

1. Project evaluation before Directive 2010/63/EU

Before the Directive 2010/63/EU the ethical review was mandatory. There was a national ethics committee, established by the State Food and Veterinary Agency since 1999. It was composed by representatives from major stakeholders in the field of biomedical research [also, the committees' composition must be approved by these institutions/organizations – e.g. State Drug Control Agency, Lithuanian Association of Laboratory Animals, Department of Biology and Genetics of Vilnius University, National Public Health Centre, Department of Biochemistry and Biophysics of Vilnius University, Lithuanian Academy of Veterinary, National Laboratory of Veterinary, Institute of Biochemistry, Institute of Immunology, Lithuanian Institute of Veterinary, Institute of Biomedical Research of Kaunas Medical University, Lithuanian Oncology Centre].

The project authorisation was provided by the State Food and Veterinary Service with advice from this committee.

2. Implementation of Directive 2010/63/EU

The Directive is already transposed into the national legislation. Lithuania has transposed Directive 2010/63/EC through secondary legislation (regulations) implementing provisions of the Law No VIII-500 of the Republic of Lithuania on Animal Welfare and Protection of 3 October 2012. The legal document is available at:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=437083&p_query=&p_tr2=2 .

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

The major changes introduced by the transposition of the Directive are:

- i. New committee,
- ii. New project evaluation,
- iii. More establishments of animal users started working in this field in the country,
- iv. More training organizers started organize regular training courses for students and other persons working with lab animals.

4. Regulation and authorisation process: main actors

4.1. Competent authority: Under the Law on Animal Welfare and Protection (Law No VIII-500), the State Food and Veterinary Service (SFVS) and its territorial divisions are the competent authorities for the implementation of the Directive's requirements. SFVS develops and implements the Government's policy in food safety and quality as well as in animal health and welfare. The SFVS is accountable to the Government of the Republic of Lithuania.

4.2. Entity responsible for the project authorisation: State Food and Veterinary Service with advice from the national ethics committee

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

5.1. Geographical organization of the project evaluation process

The project evaluation is conducted by one national ethics committee, under supervision of the State Food and Veterinary Service. The members of this committee can also participate in the inspections conducted by competent authority. The authorisation is provided by 3 officers at the State Food and Veterinary Service with background/expertise in law and veterinary (1 lawyer and 2 veterinarians).

5.2. Evaluators

The evaluation is conducted by the national committee.

5.2.1. Committee's composition

The committee is composed by 10 members:

- 2 from State Food and Veterinary Service,
- 5 from Universities,
- 1 from Vilnius Public Health Centre,
- 1 from National Food and Veterinary Risk Assessment Institute,
- 1 from the State Drug Control Service.

The members are appointed by the competent authority for the implementation of the Directive (SFVS). They have background/ expertise in biology, medicine, veterinary, law and, for example, in organizing trainings for people working with laboratory animals.

5.3. Protocol submission

The protocols are submitted through e-mail. Currently, there is a non-official form in Lithuanian that will be updated in the near future.

5.4. Fees

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

5.5. Guidelines for project evaluation

A regulation under the name 'Requirements for accommodation, care and use of animals used for scientific and educational purposes' (B1-866) transposes the majority of the Directive's provisions and a regulation called 'Rules of procedures of the Lithuanian testing animal use ethics commission under the State Food and Veterinary Service' (B1-870) transposes the Directive's requirements related to the authorisation of breeders, suppliers and users.

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

The State Food and Veterinary Service and its territorial divisions are responsible for the follow-up of projects' authorisation.

6. Changes expected to occur in 2015

Official form related to ethical evaluation of the projects.