

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 (Text with EEA relevance)

CHAPTER IV
AUTHORISATION

Section 3

Requirements for projects

Article 36

Project authorisation

1 Member States shall ensure, without prejudice to Article 42, that projects are not carried out without prior authorisation from the competent authority, and that projects are carried out in accordance with the authorisation or, in the cases referred to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority.

2 Member States shall ensure that no project is carried out unless a favourable project evaluation by the competent authority has been received in accordance with Article 38.

Article 37

Application for project authorisation

1 Member States shall ensure that an application for project authorisation is submitted by the user or the person responsible for the project. The application shall include at least the following:

- a the project proposal;
- b a non-technical project summary; and
- c information on the elements set out in Annex VI.

2 Member States may waive the requirement in paragraph 1(b) for projects referred to in Article 42(1).

Article 38

Project evaluation

1 The project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria:

- a the project is justified from a scientific or educational point of view or required by law;
- b the purposes of the project justify the use of animals; and

- c the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.
- 2 The project evaluation shall consist in particular of the following:
- a an evaluation of the objectives of the project, the predicted scientific benefits or educational value;
 - b an assessment of the compliance of the project with the requirement of replacement, reduction and refinement;
 - c an assessment and assignment of the classification of the severity of procedures;
 - d a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment;
 - e an assessment of any justification referred to in Articles 6 to 12, 14, 16 and 33; and
 - f a determination as to whether and when the project should be assessed retrospectively.
- 3 The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas:
- a the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;
 - b experimental design, including statistics where appropriate;
 - c veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;
 - d animal husbandry and care, in relation to the species that are intended to be used.
- 4 The project evaluation process shall be transparent.

Subject to safeguarding intellectual property and confidential information, the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties.

Article 39

Retrospective assessment

- 1 Member States shall ensure that when determined in accordance with Article 38(2)(f), the retrospective assessment shall be carried out by the competent authority which shall, on the basis of the necessary documentation submitted by the user, evaluate the following:
- a whether the objectives of the project were achieved;
 - b the harm inflicted on animals, including the numbers and species of animals used, and the severity of the procedures; and
 - c any elements that may contribute to the further implementation of the requirement of replacement, reduction and refinement.
- 2 All projects using non-human primates and projects involving procedures classified as 'severe', including those referred to in Article 15(2), shall undergo a retrospective assessment.
- 3 Without prejudice to paragraph 2 and by way of derogation from Article 38(2)(f), Member States may exempt projects involving only procedures classified as 'mild' or 'non-recovery' from the requirement for a retrospective assessment.

Article 40

Granting of project authorisation

- 1 The project authorisation shall be limited to procedures which have been subject to:
 - a a project evaluation; and
 - b the severity classifications assigned to those procedures.
- 2 The project authorisation shall specify the following:
 - a the user who undertakes the project;
 - b the persons responsible for the overall implementation of the project and its compliance with the project authorisation;
 - c the establishments in which the project will be undertaken, where applicable; and
 - d any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively.
- 3 Project authorisations shall be granted for a period not exceeding 5 years.
- 4 Member States may allow the authorisation of multiple generic projects carried out by the same user if such projects are to satisfy regulatory requirements or if such projects use animals for production or diagnostic purposes with established methods.

Article 41

Authorisation decisions

- 1 Member States shall ensure that the decision regarding authorisation is taken and communicated to the applicant 40 working days at the latest from the receipt of the complete and correct application. This period shall include the project evaluation.
- 2 When justified by the complexity or the multi-disciplinary nature of the project, the competent authority may extend the period referred to in paragraph 1 once, by an additional period not exceeding 15 working days. The extension and its duration shall be duly motivated and shall be notified to the applicant before the expiry of the period referred to in paragraph 1.
- 3 Competent authorities shall acknowledge to the applicant all applications for authorisations as quickly as possible, and shall indicate the period referred to in paragraph 1 within which the decision is to be taken.
- 4 In the case of an incomplete or incorrect application, the competent authority shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

Article 42

Simplified administrative procedure

- 1 Member States may decide to introduce a simplified administrative procedure for projects containing procedures classified as 'non-recovery', 'mild' or 'moderate' and not using non-human primates, that are necessary to satisfy regulatory requirements, or which use animals for production or diagnostic purposes with established methods.

2 When introducing a simplified administrative procedure, Member States shall ensure that the following provisions are met:

- a the application specifies elements referred to in Article 40(2)(a), (b) and (c);
- b a project evaluation is performed in accordance with Article 38; and
- c that the period referred to in Article 41(1) is not exceeded.

3 If a project is changed in a way that may have a negative impact on animal welfare, Member States shall require an additional project evaluation with a favourable outcome.

4 Article 40(3) and (4), Article 41(3) and Article 44(3), (4) and (5) shall apply *mutatis mutandis* to projects that are allowed to be carried out in accordance with this Article.

Article 43

Non-technical project summaries

1 Subject to safeguarding intellectual property and confidential information, the non-technical project summary shall provide the following:

- a information on the objectives of the project, including the predicted harm and benefits and the number and types of animals to be used;
- b a demonstration of compliance with the requirement of replacement, reduction and refinement.

The non-technical project summary shall be anonymous and shall not contain the names and addresses of the user and its personnel.

2 Member States may require the non-technical project summary to specify whether a project is to undergo a retrospective assessment and by what deadline. In such a case, Member States shall ensure that the non-technical project summary is updated with the results of any retrospective assessment.

3 Member States shall publish the non-technical project summaries of authorised projects and any updates thereto.

Article 44

Amendment, renewal and withdrawal of a project authorisation

1 Member States shall ensure that amendment or renewal of the project authorisation is required for any change of the project that may have a negative impact on animal welfare.

2 Any amendment or renewal of a project authorisation shall be subject to a further favourable outcome of the project evaluation.

3 The competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation.

4 Where a project authorisation is withdrawn, the welfare of the animals used or intended to be used in the project must not be adversely affected.

5 Member States shall establish and publish conditions for amendment and renewal of project authorisations.

Article 45

Documentation

1 Member States shall ensure that all relevant documentation, including project authorisations and the result of the project evaluation is kept for at least 3 years from the expiry date of the authorisation of the project or from the expiry of the period referred to in Article 41(1) and shall be available to the competent authority.

2 Without prejudice to paragraph 1, the documentation for projects which have to undergo retrospective assessment shall be kept until the retrospective assessment has been completed.