

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 one of the 7 regional committees. There were no fees for the ethical review.

2. Implementation of Directive 2010/63/EU

The Directive is already transposed to national law. It is implemented since 1st January 2013 primarily within the Animal Welfare Act, 1988:534, the Animal Welfare Ordinance 1988:539 and Code of Statutes on Laboratory Animals issued by the Swedish Board of Agriculture (SJVFS: 2012:26).

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

The major changes introduced by the directive are:

- i) Confirmation of the severity classification;
- ii) Decisions on whether or not a project shall be evaluated retrospectively;
- iii) Decisions on whether or not exemptions according to Article 38.2.e shall be granted.

4. Regulation and authorisation process: main actors

4.1. Ministry: Ministry for Rural Affairs

4.2. Competent authority: Swedish Board of Agriculture and the County Administrative Boards (inspections)

4.3. Entity responsible for the project authorisation: Regional Animal Ethics Committees (AEC)

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

5.1. Geographical organization of the ethical review process

There are seven regional ethical committees: Stockholm Northern; Stockholm South; Uppsala; Linköping; Malmö / Lund; Gothenburg, and Umeå. The committee that performs the evaluation depends on the county where the animal experiment will be performed and at some extent it also depends on the nature of the experiment - some issues need to be designated to specific boards: exemption from immunisation and booster injections to Stockholm North; exemption from destination bred animals and clinical trials of veterinary medicines to Uppsala; applications from Defence forces to Umeå. Appeals could be submitted to the Central ethical committee on animal experiments.

5.2. Evaluators

The evaluation is performed by one of the seven regional committees. Normally the committee meets once a month. However the committee is divided into smaller groups which prepare the application for decision in the committee. These groups often have direct contact with the applicant to discuss different aspects of the application. During this process mutual agreements can be made to introduce amendments to the application.

5.2.1. Committees' composition

Each committee has 14 members:

- i) The chairman and the vice-chairman are lawyers;
- ii) 6 members are detached scientists, laboratory animal technicians and other animal facility personnel;
- iii) 6 members are laymen – at least one, maximum two of these, come from animal welfare organizations.

Members of ii) and iii) also have personal substitutes.

5.3. Protocol submission

There is a standard form to be used by the applicants, available at:

<http://www2.jordbruksverket.se/webdav/files/SJV/blanketter/Djur/djurskydd/D174.pdf>

The protocols are submitted by mail but a new system has been developed to make it possible for the applicant to submit the protocol electronically. The system will be up and running mid-2015.

5.4. Fees

Since 1st January 2013: 6000 SEK for a new common application; 1500 SEK to request an amendment of an authorisation that is not likely to adversely affect animal welfare, or whether it is an extension of approval that does not involve any change; 3000 SEK to perform pilot studies, i.e. studies being conducted with a small number of animals, or otherwise limited extent, or if it only involves the use of animals not kept in a laboratory animal facility privately owned animals, animals in the zoo or free-living animals.

5.5. Guidelines for project evaluation

Instructions available, in Swedish, at [Chapter 7]:

<http://www.jordbruksverket.se/download/18.3c1967aa13afeea1eb880002406/1353660757041/2012-026.pdf>

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

The follow-up is conducted by the county administrative boards through the inspections. Animal welfare body shall follow the development and result of the projects especially concerning animal welfare aspects.

6. Changes expected to occur in 2015

A change enabling the researchers to apply for an amendment to an existing authorisation that is likely to adversely affect animal welfare is foreseen during 2015. Also the fee for dealing with such amendments will be adjusted.