

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

Before the Directive 2010/63/EU there was a mandatory requirement for ethical review, which comprised the evaluation of the scientific justification of the project and the application of the 3R principles.

Legal background:

- Parliamentary Act No. XXVIII of 1998 on the Protection and Welfare of Animals
- Government Ordinance No. 243/1998 (XII.31.) on scientific research on animals
- Order No. 36/1999 (IV.2.) of the ministers responsible in charge of agriculture, environment protection and economy

The authorisation was given (and the experiment was monitored) by the Veterinary Authority, with expert opinion from the National Scientific Ethical Committee on Animal Experimentation of the Animal Protection Advisory Board.

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

On May 30 2013, the European Commission has announced that a reasoned opinion (second step of the infringement procedure) has been sent to Hungary regarding the transposition of Article 10 and 64 of the Directive. The Directive is now transposed into the Hungarian national legislation through the amendments to Law No. XXVIII of 1998, the Protection and Welfare of Animals Act. The consolidated version of this Law entered into force on 1 January 2013 through the Governmental Decree No. 40 of 2013 (II. 14.), available at: [http://faolex.fao.org/cgi-bin/faolex.exe?rec\\_id=124420&database=faolex&search\\_type=link&table=result&lang=eng&format\\_name=@ERALL](http://faolex.fao.org/cgi-bin/faolex.exe?rec_id=124420&database=faolex&search_type=link&table=result&lang=eng&format_name=@ERALL)

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

Before the Directive 2010/63/EU there was a mandatory requirement for ethical review, which comprised the evaluation of the scientific justification of the project and the application of the 3R principles. However, harm-benefit analysis and severity classification did not form part of the ethical review and were introduced by the transposition of the Directive.

### 4. Regulation and authorization process: main actors

**4.1. Ministry:** Minister of Agriculture and Rural Development

**4.2. Competent authority:** National Food Chain Safety Office - this Office holds a centre and 19 regional organizations

**4.3. Entity responsible for the project authorisation:** Regional National Food Chain Safety Offices with advice from a national animal ethics committee ("Állatkísérleti Tudományos Etikai Tanács – ÁTET")

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

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

All applications should be reviewed and approved by the institutional AWB [animal welfare bodies]. After that, they should be submitted to one of the regional National Food Chain Safety Office (one in each 20 Hungarian administrative regions). Project evaluation is then carried out by the national ethics committee ("Állatkísérleti Tudományos Etikai Tanács - ÁTET"). The outcome of the evaluation conducted by the committee is forwarded to the regional National Food Chain Safety Office, entity responsible for providing the project authorisation.

#### 5.2. Evaluators

The project evaluation is conducted by the national ethics committee ("Állatkísérleti Tudományos Etikai Tanács - ÁTET"). This committee was created to discuss and monitor issues concerning the protection and welfare of animals used for scientific purposes. It is responsible for:

- The assessment of research projects, including the retrospective severity assessment when it is needed;

- Advise the Minister responsible for animal protection and welfare on matters of legal regulation of the animal experimentation
  - Advise local committees with regard the acquisition, breeding, accommodation, care and use of research animals.
- It should also make recommendations and guidelines, promote the share of best practices and build international relations and exchange of experience with similar bodies in other EU member states.

At the National Food Chain Safety Office, the officers responsible for providing the authorisation are veterinarians (some of them are trained in lab animal medicine/science)

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

The committee is composed by 13 members, nominated for 5 years by the head of the National Food Chain Safety Office. Since 2003, the head/chairman of the committee is Istvan Gyertyan. The committee members must have at least a BSc/MSc in natural/life sciences. Currently, the committee is composed by 5 biologists, 4 veterinarians and 4 medical doctors, with expertise in different animals (2 members in laboratory animals, 1 member in farm animals, 1 member in endangered species and 1 member in GMOs); procedures (4 members in basic science, 3 members in experimental surgery, 3 members in drug research, 5 members in higher education, 1 member in field experiments and 2 members in agricultural production studies) and 3 R's (2 members in alternative methods, 1 member in bioethics, 2 members in biostatistics, 3 members in perioperative care, 2 members in environmental enrichment/housing and 2 members in behavioural assessment, including pain). Also, 1 member has authority experience, 1 member has NGO experience and 1 has experience in legal regulation.

#### **5.3. Protocol submission**

There is no official standard form available, the annex of the Hungarian regulation (2. Annex of 40/2013 (II. 14.) Korm. Rendelet) is used with this purpose. Applications are submitted through e-mail to the regional National Food Chain Safety Office.

#### **5.4. Fees**

Currently, the project authorisation process is free of charge.

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

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

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

The inspections are conducted by the National Food Chain Safety Office; the retrospective review is conducted by the national ethics committee.

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

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