

1. Project evaluation before Directive 2010/63/EU

According to the FELASA Report (2005, p. 10), the ethical review was mandatory and was conducted by local (mostly institutional) committees – who could advise more than one institution. There were also:

- i) Independent committees whose services could be hired by institutions without an ethics committee;
- ii) A national committee, which acted as a “court of appeal” when the proposals were rejected by the local/institutional committees.

The local/institutional committees should be composed by scientists using animals and a veterinarian (“or other FELASA Category D (occasionally) C trained person – in attendance, not voting)” (p.23).

Each committee had its own application procedure and there was not standard form for the applications (p.20). There were also fees for the ethical review, and the cost [that could reach 500€] was defined by each committee.

Usually the committees conducted “ongoing review” – i.e. reviewed single experiments instead of entire projects (p.22) - and the Dutch legislation demanded that “information on the degree of discomfort experienced by the animals has to be reported after experiments have been performed. A summary of these data is published in Dutch annual statistics on animal experiments, according to whether the suffering experienced by the animals was: ‘minor’, ‘minor/moderate’, ‘moderate’, ‘moderate/ severe’, ‘severe’, or ‘very severe’” (p.18).

2. Implementation of Directive 2010/63/EU

The Directive was transposed into the Dutch national legislation in December 2014. The new legislation is available at: http://wetten.overheid.nl/BWBR0003081/geldigheidsdatum_21-05-2015

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

The major changes introduced were:

- i. The introduction of a central authority for project authorisation (CCD)
- ii. The project evaluation for entire projects instead of the evaluation of single experiments.

4. Regulation and authorisation process: main actors

4.1. Ministry: Ministry of Economic Affairs

4.2. Competent authority: Central Committee Animal Experiments (CCD)

4.3. Entity responsible for the project authorisation: Central Committee Animal Experiments (CCD) with advice from the established Animal Experiments Committees (DECs).

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 firstly conducted at an institutional/local level by one of the 17 established DECs. The DEC gives advice to the CCD (and not as in the past to the licence-holder). Subsequently, the application is evaluated by the CCD for authorisation.

5.2. Evaluators

The evaluation is conducted by a committee: the CCD. The CCD comprises five high-ranking specialists in their fields. The evaluation is based on the advices of the remaining 17 DECs. The decision making process is further supported by a secretariat consisting of skilled staff with a technical (such as PhD’s), administrative or legal background.

5.2.1. Committees' composition

The CCD's composition, background, expertise, representation and interests are published on the website of the CCD - <http://www.centralecommissiedierproeven.nl/over-ccd/samenstelling-ccd>

The DEC consists of at least seven members with expertise in the following areas:

- Animal testing,
- Alternatives,
- Animal protection;
- Ethical review.

At least 4 persons, including the chair, should have no formal relation with the institute that applied for project evaluation.

The committees have regular meetings to discuss the applications.

5.3. Protocol submission

The protocols are submitted for evaluation by digital submission in a secured ICT-system, followed by a signed application-form. The standard form is available at

<http://www.centralecommissiedierproeven.nl/onderwerpen/aanvraag-vergunning>

5.4. Fees

DECs charge variable fees for advice. Internal DEC's are mostly paid by the institutions. The charge for other applicants can cost up to 3500 euros. CCD fees are between 450 euro (modifications of existing projects) and 750 euros (new projects).

5.5. Guidelines for project evaluation

At this moment the EU-guidelines are used. Because that framework doesn't pay so much attention to societal values (other than harm-benefit) a new ethical framework is in development.

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

The follow-up is conducted by CCD (retrospective review) and by the Netherlands Food and Consumer Product Safety Authority (NVWA) (inspection and registration)

6. Changes expected to occur in 2015

There are no changes expected to occur in 2015.