European legislation
Impact on the scientific use of animals

Member state: Slovenia

1. Project evaluation before Directive 2010/63/EU

Before the Directive, Slovenia already had legislation regarding the protection of animals used for scientific purposes, namely the Animal Protection Act (1999) and other subsidiary legal acts that in detail defined legitimate purposes and conditions on which animals for experimental purposes may be used. When these rules came into force in 2004, the use of animals in scientific or research purposes was allowed after obtaining the permit for each single experiment or series of experiments for a limited period of time. Permit was granted only if applicant meets all legal requirements and gets positive evaluation by the Animal Ethical Committee (Art. 4 and 21). This national ethics committee was established in 2005 and was set up by the Ministry responsible for the Veterinary Service, the Ministry for Science and Technology, the Ministry for Education and the Ministry for Environment (Art. 21).

2. Implementation of Directive 2010/63/EU

The Directive is transposed into the national legislation on two levels:

1. "Animal Protection Act" (Zakon o Zaščiti Živali) available at http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO1353) (OJ of RS, no 38/13) and
2. "Rules on conditions for experiments on animals" (Pravilnik o pogojih za izvajanje poskusov na živalih, available at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV11176) (OJ of RS, no. 37/13 and 89/14).

Other legal document also dealing with protection of experimental animals is:

- "Rules on the Ethical Commission for the experiments on animals" (Pravilnik o etični komisiji za poskus na živalih), available at http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV11738 (OJ of RS, no 31/14);

3. Regulation and authorisation process: main actors

3.1. Ministry: Ministry of Agriculture, Forestry and Food

3.2. Competent authority: Administration for Food Safety, Veterinary Sector and Plant Protection (AFSVSPP)

3.3. Entity responsible for the project authorisation: AFSVSPP (regional office)

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

4.1. Geographical organization of the project evaluation process

The evaluation is conducted at a national level by an ethical committee. The ethical committee has to verify whether the project is scientifically or ethically justified or is prescribed in legislation. However, if the project was already scientifically evaluated (by other competent experts) there is no need for scientific evaluation of the project but only for the ethical evaluation of the project according to the "Rules on conditions for experiments on animals".

4.2. Evaluators

The evaluation is conducted by a national ethical committee, established since 2005.

4.2.1. Committee's composition

The committee is composed by 6 members, acknowledged scientists/experts from several fields: medicine, veterinary medicine/science, biology, zoo technology, pharmacology and ethics in research. One of the members can also be a member of NGO, working in the field of animal welfare and protection. The members are appointed for four years by the Minister of Agriculture, Forestry and Food, in agreement with the Minister of Education, Science and Sport, and the Minister for Environment and Spatial Planning. The committee should meet at least 4 times per year. At least 5 members should attend the meeting in order to form a quorum. Representative of AFSVSPP provides administrative support to the committee.

4.3. Protocol submission

The legislation demands to fill in the standard form available at the one of the appendixes of the subsidiary act "Rules on conditions for experiments on animals" (OJ of RS, no. 37/13 and 89/14).

Projects are authorised by AFSVSPP (regional office), so the application for the project authorisation is submitted to the regional office by e-mail. The official veterinarian submits then the application to the president of the ethical committee by e-mail and the president than organises a meeting. As prescribed in Article 6 of the Rules on the Ethical Commission for the experiments on animals, the ethical committee has to have at least 4 meetings, or more, depending on the amount of applications submitted.

4.4. Fees

The applicants need to pay 170 euros for the project evaluation and opinion of the committee on scientific justifications on the use of non-experimental animals. If the application need to be assessed again (completion of application), the fee is 85 euros.

4.5. Guidelines for project evaluation

The document "Rules on the Ethical Commission for the experiments on animals" (OJ of RS, no 31/14) describes the administrative functioning of the ethics committee. Article 22 of "Rules on conditions for experiments on animals" lays down detailed description of project evaluation. Members of the committee also received Guidance document of project evaluation and risk assessment, prepared by the EC and the experts working group.

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

The inspections are performed by regional offices of AFSVSPP. Official veterinarians at AFSVSPP regional offices are responsible for the control of user, breeder and supplier establishments. During inspections in user establishment, official veterinarian can always check project documentation (adequately educated and trained personnel, reports on performed experiments in the project, number of used experimental animals, etc.). Retrospective assessment is performed by Ethical committee, for projects which include severe experiments.

5. Changes expected to occur in 2015

No change in the project evaluation process is expected in 2015.