

1. Project evaluation before Directive 2010/63/EU

The project evaluation was mandatory in Czech Republic under the Act No 246/1992 Coll. (The protection of animals against cruelty), as amended. The process of evaluation was composed of two levels:

- i. Firstly, an evaluation by the establishments' committee;
- ii. Secondly, an evaluation by one of the 8 ethical committees existent in Czech Republic (all Ministries involved in animal experiments and the Czech Academy of Sciences).

2. Implementation of Directive 2010/63/EU

The directive is already transposed into the national legislation through the Act No. 246/1992 Coll. (The protection of animals against cruelty), the Decree No. 22/2013 Coll. (Education on field of animal protection against cruelty) and the Decree No. 419/2012 Coll. (About protection of experimental animals). These documents are available at: www.oz.mze.cz (only in Czech language).

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

The major changes introduced by the directive are:

- i. New standard form for project application;
- ii. Retrospective assessment;
- iii. Nontechnical project summaries.

4. Regulation and authorisation process: main actors

4.1. Ministries: Ministry of Agriculture, Ministry of Environment, Ministry of Health, the Czech Academy of Science, Ministry of Education Youth and Sports, Ministry of Industry and Trade, Ministry of Culture, Ministry of Defence

4.2. Competent authority: Ministry of Agriculture

4.3. Entities responsible for the project authorisation: Ministry of Agriculture, Ministry of Environment, Ministry of Health, the Czech Academy of Science, Ministry of Education Youth and Sports, Ministry of Industry and Trade, Ministry of Culture, Ministry of Defence

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

5.1. Geographical organization of the project evaluation process

The evaluation is firstly conducted at an institutional level. After approval by one of the institutional committees (animal welfare bodies), the applications are forwarded to one of the 8 committees of Ministries and the Czech Academy of Science regarding the type of the institution (e.g. one ethics committee review applications from all hospitals in Czech republic; an application from a research institute belonging to the Academy of Sciences (AS) will be evaluated by an ethics committee specific for all AS institutes). Project evaluation is conducted by these committees and the project authorisation is issued by one of the Ministries or the Czech Academy of Science.

5.2. Evaluators

Project evaluation is conducted by committees: firstly by an institutional committee and after that by one of the 8 committees of Ministries and the Czech Academy of Science.

5.2.1. Committees' composition

The composition of the committees it is not public.

Under Article 15g (3) of the Act 246/1992 Coll., the institutional committee (animal welfare body) has to be composed from all persons responsible for overseeing the welfare and care of the animals and scientific expert who have to be adequately educated (veterinary, medicine, etc.). Minimum composition of an institutional committee (animal welfare body) is 3 persons.

Under Article 15g (3) of the Act 246/1992 Coll., the committees of Ministries and the Czech Academy of Science have usually 5-8 persons and have to be composed from persons who are adequately educated for carrying out procedures on animals and designing procedures and projects or veterinary doctor authorised to conduct the supervision of animal welfare (Article 26 of the Act 246/1992 Coll.).

5.3. Protocol submission

There is a standard form, available in the Decree No. 419/2012 Coll. Project application is submitted to the Ministry or the Czech Academy of Science by mail and Ministry or the Academy of Science submits this application to committee.

5.4. Fees

There are no fees for project evaluation in Czech Republic.

5.5. Guidelines for project evaluation

The members of major committees have regular trainings and they have also available guidelines of Europe commission for project evaluation and retrospective assessment.

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

The State Veterinary Administration provides inspection and enforcement. Retrospective assessment is provided by Ministries and the Czech Academy of Science via committees.

6. Changes expected to occur in 2015

There are no changes expected to occur in 2015.