Member state: Poland

1. Project evaluation before Directive 2010/63/EU

Before the transposition of the Directive 2010/63/EU, the use of animals in research in Poland was regulated by the Act from 21 of January 2005 on experiments on animals (Ustawa z dnia 21 stycznia 2005 r. o doświadczeniach na zwierzętach). The system of granting authorisation for experiments on animals was composed by 18 local ethics committees and 1 national ethics committee.

The local ethic committees were responsible for the projects' evaluation and authorisation (previously accepted by the director of the institution where the experiments were carried out) and for inspections carried out to assess the compliance with the projects' authorization previously issued.

The National Ethics Committee (NEC) was competent for an appeal procedure in the case of refusal of granting experiment authorisation; formulating the ethical standards of carrying out experiments on animals; appoint the local ethics committees' members; and presenting opinions on ethical standards in carrying out experiments.

2. Implementation of Directive 2010/63/EU

The Directive is already transposed into national law through the Act from 15th January on the Protection of Animals used for Scientific and Educational Purposes ("USTAWA z dnia 15 stycznia 2015 r. o ochronie zwierząt wykorzystywanych do celów naukowych lub edukacyjnych").

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

There were some changes regarding the:

- Information requested in an application submitted to local ethics committees – e.g. a non-technical summary should be attached to the application for granting authorisation (it was previously not required).
- Demand for retrospective assessment - during the evaluation process the local ethics committees should decide if the experiment will be subject to retrospective assessment.
- Term for evaluation process and granting authorisation - the provisions of Directive 2010/63/EU require that the process of evaluation and taking the decision regarding authorisation is done within 40 working days.

4. Regulation and authorisation process: main actors

4.1. Ministry: The Ministry of Science and Higher Education is responsible for transposing the Directive 2010/63/EU and for reporting to the European Commission the information regarding the use of animals in procedures and experiments.

4.2. Competent authority: The Minister of Science and Higher Education appoints the National Ethics Committee which nominates members of Local Ethics Committees. These bodies are responsible for authorising projects performed on animals.

4.3. Entity responsible for the project authorisation: Local ethics 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 and authorisation is conducted by the existent 11 local ethics committees. The National Ethics Committee (NEC) supervises these committees. The geographical scope of these committees is determined by the Regulation of Ministry of Science and Higher Education. The rationale for the geographical scope of the committees is to provide the effective work of local ethics committee and guarantee conducting the evaluation

process and granting the experiment authorisation within 40 days. The establishments' location and the number of experiments carried out were taken into account in the definition of the committees' geographical scope.

The NEC is a national committee that i) serves as an appeal instance when a local ethics committee refuses granting of project authorisation; ii) provides opinions on issues concerning protection of animals used for scientific or educational purposes for breeders, suppliers and users; iii) develops good practices for users concerning planning and caring out the procedures, on applying principle of replacement, reduction and refinement and on alternative methods; iv) appoints and dismiss members of local ethics committees.

5.2. Evaluators

The evaluation is conducted by one of the 11 local ethics committees.

5.2.1. Committees' composition

The local ethics committees are composed by 12 members:

- 6 representatives of biological, pharmaceutical, medical, agricultural or veterinary sciences with a degree or a PhD and knowledge and experience of using animals for research or educational purposes;
- 3 representatives of the humanities or social sciences, in particular in ethics, philosophy or law, among them 1 representative of an organization with the protection of the patients' rights as a statutory goal;
- 3 representatives of NGOs with animal protection as a statutory goal.

The NEC (National Ethics Committee) is composed by 15 members:

- 9 representatives of biological, pharmaceutical, medical, agricultural or veterinary sciences with a degree or a PhD and knowledge and experience in using animals for research or educational purposes;
- 3 representatives of the humanities or social sciences, in particular in ethics, philosophy or law;
- 3 representatives of NGOs with animal protection as a statutory goal.

5.3. Protocol submission

There is no online platform for submitting the applications. The applications are submitted to the local ethics committees by email or in paper form. There are two forms of applications: a regular administrative procedure and a simplified administrative procedure.

5.4. Fees

There are no fees; the project evaluation is free of charge.

5.5. Guidelines for project evaluation

There are no guidelines for the project evaluation yet.

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

The local ethics committees are responsible for the retrospective assessment. The inspections of breeders, suppliers and users are carried out by the Veterinary Inspection.

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

The Act from 15 of January on the Protection of Animals used for Scientific and Educational Purposes came into force on 27th of May 2015. There are no changes to projects' evaluation planned for this year.

7. Additional information

Breeders, suppliers and users are authorised by the Veterinary Inspection and registered by the Ministry of Science and Higher Education.

The Minister of Agriculture and Rural Development describes the minimum requirements for establishments and conditions of care of animals kept in the establishment.