolagus cuniculus*)

---

Cats (*Felis catus*)

---

Dogs (*Canis familiaris*)

---

Ferrets (*Mustela putorius furo*)

---

Other carnivores (other *Carnivora*)

---

Horses, donkeys and cross-breeds (*Equidae*)

---

Pigs (*Sus scrofa domesticus*)

---

Goats (*Capra aegagrus hircus*)

---

Sheep (*Ovis aries*)

---

Cattle (*Bos taurus*)

---

Prosimians (*Prosimia*)

---

Marmoset and tamarins (eg. *Callithrix jacchus*)

---

Cynomolgus monkey (*Macaca fascicularis*)

---

Rhesus monkey (*Macaca mulatta*)

---

Vervets (*Chlorocebus spp.*) (usually either *pygerythrus* or *sabaeus*)

---

Baboons (*Papio spp.*)

---

Squirrel monkey (eg. *Saimiri sciureus*)

---

Other species of New World monkeys (other species of *Ceboidea*)

---

Other species of Old World monkeys (other species of *Cercopithecoidea*)

---

Apes (*Hominoidea*)

---

Other mammals (other *Mammalia*)

---

---

Domestic fowl (*Gallus gallus domesticus*)

---

Turkey (*Meleagris gallopavo*)

---

Other birds (other *Aves*)

---

Reptiles (*Reptilia*)

---

Rana (*Rana temporaria* and *Rana pipiens*)

---

Xenopus (*Xenopus laevis* and *Xenopus tropicalis*)

---

Other amphibians (other *Amphibia*)

---

Zebra fish (*Danio rerio*)

---

Sea bass (spp. from families e.g. *Serranidae*, *Moronidae*)

---

Salmon, trout, chars and graylings (*Salmonidae*)

---

Guppy, swordtail, molly, platy (*Poeciliidae*)

---

Other fish (other *Pisces*)

---

Cephalopods (*Cephalopoda*)

---

- 1.1. Fish shall be reported from the stage of independent feeding when the gut is open end to end and the fish would normally take food.
- 1.2. The time at which fish feed independently is different for each species and in many cases dependent on the temperature at which they are kept. Temperature should be set to maintain optimal welfare, as determined by the person responsible for the welfare and care of the animals and for species specific information in coordination with the designated veterinarian. Zebrafish larvae, which are kept at approximately + 28 °C shall be reported 5 days post fertilisation.
- 1.3. Due to the small size of some fish and cephalopod species, the count may be done on the basis of estimation.
- 1.4. All cephalopod species shall be reported under the heading 'cephalopod' from the stage at which the animal becomes capable of independent feeding, that is to say immediately after hatching.

## 2. Reuse

---

Reuse (No/Yes)

---

### 2.1. General

- 2.1.1. Each use of the animal shall be reported at the end of each procedure.
- 2.1.2. Information on the place of birth and for non-human primates also the generation and information on whether the animal was obtained from a self-sustaining colony shall only be reported for naïve animals, that is to say animals used for the first time. For reused animals, this information is therefore not recorded.
- 2.1.3. Any subsequent categories shall show the number of uses of animals in procedures. These numbers cannot be cross referenced with the total numbers of naïve animals.
- 2.1.4. The actual suffering of the animal in the procedure shall be reported. In some cases this could be influenced by a previous use. However, the severity will not always increase in a subsequent use and in some cases may even decrease as a result (habituation). Therefore, the actual severity to be reported shall always be determined on a case-by-case basis taking account of any impact from previous uses.

## 2.2. Reuse versus continued use

For the purposes of determining whether there is a 'reuse', the following shall apply:

- 2.2.1. A single use is the use of one animal for a single scientific/experimental/educational/training purpose. A single use extends from the time when the first technique is applied to the animal until the completion of data collection, observations or achievement of educational objective. This is usually a single experiment, test or training of a technique.
- 2.2.2. A single use may contain a number of steps (techniques) all necessarily related to achieve a single outcome and which require the use of the same animal.
- 2.2.3. Examples of preparation for the purposes of continued use include:
- (a) surgical techniques (such as cannulation, implantation of telemetry, ovariectomy, castration, hypophysectomy);
  - (b) non-surgical techniques (such as feeding modified diets, induction of diabetes, induction of transgene expression);
  - (c) breeding of genetically altered animals of harmful phenotype;
  - (d) genetic characterisation using an invasive method (which was not carried out for the purposes of identification/marketing of the animal) and where an animal of that genotype is required for the next step.
- 2.2.4. When the prepared animal is used in the procedure intended for it, the entire procedure, including any preparation (regardless of the location this has taken place) is reported at the end taking into account the severity associated with the preparation. For example, for the breeding of a genetically altered animal and its end use, the reporting shall take into account the severity associated with all the steps (for example, the effect of the phenotype, if expressed; genetic characterisation, if performed; and end use).
- 2.2.5. The use of an animal is only reported once at the end of the complete procedure including where the preparatory steps described in point 2.2.3 and the end use have been carried out under separate projects.
- 2.2.6. Where a prepared animal is not subsequently used for a scientific purpose, the establishment in which the animal is killed shall report the preparation as an independent use in the statistics as per the intended purpose, provided that the preparation of the animal has been above the threshold of minimum pain, suffering, distress and lasting harm. However, if this preparation concerns maintenance of a genetically altered animal line, the criteria by which animals are reported are provided for in section B.10.7.
- 2.2.7. If the animal has been genotyped (genetic characterisation/tissue sampling) as part of a routine verification in a genetically altered breeding colony of an established line to confirm that the genotype has not varied from the intended genetic background and that animal is later used in another procedure, not requiring that particular genotype, that use is considered reuse and all such uses shall be reported separately in the statistics, that is to say:
- (a) first use under 'maintenance of the established genetically altered line' with the severity related to the actual severity experienced by the animal as the result of the invasive genotyping, and
  - (b) as reuse under the specific purpose the animal is used for.

## 3. **Species other than non-human primate – Place of birth**

---

Animals born at an authorised breeder in the Union

---

Animals born in the Union but not at an authorised breeder

---

Animals born in rest of Europe

---

Animals born in elsewhere

---

- 3.1. Origin is based on the place of birth, that is to say 'born in' and not according to where the animal is supplied from.
- 3.2. 'Animals born at an authorised breeder in the Union' refers to animals born at breeders authorised and registered under Article 20 of Directive 2010/63/EU.
- 3.3. 'Animals born in the Union' but not at an authorised breeder includes, amongst others, wild animals, farm animals (unless the breeder is authorised under Article 20 of Directive 2010/63/EU), as well as any exemptions granted under Article 10(3) of Directive 2010/63/EU.
- 3.4. 'Animals born in the rest of Europe' includes, amongst others, animals born in Switzerland, Turkey, Russia and Israel, and groups together all animals, irrespective of whether they have been bred in registered breeding establishments or other establishments, and includes, amongst others, animals that have been captured in the wild.
- 3.5. 'Animals born elsewhere' groups together all animals, irrespective of whether they have been bred in registered breeding establishments or other establishments, and includes, amongst others, animals that have been captured in the wild.

#### 4. **Non-human primate (NHP) – Place of birth**

---

NHP born at an authorised breeder in the Union

---

NHP born in the Union but not at an authorised breeder, and NHP born in rest of Europe

---

NHP born in Asia

---

NHP born in America

---

NHP born in Africa

---

NHP born elsewhere

---

- 4.1. Origin is based on the place of birth, that is to say 'born in' and not the place where the animal is supplied from.
- 4.2. 'NHP born at an authorised breeder in the Union' (and Norway) refers to NHP born at breeders as authorised and registered under Article 20 of Directive 2010/63/EU.
- 4.3. 'NHP born in the Union but not at an authorised breeder, and NHP born in rest of Europe' includes, amongst others, animals born in Switzerland, Turkey, Russia and Israel.
- 4.4. 'NHP born in Asia' includes, amongst others animals born in China.
- 4.5. 'NHP born in America' refers to animals born in the North, Central and South America.
- 4.6. 'NHP born in Africa' includes also animals born in Mauritius.
- 4.7. 'NHP born elsewhere' includes also animals born in Australasia. The origins of NHP born elsewhere shall be reported.

#### 5. **Non-human primate – Colony type**

---

Self-sustaining colony (No/Yes)

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'Self-sustaining colony' covers non-human primates obtained from colonies in which animals are bred only within the colony or sourced from other self-sustaining colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans.

## 6. **Non-human primate – Generation**

---

F0

---

F1

---

F2 or greater

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- 6.1. 'F0' refers to animals that are captured from the wild.
- 6.2. 'F1' refers to animals that are born in captivity to one, or two parents, that were captured from the wild.
- 6.3. 'F2 or greater' refers to animals that are born in captivity to parents both of which were themselves born in captivity.

## 7. **Genetic status**

---

Not genetically altered

---

Genetically altered *without* a harmful phenotype

---

Genetically altered *with* a harmful phenotype

---

- 7.1. 'Not genetically altered' refers to all animals that have not been genetically altered, including also genetically normal parent animals used for the creation of a new genetically altered animal line/strain.
- 7.2. 'Genetically altered without a harmful phenotype' refers to
- (a) animals used for the creation of a new line, carrying the genetic alteration but exhibiting no harmful phenotype;
  - (b) genetically altered animals used in other procedures (not for creation or maintenance) but exhibiting no harmful phenotype.
- 7.3. 'Genetically altered with a harmful phenotype' refers to
- (a) animals used for the creation of a new line and exhibiting a harmful phenotype;
  - (b) those used for maintaining an established line with an intended harmful phenotype and exhibiting a harmful phenotype;
  - (c) genetically altered animals used in other procedures (not for creation or maintenance) and exhibiting a harmful phenotype.

## 8. **Creation of a new genetically altered line**

---

Animals used for the creation of a new genetically altered line/strain (No/Yes)

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Animals used for the creation of a new genetically altered line/strain identifies animals which are used for the creation of a new genetically altered line/strain, separating from other animals used for the purposes of 'basic research' or 'translational and applied research'. This includes the crossing of different lines to create a new genetically altered line where the phenotype of the new line cannot be determined prospectively as non-harmful.

## 9. Severity

---

Non-recovery

---

Mild (up to and including)

---

Moderate

---

Severe

---

9.1. Actual severity shall be reported for each animal individually by reference to the most severe effects experienced by that animal during the course of the entire procedure. Those effects can occur during any of the steps (not necessarily the last) of a multi-step procedure. Actual severity may be higher or lower than the classification predicted prospectively. Cumulative suffering shall also be considered when assigning actual severity.

9.2. Severity categories

9.2.1. **Non-recovery** – Animals, which have undergone a procedure that has been performed entirely under general anaesthesia and from which the animals have not recovered consciousness shall be reported as 'Non-recovery'. This also includes the situation where animals have failed to recover consciousness from anaesthesia during the first step of a planned recovery procedure.

9.2.2. **Mild (up to and including)** – Animals, which have undergone a procedure as a result of which the animals have experienced short-term mild pain, suffering or distress shall be reported as 'Mild' This includes situations where there has been no significant impairment of the well-being or general condition of the animals.

This category shall also include animals used in an authorised project, but which have ultimately not been observed to have experienced a level of pain, suffering, distress or lasting harm equivalent to that caused by the introduction of a needle in accordance with good veterinary practice with the exception of animals required for the maintenance of colonies of genetically altered animals of established lines with an intended harmful phenotype and which have not exhibited pain, suffering, distress or lasting harm as a consequence of the harmful genotype.

9.2.3. **Moderate** – Animals, which have undergone a procedure as a result of which the animals have experienced short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that cause moderate impairment of the well-being or general condition of the animals, shall be reported as 'Moderate'.

9.2.4. **Severe** – Animals, which have undergone a procedure as a result of which the animals have experienced severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as procedures that have caused severe impairment of the well-being or general condition of the animals shall be reported as 'Severe'.

9.2.5. If the 'Severe' classification is exceeded, whether pre-authorised or not, these animals and their use are to be reported as 'Severe'. Commentary shall be added in the 'Member State' narrative in section C of this Annex. In such cases, the following shall be reported: species, numbers, whether prior exemption was authorised, details of the use and reasons why the 'Severe' classification was exceeded.

9.3. Animals found dead

9.3.1. With respect to animals that are found dead, severity shall be determined by reference to whether the death is the result of factors related to the procedure that the animal was undergoing. If not related (such as in the case of death due to deficiencies in equipment or environmental controls; inappropriate husbandry practices; unrelated disease and infections), the actual reported severity shall reflect the most severe effects experienced by that animal during the course of the procedure (excluding the experience preceding the death).

9.3.2. If the death is related to the procedure, the actual reported severity shall be 'severe' unless an informed decision can be made that the severity can be assigned a lesser category.

#### 9.4. Capture and transport of animals taken from the wild

The actual severity shall only relate to the effects of the scientific procedure carried out on that animal. Capture and transport (unless these are the specific, or a component of the, objective of the scientific procedures) shall therefore not be taken into account in the reporting of actual severity, including if the animal dies during capture or transport.

### 10. Purposes

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Basic research

---

Translational and applied research

---

Regulatory use and routine production

---

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

---

Preservation of species

---

Higher education

---

Training for the acquisition, maintenance or improvement of vocational skills

---

Forensic enquiries

---

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

---

#### 10.1. Basic research

10.1.1. 'Basic research' refers to studies of a fundamental nature including physiology; studies that are designed to add knowledge about normal and abnormal structure, functioning and behaviour of living organisms and environment, this includes also 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.

10.1.2. The animals used for the creation of a new genetically altered animal line (including crossing of two lines) intended to be used for the purposes of basic research (for example, developmental biology, immunology) shall be reported according to the purpose category they are being created for. In addition, they are reported in 'Creation of a new genetic line – Animals used for the creation of a new genetically altered line/strain'.

10.1.3. All animals carrying the genetic alteration shall be reported during the creation of a new line. Also animals used in creation, such as for superovulation, vasectomy and embryo implantation, are reported here. The reporting shall exclude non-genetically altered (wild type) offspring, unless that animal has been genotyped (genetic characterisation/tissue sampling) using an invasive method, which was not carried out for the purposes of identification/marketing of the animal.

10.1.4. A new strain or line of genetically altered animals is considered to be 'established' where transmission of the genetic alteration is stable, which will be a minimum of two generations, and a welfare assessment has been completed.

#### 10.2. Translational and applied research

10.2.1. 'Translational and applied research' refer to animals used for purposes as described in Article 5(b) and (c) excluding any regulatory use of animals (see point 10.3. below).

10.2.2. This also includes discovery toxicology and investigations to prepare for the regulatory submission and method development. This does not include studies required for regulatory submissions.

10.2.3. The animals used for the creation of a new genetically altered animal line intended to be used for the purposes of translational or applied research (for example, cancer research, vaccine development) shall be recorded according to the purpose they are being created for. In addition, they shall be reported in 'Creation of a new genetic line – Animals used for the creation of a new genetically altered line/strain'.



- 10.2.4. All animals carrying the genetic alteration shall be reported during the creation of a new line. Also animals used in creation, such as for superovulation, vasectomy and embryo implantation shall be reported here. The reporting shall exclude non-genetically altered (wild type) offspring.
- 10.2.5. A new strain or line of genetically altered animals is considered to be 'established' where transmission of the genetic alteration is stable, which will be a minimum of two generations, and a welfare assessment has been completed.
- 10.3. Regulatory use and Routine production
- 10.3.1. 'Regulatory use' covers the use of animals in procedures with a view to satisfying regulatory requirements, that is to say for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed.
- 10.3.2. This includes tests carried out in respect of products/substances for which a regulatory submission was foreseen but ultimately not made, for instance because they were deemed unsuitable for the market by the developer and thus fail to reach the end of the development process.
- 10.3.3. 'Routine production' includes animals used in the manufacturing process of products such as antibodies and blood based products, for example, animals used in the manufacturing of serum-based medicinal products shall be included within this category.
- 10.3.4. Efficacy testing during the development of new medicinal products is excluded and shall be reported under category 'Translational and applied research'.
- 10.4. Protection of the natural environment in the interests of the health or welfare of human beings or animals
- 10.4.1. This refers to studies aimed at investigating and understanding phenomena such as environmental pollution, loss of biodiversity, and epidemiology studies in wild animals.
- 10.4.2. This excludes any regulatory use of animals for ecotoxicology purposes.
- 10.5. Higher education
- This refers to animals used for delivering theoretical knowledge within a higher education programme.
- 10.6. Training for the acquisition, maintenance or improvement of vocational skills
- This refers to animals used for training to acquire and maintain practical vocational skills, such as animals used in the training of medical doctors.
- 10.7. Maintenance of colonies of established genetically altered animals, not used in other procedures
- 10.7.1. This contains animals required for the maintenance of colonies of genetically altered animals of established lines with an intended harmful phenotype and which have exhibited pain, suffering, distress or lasting harm as a consequence of the harmful genotype. The intended purpose which the line is being bred for is not recorded.
- 10.7.2. This category also includes genetically altered animals during maintenance of an established line, irrespective of whether the line is of non-harmful or harmful phenotype, and either of the following applies:
- (a) the genotype has been *confirmed using an invasive method*, which was not carried out for the purposes of identification/marketing of the animal, and the animal is killed without further use;
- (b) the animals are of *unsuitable genotype, confirmed using an invasive method*, which was not carried out for the purposes of identification/marketing of the animal.
- 10.7.3. This category also includes re-derivation where it is done solely for scientific purposes (that is to say not to benefit health/welfare of colony) during maintenance of an established line, and animals used for embryo transfer and vasectomy.
- 10.7.4. This excludes all animals needed for the creation of a new genetically altered line and those used in other procedures (that is to say other than creation/maintenance).

## 11. Basic research studies

---

Oncology

---

Cardiovascular Blood and Lymphatic System

---

Nervous System

---

Respiratory System

---

Gastrointestinal System including Liver

---

Musculoskeletal System

---

Immune System

---

Urogenital/Reproductive System

---

Sensory Organs (skin, eyes and ears)

---

Endocrine System/Metabolism

---

Developmental Biology

---

Multisystemic

---

Ethology/Animal Behaviour/Animal Biology

---

Other Basic Research

---

### 11.1. Oncology

Any research studying oncology shall be included here regardless of the target system.

### 11.2. Nervous system

This category includes, amongst others, neuroscience, peripheral or central nervous system, psychology.

### 11.3. Musculoskeletal System

This category includes, amongst others, dentistry.

### 11.4. Sensory Organs (skin, eyes and ears)

Studies on nose shall be reported under 'Respiratory System' and those on tongue under 'Gastrointestinal System including Liver'.

### 11.5. Developmental Biology covers studies of changes associated with an organism from embryogenesis (when not carried out as part of reproductive toxicity study), to growth, aging and death, and includes, amongst others, cell differentiation, tissue differentiation and organogenesis.

### 11.6. Multisystemic

This shall only include research where more than one system is the primary interest, such as on some infectious diseases, and excluding oncology.

### 11.7. '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.

### 11.8. Other Basic Research

#### 11.8.1. Research that is not related to an organ/system listed above or is not organ/system specific.

#### 11.8.2. Particular attention needs to be paid before using category 'other' to ensure that none of the pre-defined categories could be used.

## 11.9. Remarks

- 11.9.1. Animals used for the production and maintenance of infectious agents, vectors (for example, arthropod feeding) and neoplasms, animals used for other biological material and animals used for the production of antibodies for the purposes of research, but excluding the growth of hybridoma cells by ascites method in the production of monoclonal antibodies (which is covered under category 'Regulatory use and Routine production by product type'), shall be reported in the respective categories under 'Basic research' studies.
- 11.9.2. Where more than one category applies to the purpose of the animal use, only the main purpose shall be reported.

12. **Translational and applied research**


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 Human Cancer
 

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 Human Infectious Disorders
 

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 Human Cardiovascular Disorders
 

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 Human Nervous and Mental Disorders
 

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---

 Human Respiratory Disorders
 

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---

 Human Gastrointestinal Disorders including Liver
 

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---

 Human Musculoskeletal Disorders
 

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---

 Human Immune Disorders
 

---



---

 Human Urogenital/Reproductive Disorders
 

---



---

 Human Sensory Organ Disorders (skin, eyes and ears)
 

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---

 Human Endocrine/Metabolism Disorders
 

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---

 Other Human Disorders
 

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 Animal Diseases and Disorders
 

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 Animal Nutrition
 

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 Animal Welfare
 

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 Diagnosis of Diseases
 

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 Plant Diseases
 

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 Non-regulatory Toxicology and Ecotoxicology
 

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- 12.1. Any applied research on human cancer shall be included in category 'Human cancer' regardless of the target system.
- 12.2. Any applied research on human infectious disorders shall be included in 'Human Infectious Disorders' regardless of the target system.
- 12.3. Any regulatory use of animals, such as regulatory carcinogenicity studies, shall be excluded from category 'Translational and applied research' and reported under category 'Regulatory use and routine production'.
- 12.4. Studies on disorders of the nose shall be reported under 'Human Respiratory Disorders' and those of the tongue shall be reported under 'Human Gastrointestinal Disorders including Liver'.
- 12.5. Particular attention shall be paid before using category 'Other Human Disorders' to ensure that none of the pre-defined categories should be used instead.
- 12.6. 'Diagnosis of Diseases' includes, amongst others, animals used in direct diagnosis of diseases such as rabies, botulism, but excluding those covered under regulatory use.

- 12.7. 'Non-regulatory Toxicology and Ecotoxicology' refers to discovery toxicology and investigations to prepare for the regulatory submission and method development. This category does not include studies required for regulatory submissions (preliminary studies, MTD (Maximum Tolerated Dose)). Dose-range-finding (DRF) studies, when carried out with a view to satisfying legislative requirements, are also excluded and covered in 'Regulatory use and routine production' under 'Other efficacy and tolerance testing'.
- 12.8. 'Animal welfare' refers to studies as per Article 5(b)(iii) of Directive 2010/63/EU.
- 12.9. Remarks
- 12.9.1. Animals used for the production and maintenance of infectious agents, vectors (for example, arthropod feeding) and neoplasms, animals used for other biological material and animals used for the production of antibodies for the purposes of translational and applied research, but excluding the growth of hybridoma cells by ascites method in the production of monoclonal antibodies (which is covered under category 'Regulatory use and routine production by type') shall be reported in the respective categories under 'Translational and applied research'.
- 12.9.2. Where more than one category applies to the purpose of the animal use, only the main purpose shall be reported.

### 13. **Regulatory use and Routine production**

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Quality control (including batch safety and potency testing)

---

Other efficacy and tolerance testing

---

Toxicity and other safety testing including pharmacology

---

Routine production by product type

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- 13.1. Efficacy testing during the development of new medicinal product is excluded and shall be reported under category 'Translational and Applied research'.
- 13.2. Quality control refers to 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, amongst others, pyrogenicity testing.
- 13.3. 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. This covers also dose-range-finding studies when carried out with a view to satisfying legislative requirements.
- 13.4. Toxicity and other safety testing (including safety evaluation of products and devices for human medicine and dentistry and veterinary medicine)
- 13.4.1. This 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.
- 13.4.2. Where studies involve both mother and offspring, the mother shall be reported if she has been subject to a procedure above the threshold of minimum pain, suffering, distress and lasting harm. Offspring shall be reported if they are an integral part of the procedure such as in the case of end-points for reproduction.

13.5. Routine production by product type

13.5.1. This covers the production of antibodies and blood products by established methods. This excludes immunisation of animals for subsequent hybridoma production carried out for the purposes of basic or applied and translational research within a given project, which shall be captured under basic or applied research under the appropriate category.

13.5.2. The use of animals for antibody production for commercial purposes, including immunisation for the subsequent hybridoma production, shall be reported under 'Routine production'/Monoclonal and polyclonal antibodies (excluding ascites method). All use of the ascites method for the culture of monoclonal antibodies shall be reported under 'Routine production'/Monoclonal antibodies by ascites method only'.

14. **Quality control (including batch safety and potency testing)**

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Batch safety testing

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Pyrogenicity testing

---

Batch potency testing

---

Other quality controls

---

Batch safety testing excludes pyrogenicity testing which shall be reported separately under 'Pyrogenicity testing'.

15. **Toxicity and other safety testing by test type**

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Acute (single dose) toxicity testing methods (including limit test)

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Skin irritation/corrosion

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Skin sensitisation

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Eye irritation/corrosion

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Repeated dose toxicity

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Carcinogenicity

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Genotoxicity

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Reproductive toxicity

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Developmental toxicity

---

Neurotoxicity

---

Kinetics (pharmacokinetics, toxicokinetics, residue depletion)

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Pharmaco-dynamics (including safety pharmacology)

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Phototoxicity

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Ecotoxicity

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Safety testing in food and feed area

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Target animal safety

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Combined end-points

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Other toxicity or safety testing

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- 15.1. 'Repeated dose toxicity' includes also immunotoxicological studies.
- 15.2. 'Reproductive toxicity' includes, amongst others, extended one-generation reproductive toxicity studies, also when including cohorts for developmental neuro- and immunotoxicity.
- 15.3. 'Developmental toxicity' includes also developmental neurotoxicity studies. Extended one-generation reproductive toxicity studies including cohort for developmental neurotoxicity shall be reported under reproductive toxicity.
- 15.4. 'Neurotoxicity' includes, amongst others, acute delayed effects (for example, delayed neurotoxicity of organophosphorus substances following acute exposure) and repeated dose studies for the purposes of neurotoxicity, but excludes developmental neurotoxicity. Extended one-generation reproductive toxicity studies including cohort for developmental neurotoxicity shall be reported under reproductive toxicity.
- 15.5. 'Kinetics' refers to pharmacokinetics, toxicokinetics and residue depletion. However, if testing for toxicokinetics is performed as part of the regulatory repeated dose toxicity study, it shall be reported under repeated dose toxicity.
- 15.6. 'Safety testing in the food and feed area' includes also testing of drinking water (including target animal safety testing).
- 15.7. 'Target animal safety' testing ensures that a product for a specific animal can be used safely on that species (excluding batch safety testing which is covered under quality control).
- 15.8. 'Combined end-points' include, amongst others, combination of carcinogenicity and chronic toxicity study, screening studies combining reproductive toxicity and repeated dose toxicity.

16. **Acute toxicity testing methods**

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LD50, LC50

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Other lethal methods

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Non-lethal methods

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- 16.1. The sub-category shall be reported on the basis of the type of method used and not on the basis of the level of severity experienced by the animal as a result of that method.
- 16.2. 'LD50, LC50' refer only to test methods that provide a point estimate for LD50/LC50 such as OECD test guidelines 203, 403 and 425.
- 16.3. 'Other lethal methods' refers to those methods that categorise substances in a class, that is to say, methods involving assignment of a range in which LD50 would fall, such as fixed dose methods and acute toxic class methods. It is likely that a number of deaths will occur but not as many as those expected in LD50-type methods.

17. **Repeated dose toxicity**

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28 days or less

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29 – 90 days

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more than 90 days

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**18. Ecotoxicity**

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Acute toxicity (ecotoxicity)

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Chronic toxicity (ecotoxicity)

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Reproductive toxicity (ecotoxicity)

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Endocrine activity (ecotoxicity)

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Bioaccumulation (ecotoxicity)

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Other ecotoxicity

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- 18.1. Ecotoxicity refers to toxicity relating to the aquatic and terrestrial environment.
- 18.2. Ecotoxicity studies addressing short-term toxicity to determine LC/LD50 shall be reported under 'acute toxicity (ecotoxicity)'.
- 18.3. Ecotoxicity studies addressing long-term toxicity, for example, early life cycle test or full life cycle tests, shall be reported under 'chronic toxicity (ecotoxicity)'.
- 18.4. Ecotoxicity studies carried out to primarily assess endocrine properties of substances and addressing, for example, amphibian metamorphosis, development and growth, fish sexual development and reproduction, shall be reported under 'endocrine activity (ecotoxicity)'.

**19. Type of legislation**

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Legislation on medicinal products for human use

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Legislation on medicinal products for veterinary use and their residues

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Medical devices legislation

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Industrial chemicals legislation

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Plant protection product legislation

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Biocides legislation

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Food legislation including food contact material

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Feed legislation including legislation for the safety of target animals, workers and environment

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Cosmetics legislation

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Other legislation

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- 19.1. The type of legislation shall not be reported for animals whose use falls within the category 'Routine production'.
- 19.2. The type of legislation shall be reported by reference to the intended primary use.
- 19.3. Testing of the quality of water, other than waste water, shall be reported under 'Food legislation'. Quality testing of waste water shall be reported under 'Other legislation'.

## 20. Origin of legislation

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Legislation satisfying Union requirements

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Legislation satisfying national requirements only (within Union)

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Legislation satisfying Non-Union requirements only

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- 20.1. The origin of legislation shall not be reported for animals whose use falls within the category 'Routine production'.
- 20.2. The use shall be reported in reference to the region for which the test is being carried out, not where it is carried out.
- 20.3. Where national legislation is derived from Union legislation, the use shall be reported under 'Legislation satisfying Union requirements'.
- 20.4. 'Legislation satisfying Union requirements' also includes any international requirement, which at the same time satisfies Union requirements (such as testing to ICH <sup>(1)</sup>, VICH <sup>(2)</sup>, OECD guidelines, European Pharmacopoeia monographs).
- 20.5. Where the test is carried out to satisfy the legislation of one or more Member States (not necessarily the one in which the test is being carried out), and the requirement is not derived from Union law, the use shall be reported under 'Legislation satisfying national requirements only (within Union)'.
- 20.6. Legislation satisfying Non-Union requirements is to be chosen only where there is no equivalent requirement to carry out the test to satisfy Union legislation.

## 21. Routine production by product type

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Blood based products

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Monoclonal antibodies by ascites method only

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Monoclonal and polyclonal antibodies (excluding ascites method)

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Other products

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- 21.1. Routine production by product type covers the production of antibodies and blood products using established methods. This excludes immunisation of animals for subsequent hybridoma production when carried out for the purposes of basic or applied research within a given project. That immunisation shall be captured under basic or applied research under the appropriate category.
- 21.2. All use of the ascites method for the culture of monoclonal antibodies shall be reported under 'Monoclonal antibodies by ascites method only'.
- 21.3. The use of animals for antibody production for commercial purposes, including immunisation for the subsequent hybridoma production, shall be reported under 'Monoclonal and polyclonal antibodies (excluding ascites method)'.

## C. MEMBER STATE NARRATIVE

1. Member States shall provide a narrative on the statistical data. That narrative shall contain the following:
- (a) general information on any changes in trends observed since the previous reporting period;

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<sup>(1)</sup> The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

<sup>(2)</sup> The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products



- (b) information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof;
  - (c) information on any changes in trends in actual severities and analysis of the reasons thereof;
  - (d) information on particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any;
  - (e) further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category;
  - (f) information on the uses of animals in categories where a method or testing strategy for obtaining the results sought, not entailing the use of live animals, is recognised under the legislation of the Union;
  - (g) details on cases where the 'severe' classification is exceeded, whether pre-authorised or not.
2. For the purposes of point 1(g), the following shall be reported:
- (a) species;
  - (b) numbers of animals;
  - (c) whether exceeding the 'severe' classification was pre-authorised or not;
  - (d) details of the use;
  - (e) reasons why the 'severe' classification was exceeded.
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## ANNEX V

**CORRELATION TABLE**

| Implementing Decision 2012/707/EU | This Decision |
|-----------------------------------|---------------|
| Article 1                         | Article 2     |
| Article 2                         | Article 3     |
| Article 3                         | Article 4     |
| Article 4                         | Article 6     |
| ANNEX I                           | ANNEX II      |
| ANNEX II                          | ANNEX III     |
| ANNEX III                         | ANNEX IV      |