

1. Project evaluation before Directive 2010/63/EU

According to the FELASA Report (2005, p. 10), the ethical review was mandatory and was carried out by the “Official veterinarian from the Local Veterinary Service in each Prefecture, who may take advice from scientists in the relevant field of work”. As part of a voluntary process, there were “institutional committees in Medical Faculties and some research institutions”.

2. Implementation of Directive 2010/63/EU

The Directive is already transposed into national legislation by the Presidential Decree n° 56/2013. There is also other legal document, named “Instructions for the interpretation of application PD 56/2013 for the protection of animals used for scientific purposes”, under the Minister of Rural Development and Food, to clarify some aspects that were missing in the Presidential Decree.

3. Major changes introduced by the Directive 2010/63/EU in the project evaluation process

The Directive introduced the “project evaluation committees”, institutional entities responsible for the projects’ evaluation.

4. Regulation and authorisation process: main actors

4.1. Ministry: Minister of Rural Development and Food

4.2. Competent authority: Regional Veterinarian Authority [there are 54 regional authorities]

4.3. Entity responsible for the project authorisation: Regional Veterinarian Authority with advice from the project evaluation committees

5. Project evaluation according to Article 38 of Directive 2010/63/EU

5.1. Geographical organization of the project evaluation process

The evaluation is conducted by the project evaluation committees, which are mainly institutional (associated to an institution, but can be shared between institutes since there is no conflict of interest). These committees are approved by the Head of the Local Prefectural Service. The project authorisation is delegated to the local Prefectural Veterinary Services. The officers who handle project authorisations at these regional veterinarian authorities have background/expertise in veterinary (in some cases have also undergone special training -mainly in Athens and Thessaloniki).

5.2. Evaluators

The evaluation is conducted by the project evaluation committees. Currently, the Greek Competent Authority has the registration of 40 committees but the number is subject to continuous expansion due to the ongoing implementation of the European Directive by institutions.

5.2.1. Committees’ composition

The committees must have at least 3 members:

- i) The chairman must have a scientific background: a scientist from biomedical sciences or an expert in the field of the institute’s research;
- ii) The responsible veterinarian
- iii) An expert in statistics and experimental design (an expert in these fields or a scientist with experience and background in these fields).

Additionally (it is not mandatory), the committee may also invite a representative from the Local Prefectural Service – in this case, the local representative has the right to vote and is always a Veterinarian responsible for the inspection of the legislation on animals used for scientific purposes in Greece.

In total, 4 members can vote. In case of tie, the chairman's vote is double to allow the committee to have a final decision. The members are appointed by the Regional Veterinarian Authority. The applicant may also be invited to a meeting, but cannot vote.

5.3. Protocol submission

There is a new standard form, available in the Annex 2 of the document "Instructions for the interpretation of application PD 56/2013 for the protection of animals used for scientific purposes". The applicants must fulfil this form and submit the protocol to evaluation by the institutional project evaluation committee. After a positive feedback/approval from this committee, the applicants must submit the protocol to the competent authority (the Regional Veterinary Authority), who will provide authorisation. There is no online platform. The applications can be submitted through e-mail but usually they are submitted "face-to-face".

5.4. Fees

There are no fees for the project evaluation, so it has no costs for the applicants.

5.5. Guidelines for project evaluation

Some aspects are mentioned in the document "Instructions for the interpretation of application PD 56/2013 for the protection of animals used for scientific purposes", but they are very general. There are no more official specific guidelines for the project evaluation.

5.6. Follow-up of projects' authorisation (I.e. inspections, retrospective review, etc.)

The Local Prefectural Veterinary Services are responsible for the follow up of the projects' authorisation.

6. Changes expected to occur in 2015

There are no changes expected to occur in 2015 in the project evaluation process.

7. Additional information

Consultation during the formulation of regulations has been provided by experts from the Hellenic Society of Biomedical and Laboratory Animal Science (HSBLAS).