

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

Before the transposition of the Directive, the scientific use of animals was regulated by the Law 471/2002, which approved the Romanian Governmental Ordinance 37/2002. This ordinance established and defined the role of the National Sanitary-Veterinary and Food Safety Authority, the national competent authority regarding animal welfare, under the Ministry of Agriculture, Food and Forests. In institutions there were local committees which evaluate the research projects regarding animal bioethics. It is not clear if this ethical review was mandatory.

Also, national legislation included the common Order MAPM (Ministry of Agriculture, Food Safety and Forests) no. 400 of 20 May 2002 / M.A.A.P (Ministry for Water and Environment) no. 143 of 1 April 2002 to approve the Guidelines for accommodation and care of animals used for scientific or other experimental purposes, published in Official Gazette no. 697 of 24 September 2002. It was repealed by the common Order ANSVSA MS MMSC that sets mandatory minimum standards for housing and care of animals used for scientific purposes and the procedure for granting exemptions provided for in art. 32, para. (7) of Law no. 43/2014 on the protection of animals used for scientific purposes

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

The Directive is already transposed into the national legislation by the Law 43/2014 on the protection of animals used for scientific purposes, published in Romanian Official Gazette no. 326/6 from May 2014.

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

The major changes introduced by the Directive were:

- i. Procedure for projects' evaluation. Under the new provisions, no project can be held and cannot receive authorisation if it is not properly assessed beforehand.
- ii. Promotion of the concept of 3R, so the procedure to use a reduced number of live animals and whenever possible, to use organs and/or tissues.

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

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

**4.2. Competent authority:** National Sanitary-Veterinary and Food Safety Authority [NSVFSA]

**4.3. Entity responsible for the project authorisation:** National Sanitary-Veterinary and Food Safety Authority through sanitary veterinary and food safety directorates in counties with advice from ethics committees

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

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

The procedure for evaluation of projects it is established by order of the NSVFSA. This order is currently in the draft stage, and is expected that to be published in the first quarter of 2015 in the Official Gazette.

For this situation, it was decided that it is appropriate for the evaluation of projects to be carried out by the Ethics Commission established in the specialized academic centers or user establishments in which the project will take place for the project evaluation be performed by specialists with expertise in the field. After evaluation by these ethics committees, the project authorisation is issued by the sanitary veterinary and food safety directorates in counties / Bucharest, on the area where the establishment is operating.

## **5.2. Evaluators**

The project evaluation is performed by the ethics committees established in the specialized academic centers or user establishments in which the project will take place.

## **5.3. Fees**

There are no fees for project evaluation. The national legislation established a fee only for the approval of establishments' user / supplier / breeders of animals used for scientific purposes. It is in the amount of 114 RON, about 25 Euros.

## **5.4. Guidelines for project evaluation**

European Commission DG Environment has promoted some good practice guides, one of which refers to the evaluation of projects and retrospective assessment. It will be translated into Romanian and taken for use.

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

NSVFSA is responsible for both controls to the units and for retrospective assessment. The inspections are performed by the National Sanitary-Veterinary and Food Safety Authority through sanitary veterinary and food safety directorates in counties.

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

NSVFSA will publish the procedure for projects' evaluation.