

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 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.

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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.