

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

The project evaluation in Croatia has been established in 2006 by the Animal Protection Act, OG 135/06 and 37/13. The evaluation was conducted by a national ethics committee. The role of this ethics committee was to i) give opinions on ethical and animal protection issues considering the use of animals for experimental and educational purposes; and ii) propose criteria and give opinions to the competent authority during the procedure for granting authorisation to carry out an experiment.

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

The directive is already transposed into the national legislation through amendments of the Animal Protection Act in 2013 (OG, 37/13) (this document gives the frame for fully transposition of the Directive) and through the Ordinance on the protection of animals used for scientific purposes, OG 55/13. The Animal Protection Act, OG 135/06 and 37/13 is available at <http://www.veterinarstvo.hr/default.aspx?id=9> and the Ordinance on the protection of animals kept for scientific purposes is available at <http://www.veterinarstvo.hr/default.aspx?id=64>.

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

The transposition of the Directive did not introduce many changes in the project evaluation process. The most important changes introduced were: i) the stress on the alternative methods and ii) the severity assessment of the proposed procedures.

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

**4.1. Ministry:** Ministry of Agriculture

**4.2. Competent authority:** Veterinary and Food Safety Directorate

**4.3. Entity responsible for the project authorisation:** Veterinary and Food Safety Directorate with advice from a national 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 a national ethics committee, who advises the national competent authority - the Veterinary and Food Safety Directorate. However, it is encouraged/recommended a first evaluation by a committee at an institutional level.

#### **5.2. Evaluators**

The formal evaluation is conducted by a national ethics committee that has regular meetings to discuss the applications.

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

The national ethics committee has 6 members appointed by the Minister. The committee's composition is regulated by Animal Protection Act and should include experts in the fields of veterinary medicine, human medicine, biology, pharmacy, biochemistry and agronomy, as well as representatives from the state administration body responsible for science and education and representatives from animal protection associations.

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

The protocols are submitted for evaluation through mail. A standard form is available on the Veterinary and Food Safety Directorate website, at <http://www.veterinarstvo.hr/default.aspx?id=64> (Zahtjev za odobrenje projekta).

#### **5.4. Fees**

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

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

The members of the national ethics committee use the EU Working document on Project Evaluation and Retrospective Assessment.

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

The competent authority, the Veterinary and Food Safety Directorate, is responsible for the follow-up of projects' authorisation.

### **6. Changes in the project evaluation expected to occur in 2015**

There are no changes expected to occur in 2015.