

1. Project evaluation before Directive 2010/63/EU

According to the FELASA Report (2005, p. 10), the ethical review was mandatory and conducted by a “national committee appointed by the Minister of Justice which directs a Government inspectorate”. As a voluntary process there were four institutional committees.

As mentioned in this report (p.23), the national committee was composed by:

- 4 Scientists using animals (3 scientists from academia, 1 from industry),
- 4 Members from Animal welfare/ protection societies,
- 1 Lay person (i.e. the Chairman, who shall be qualified for appointment as a judge),
- 2 Government representatives.

2. Implementation of Directive 2010/63/EU

The Directive is already transposed into national legislation. The new Danish law, the Danish Act on Animal Experiments, is available at: <https://www.retsinformation.dk/Forms/R0710.aspx?id=162938>.

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

The Directive did not introduce major changes in the project evaluation process; it only established new requirements that must be taken into account when processing applications.

4. Regulation and authorisation process: main actors

4.1. Ministry: Ministry of Food, Agriculture and Fisheries (Veterinary and Food Administration).

4.2. Competent authority: Ministry of Food, Agriculture and Fisheries (Veterinary and Food Administration).

4.3. Entity responsible for the project authorisation: Animal Experiments Inspectorate (AEI) - national entity under the Ministry of Food, Agriculture and Fisheries, constituted by a one secretariat and the Board of/Council for Animal Experiments. The secretariat, which is responsible for the day-to-day keeping of the AEI, comprises 5 employees (Head of secretariat, two academic staff members, head clerk and one student). The Board/Council manages the AEI.

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

5.1. Geographical organization of the project evaluation process

The evaluation is conducted at a national level, by the Board of/Council for Animal Experiments, a national committee under the AEI.

5.2. Evaluators

The evaluation is conducted by the Board of/Council for Animal Experiments (all applications must be accepted by the Board). Amendments to permissions may be accepted by the secretariat if they do not substantially differ from what the Board/Council has accepted.

The applications are prepared by the secretariat and analyzed by the Board/Council once every month (except July) – the meetings' dates are available at:

http://www.foedevarestyrelsen.dk/fvst_ansvar_opgaver/Sider/Dyreforsogstilsynet.aspx?Indgang=Dyr&Ind .We have access to the summary of the applications and the council's decisions at:

<http://www.tilladelser.dyreforsogstilsynet.dk/period.aspx?type=period&id=159867> .

5.2.1. Committee's composition

The Board of/Council for Animal Experiments comprises one chairman and 10 other members, appointed by several organizations to represent the broader interests of the Danish population. This composition is public – the identities, affiliation, and the organizations that proposed them as members as well as since they became members and the identity of the substitutes, are available at:

http://www.foedevarestyrelsen.dk/fvst_ansvar_opgaver/Sider/Dyreforsogstilsynet.aspx?Indgang=Dyr&Ind

The Minister for Food, Agriculture and Fisheries appoints the Chairman and the other members for 4 years.

The Chairman is a judge and the other members are appointed after consultation and proposal of the following organizations:

- The National Research Council for Medical Sciences (1 member),
- The Danish Research Council for Technology and Production (1 member),
- The Board of Health (1 member),
- The Danish Industry (1 member),
- Major health associations (1 member),
- The Board of Animal Ethics (1 member),
- Animal protection associations (4 members).

The Minister for Food, Agriculture and Fisheries must ensure as far as possible that among the Council's members are persons with knowledge of the academic disciplines that have particular relevance to the tasks conferred on AEI.

5.3. Protocol submission

The protocols are submitted using an online application system, available at:

<http://www.indberetning.dyreforsogstilsynet.dk/forside.aspx> (the applicants must request access to the system to create and submit the application). The applications can be submitted in Swedish, Norwegian or Danish.

A blank form, only in Danish, is available at http://www.indberetning.dyreforsogstilsynet.dk/upload/bfile_33637.pdf to provide an overview of the information requested in the online platform.

5.4. Fees

The fees were introduced within the 1993 amendments. The applicants must pay 2500 DKK to obtain the license for animal experiments + 500 DKK by each year of the project. This information is available, in Danish, at: <https://www.retsinformation.dk/Forms/R0710.aspx?id=162938>

5.5. Guidelines for project evaluation

Besides what is described in the legislation, there are no specific guidelines for the committee on how to conduct the project evaluation.

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

The AEI also conducts the inspections [the Board members often participate in the inspections] and is responsible for the follow-up of the projects' authorisation.

6. Changes expected to occur in 2015

There are no expected changes in 2015, regarding the project evaluation process.

7. Additional information

When issuing regulations, the industry, animal welfare organizations and others were consulted by a public enquiry, and their views have been taken into account to the extent it has been possible.