

1. Project evaluation before Directive 2010/63/EU

According to the FELASA Report (2005, p. 10), the ethical review was mandatory and the projects were submitted to evaluation by institutional committees (that could be shared between institutions). When difficult issues arose, the projects were evaluated by a National committee.

The institutional committees were composed by (p.23):

- Government Inspector (mandatory member of each institutional ethics committee)
- Director of the institution
- Laboratory technician carrying out the experiment
- Scientist using animals
- Veterinarian, animal care staff or other animal welfare expert
- "Independent member" (a scientist not using animals, an animal welfare/protection society member or a lay person)

2. Implementation of Directive 2010/63/EU

The directive is already transposed to national law. There is a new Belgian Law on Animal Welfare from 27th December 2012 and a Royal Decree on the Protection of Laboratory Animals from 29th May 2013, applicable from 10th July 2013.

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

Projects' evaluation and ethics committees are compulsory in Belgium since 2001. No major changes were introduced by the directive, except clarifications on the necessary competencies in the committees.

4. Regulation and authorisation process: main actors

4.1. Ministry:

- Brussels: State Secretary of the Brussels-Capital Region, responsible Animal Welfare (delegated by the Minister Pascal Smet)
- Flanders: Ministry for Mobility, Public Works, the Vlaamse Rand, Tourism and Animal Welfare
- Wallonia: Ministry of the Environment, Spatial Planning, Mobility and Transport, Airports and Animal Welfare

4.2. Competent authority:

- Brussels: Brussels Environment - Inspectorate Division and contaminated lands - Animal welfare
- Flanders: Government of Flanders - Department Environment & Nature - Division Animal Welfare
- Wallonia: Public Service Wallonia – Research & Development Department – Animal Welfare

4.3. Entity responsible for the project authorisation: Institutional committees.

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 at an institutional level by a committee (that can be shared by different institutions). There are 36 ethics committees in Belgium. These committees are also responsible for the project authorisation [article 17 of the Royal Decree gives the commission the project authorisation authority. The functioning of these committees is controlled by the regional authorities, who play a major role in the regulation of the scientific use of animals].

5.2. Evaluators

The evaluation is performed by the institutional ethics committees.

5.2.1. Committees' composition

The ethical committees must have, at least, 7 members, including experts on:

- Ethics,
- Alternatives to animal experiments,
- Animal health and welfare,
- Research techniques, experimental design and statistical analysis.

The veterinarian (or the expert responsible for the animals health and welfare) of the institution should be a member.

A representative of the animal welfare body should also be a member (Royal Decree, p. 16, Art. 17, § 4.)

5.3. Protocol submission

How the protocols are submitted for evaluation will depend on the committee. However, the most likely is that the protocols are submitted by e-mail. There is a form available ("Ethische Matrix"/"Guide d'évaluation éthique"), but its utilization is not mandatory. The evaluation process is compulsory and must follow the provisions of the royal decree.

5.4. Fees

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

5.5. Guidelines for project evaluation

There are 12 criteria for project evaluation mentioned in the Annex 6 of the Royal Decree on the Protection of Laboratory Animals from 29th May 2013.

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

Each regional authority is responsible for the follow-up of projects' authorisation (and also for controlling the functioning of the committees). Government (veterinary) inspectors are involved in this control.

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

The process of the final authorisation of projects might be reviewed.

7. Additional information

At a national level, there is a Deontological Committee who is responsible for:

- 1) Provide advice on questions around animal research to the Minister, Service or EC;
- 2) Spread best practices and information on the functioning of the "welfare bodies" and project evaluation
- 3) Advise the Minister, Service or the EC about the development or applications of methods aimed at applying the 3Rs in research.

The composition of this committee was defined by the Royal Decree of 29th May 2013 – it must include representatives from the research field, the federal public services, the pharmaceutical industry and animal welfare council - different backgrounds and numbers each (Royal Decree, chapter 9, Art. 38).