

1. Project evaluation before Directive 2010/63/EU

According to the FELASA Report (2005, p. 10), the ethical review was mandatory and a “national licensing committee was established at the Estonian Ministry of Agriculture” since May 2004. This report also stated that “the committee reviews applications and grants permits for animal experiments; meetings take place according to the number of applications received.”

2. Implementation of Directive 2010/63/EU

The Directive is already transposed into national legislation through the Animal Welfare Act from 01/01/2013, available at <https://www.riigiteataja.ee/akt/13331263?leiaKehtiv#para47>. The English version of Animal Protection Act is available at: <https://www.riigiteataja.ee/en/eli/ee/Riigikogu/act/530102013045/consolide>

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

The major changes introduced by the directive were:

- i) A new composition of the committee
- ii) The maximum of 40 working days to evaluate the applications.

4. Regulation and authorisation process: main actors

4.1. Ministry: Ministry of Agriculture (Food Safety Department)

4.2. Competent authority: Ministry of Agriculture (Food Safety Department) and Veterinary and Food Board (responsible for the authorisation of breeders, supplies and users and inspections of breeders, supplies and users and over projects)

4.3. Entity responsible for the project authorisation: National committee (“project authorisation committee”).

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 at a national level.

5.2. Evaluators

The evaluation is conducted by the project authorisation committee, which has the power to accept or reject the applications. The main responsible for the final decision is the Head of the committee. The committee meets once a month.

5.2.1. Committee's composition

According to the information available at <https://www.riigiteataja.ee/akt/118012013013>, the committee is appointed by the Minister of Agriculture and has to have up to 17 members. The members are proposed by:

- 1) Minister of Agriculture: 2 members + 2 substitutes (animal protection/animal welfare member + member with judicial education - a lawyer from the Ministry is included in the Committee)
- 2) Minister of Environment: 1 member + 1 substitute (use of genetically modified animals in animal studies)
- 3) University of Tartu: 5 members + 5 substitutes (members with experience in animal experimentation, running animal facilities, ethics, statistics)
- 4) Estonian University of Life Sciences: 3 members + 3 substitutes (members with experience in animal experimentation, running animal facilities, ethics, anaesthesia)
- 5) Tallinn University of Technology: 1 member + 1 substitute

- 6) Minister of Education and Science: 1 member + 1 substitute (animal testing)
- 7) Veterinary and Food Board/ Office of Health, the Food and Veterinary Office: 1 member + 1 substitute (animal protection/animal welfare member)
- 8) General Director of Health/Health Agency: 1 member + 1 member (animal testing)
- 9) Animal protection organizations (Animal Protection Society of Estonia and the Estonian Animal Welfare League): 2 members + 2 substitutes

Currently, the committee is composed by members with expertise and experience in animal experimentation and veterinary medicine; mathematical statistics; ethics; planning animal experiments; alternative methods; reproduction and rearing; anesthesia, analgesia and pharmacology in animal experiments; farm animal breeding and reproduction; veterinary medicine in animal experiments and juridical education.

The committee's meetings must have a quorum of at least 12 members or their substitutes (including the chairman or the vice chairman). There are no requirements to elect the chairman and the vice chairman (chairman's substitute), they are elected among (and by) the committee's members.

5.3. Protocol submission

There is a standard form, in Estonian. The applications must be submitted directly to the committee through email (pm@agri.ee) or post to 39 Broad Street, Lai 41, 15056 Tallinn. The decision must be taken 40 working days after the submission.

5.4. Fees

There are no fees. The project evaluation has no costs for the applicants.

5.5. Guidelines for project evaluation

There are no specific guidelines for the committee on how to conduct the project evaluation.

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

The Veterinary and Food Board is responsible for the inspections. The project authorisation committee is responsible for the retrospective review.

6. Changes expected to occur in 2015

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