

1. Project evaluation before Directive 2010/63/EU

According to the FELASA Report (2005, p. 10), since October 2005, a national law (the Royal Decree of 2005) required “institutional committees in all State (but not other) research centres, and sets up a State Ethical Commission of Animal Welfare which must approve and supervise high severity procedures”. As result of a voluntary process, there were “institutional committees in most other research centres in the remaining regions”.

2. Implementation of Directive 2010/63/EU

The directive is transposed into national legislation through the Royal Decree 53/2013 from February 1st and Law 32/2007 from November 7th.

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

The major change introduced in the project evaluation process by the transposition of the Directive was the role of the “habilitated bodies”/“órganos habilitados”.

4. Regulation and authorisation process: main actors

4.1. Ministry: Ministry of Agriculture, Food and Environment and Ministry of Economy and Competitiveness

4.2. Competent authority: Regional administrative competent authorities

4.3. Entity responsible for the project authorisation: Regional competent authorities with advice from “habilitated bodies”

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

5.1. Geographical organization of the project evaluation process

The project evaluation process is complex and heterogeneous. With the transposition of the Directive through the Royal Decree 53/2013, the project evaluation was delegated to other entities - the “habilitated bodies”/“órganos habilitados”. These habilitated bodies usually are institutional or local ethics committees (but this is not compulsory or even recommended). The Animal Welfare Bodies (AWB) introduced by the transposition of the directive can conduct the project evaluation if they meet additional requirements and there are also some external habilitated bodies that are not connected to any institution.

After evaluation by one of these habilitated bodies, the authorisation is always performed by one of the regional competent authorities. All the contact data of competent authorities are publish at MAGRAMA’s website:

http://www.magrama.gob.es/es/ganaderia/temas/produccion-y-mercados-ganaderos/Puntos_de_contacto_de_acuerdo_al_art%C3%ADculo_41_del_RD_53_2013_tcm7-327067.pdf

5.2. Evaluators

The evaluation is always conducted by the habilitated bodies. The list of bodies that are habilitated to conduct the project evaluation is available at:

<https://sede.micinn.gob.es/portal/site/eSede/menuitem.df29f2378d5d10a0cee63510223041a0/?vgnextoid=4625f3781efed310VgnVCM1000001d04140aRCRD&vgnnextfmt=formato1> (The bodies are listed here according to the

competent authority who has habilitated and registered them, not the area in which they will evaluate projects, since these bodies can evaluate projects from all Spain).

5.2.1. Committees' composition

As described in the Royal Decree 53/2013 [art. 43], a committee habilitated to evaluate projects should include the minimum composition of an AWB (Animal Welfare Body) defined in the Directive and in this Decree + some additional members. Namely, one committee should be composed by:

- At least the person or persons responsible for the welfare and care of the animals (AWB);
- A scientific member (AWB);
- The designated veterinarian (AWB);
- Other researchers that aren't connected with the project that will be assessed;
- One person with expertise in animal welfare without direct relation with the user or the project.

These requirements, mentioned in the Royal Decree 53/2013 are just additional requirements for AWB that wants to apply for habilitated body.

5.3. Protocol submission

There is no national standard form. Some of the competent authorities at a regional level may have specific forms. Competent authority operates at a regional level (administrative regions) and these regional administrative regions may have different procedures.

Usually, there is a template that the researchers must complete and send to the "habilitated body". The process is reviewed electronically, through e-mail. There may be some web-based systems in some institutions.

5.4. Fees

There are no standard fees. The project evaluation could have costs for the applicants if it is conducted by an external habilitated body (in this case, an evaluation could cost between 200 and 500 euros).

5.5. Guidelines for project evaluation

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

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

The follow-up of projects' authorisation is conducted by the AWB's facility and the competent authority's inspectors.

6. Changes expected to occur in 2015

There are no changes expected to occur in 2015.