Member state: Italy

1. Project evaluation before Directive 2010/63/EU

According to the FELASA Report (2005, p. 10), there was "no national, mandatory requirement for prior ethical review of all regulated uses of animals in Italy" (p.3). The only legal requirement was: "a review by a special Commission at the *Istituto Superiore di Sanità* (ISS) required for: procedures involving cats, dogs, non-human primates and/or endangered species; procedures without anaesthesia; and those for education and training". The applications were submitted to the Ministry of Health, who forward them to the ISS for ethical review. The central officer at ISS received the applications and distributed them to the evaluators that are experts in the field of the project application.

As result of a voluntary ethical review process, there were "institutional committees in most research centres". The composition of these committees depended on the institutional specific requirements because there were no national rules regarding this aspect.

2. Implementation of Directive 2010/63/EU

The Directive is already transposed into the national legislation through the new law "Decreto Legislativo 4 marzo 2014, n. 26 - Attuazione della direttiva 2010/63/UE sulla protezione degli animali utilizzati a fini scientifici".

However, specific guidelines regarding the implementation of the Directive [e.g. concerning the composition and functioning of the Animal Welfare Bodies - AWB] were not approved yet.

3. Regulation and authorisation process: main actors

3.1. Ministry: Ministry of Health

3.2. Competent authority: Ministry of Health

3.3. Entity responsible for the project authorisation: Ministry of Health with advice from the *Istituto Superiore di Sanità*

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

4.1. Geographical organization of the project evaluation process

Firstly, the evaluation is conducted at an institutional level, by the institutional AWB. After this step, the applications are submitted to the national competent authority, the Ministry of Health, who authorises/rejects the projects after an evaluation conducted by the ISS.

4.2. Evaluators

The evaluation is conducted at a first level by institutional committees [AWB] and at, a second level, by individual experts at the ISS [there are about 25 – 30 evaluators distributed in different departments and with different backgrounds/expertise - e.g. biologists, pharmacologists, toxicologists].

4.2.1. Committees' composition

The minimum composition of the AWB described in the Directive and in the Italian Decree is:

- The person or persons responsible for the welfare and care of the animals,
- The designated veterinarian,
- A scientific member.

Additional guidelines regarding the composition and functioning of the AWB are to be issued / approved.

4.3. Protocol submission

There is one form available in the Italian Decree º 26. However it is not mandatory to use this form, the applications are currently being submitted in different forms.

The applicant sends the application to the Ministry. The Ministry sends it to the ISS office who distributes the protocols to the different experts. The experts' feedback is then provided to the Ministry of Health, who decides to approve or reject the applications.

4.4. Fees

Currently there are no fees for project evaluation.

4.5. Guidelines for project evaluation

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

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

The Ministry of Health is responsible for the follow-up of projects' authorisation.