

### **1. Project evaluation before Directive 2010/63/EU**

Before the transposition of the Directive, the ethical review was mandatory, in the scope of the Animal Protection Law (accepted in 01.01. 2000, amendments on 27.12.2002 - Regulation of Council of Ministers Nr. 576). The projects should be submitted to the Latvian Council of Science. The evaluation was conducted by a national ethics committee (the Ethics Committee on Laboratory Animal Use in Biomedical Research). This committee, under the Latvia Council of Science, was composed by 13-15 members, namely:

- Representatives of the Latvian Council of Science;
- Laboratory animal breeders;
- Representatives of the State Veterinary Department;
- Representatives of the Ministry of Welfare;
- Laboratory animal users from different research institutions;
- Representatives of the environment protection organisations;
- Representatives of the Baltic Laboratory Animal Science Association.

The composition of the committee should be accepted by the Latvian Council of Science, who appointed the chairman.

### **2. Implementation of Directive 2010/63/EU**

The Directive is already transposed into the national legislation through the “Terms of protection of animals used for scientific purposes” (Document Nr. 52, issued on 22.01.2013 by the Council of Ministers) and the Animal Protection Law.

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

After the Directive 2010/63 EU entry into force, several changes were done in national legislation – in Animal Protection Law and in Regulation of Council of Ministers No. 52 - Regulations Regarding the Protection of Animals Used for Scientific Purposes. The essential change is that now project evaluation is made by Food and Veterinary Service commission, when before it was made by a national ethical commission.

### **4. Regulation and authorisation process: main actors**

**4.1. Ministry:** Ministry of Agriculture

**4.2. Competent authority:** Food and Veterinary Service - Veterinary Surveillance Department

**4.3. Entity responsible for the project authorisation:** Food and Veterinary Service with advice from the Food and Veterinary Service national commission

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

#### **5.1. Geographical organization of the project evaluation process**

There is one national commission, responsible for the project evaluation, advising the competent authority, the Food and Veterinary Service.

#### **5.2. Evaluators**

The project evaluation is conducted by the national commission under the Food and Veterinary Service. After the commission positive decision, the Director General of Food and Veterinary Service authorises the project. As there is no very high quantity of applications in Latvia for scientific research using animals, the Director General of Food and Veterinary Service (who has an experience in authorising projects since 2010) authorises the project by himself after the commission decision.

### **5.2.1. Committee's composition**

The commission is composed by 10 members, who have experience in work with animals that are used for scientific purposes in different fields, for example:

- Introduction of alternative methods in order to replace, reduce and refine the existing methods
- Experimental design, including statistics where appropriate;
- Veterinary practice in experimental (laboratory) animal science or wildlife veterinary practice where appropriate;
- Animal husbandry and care, in relation to the species that are intended to be used

The commission is composed by:

- Chairman, who comes from Food and veterinary Service;
- Representative from Ministry of Agriculture Veterinary and Food Processing Department
- Representative from Ministry of Environmental Protection and Regional Development;
- Representative from Ministry of Education and Science
- One authorised veterinarian with experience in work with animals used for scientific purposes;
- Two representatives from Latvia University of Agriculture Faculty of Veterinary Medicine;
- Three representatives from different research institutions that conduct research using animals for scientific purposes.

The meetings depend from submitted applications. If there are submitted applications in Food and Veterinary Service, the evaluation of projects is made and meetings of commission are hold. In case of uncertainty and doubts about the project's necessity, novelty, usability, ethical and welfare aspects using the animals, the responsible person for project is invited to participate in commission session and is asked to answer the questions concerning the planned project.

### **5.3. Protocol submission**

There is a standard form, which request the information mentioned in the Directive. Protocols are submitted to the Food and Veterinary Service by mail, fax, e-mail or personally by paper form. Before the project description/form is send to commission members, the senior expert from Food and Veterinary Service checks the submitted information according to mentioned criteria above. If the information is correct and complete, the senior expert sends the project description to commission members.

### **5.4. Fees**

There is no payment for project evaluation process. There is only a state fee for license.

### **5.5. Guidelines for project evaluation**

There are specific guidelines for the evaluators on how to evaluate the project, where ethical aspects are included together with 3Rs principles.

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

Food and Veterinary Service is responsible for the follow-up of the project authorisation. The senior expert and inspectors from the Food and Veterinary Service are working in this field.

## **6. Changes expected to occur in 2015**

If there will be enough material resources, form the next year additional experts will be attracted to commission with aim to make a larger expertise and knowledge field.

## **7. Additional information**

The ministry of Agriculture play major role in the regulation of the scientific use of animals.

Next year they start to work the National committee for the protection of animals used for scientific purposes, that will advise the competent authority and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice. Committee will also exchange information on the operation of animal-welfare bodies and project evaluation and share best practice within the Union.