Member state: Ireland

1. Project evaluation before Directive 2010/63/EU

According to the FELASA Report (2005) there was “no national, mandatory requirement for prior ethical review of all regulated uses of animals” in Ireland (p.3).

The mandatory process was: “applications for licences must be approved by the Minister for Health and Children. A local nominated competent person (preferably a veterinary surgeon) must review each application and declare that he/she does not envisage any practical difficulties on welfare grounds and specify any reservations” (p. 10).

However, since “the government department responsible for licensing animal use expects to see evidence of local ethical review, which 'should' include review 'by an ethics and/or scientific committee in a university or research centre” (p. 11), there were “institutional committees in most institutions” (p.10). Also, as described in this report, “all the major academic institutions have internal rules that require ethical review and the State funding agency, the Health Research Board, require ethical review as a grant award condition” (p. 3).

2. Implementation of Directive 2010/63/EU

The directive is already transposed into the Irish national law, through the S.I. No. 543 of 2012, available at: http://www.hpra.ie/docs/default-source/3rd-party-documents/si-543-(changed)-of-2012.pdf?sfvrsn=2

These regulations came into force on 1st January 2013.

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

Until 31 December 2012, the competent authority was the Department of Health. With the transposition of the Directive, a new entity was created, first called “IMB – Irish Medicines Board”, since July 2014 it is now known as the “HPRA – Health Products Regulatory Authority”.

4. Regulation and authorisation process: main actors

4.1. Ministry: Ministry/Department of Health

4.2. Competent authority: The HPRA – Health Products Regulatory Authority

4.3. Entity responsible for the project authorisation: The HPRA – Health Products Regulatory Authority

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

5.1. Geographical organization of the project evaluation process

The formal project evaluation and authorisation is conducted at a national level, by the HPRA – Health Products Regulatory Authority. However, this entity encourages a previous evaluation by institutional ethical committees (that can be integrated within the Animal Welfare Bodies or can be shared by a group of user establishments). There are approximately 20 ethics committees in Ireland.

As described in the HPRA’s “Guide to Ethics Committee Assessment of Project Applications under Directive 2010/63/EU and S.I. No. 543 of 2012” (p.4), “in order to encourage the assessment of project applications by an ethics committee, the HPRA has agreed to reduce the timelines for the project evaluation from the statutory 40 or 55 working day timeline to 21 working days for those applications where a robust ethical review has been conducted.”

Also, there is a reduced fee for projects which ethical review is already conducted when submitted to evaluation by HPRA.

5.2. Evaluators

The project evaluation is conducted by the HPRA. However, to complement this assessment, the HPRA encourages prior evaluation by institutional ethics committees (this is encouraged through several measures, but is not mandatory). As mentioned in the HPRA Guide "The HPRA is conscious that, as the competent authority under the legislation, it has a duty and legal responsibility to perform its own project evaluations. However the HPRA understands the value of the role of establishment ethics committees and wishes to encourage their continued involvement into the future." (p.13).

The applicant must provide all documentation required to the HPRA. Administrative personnel check to ensure that the documents supplied are in accordance with the stated requirements. The evaluation is conducted by technical personnel who ensure the NTPS report is correct. The Management Committee of the HPRA (Heads of individual Departments plus the Chief Executive) are the body which are ultimately responsible for all authorisation decisions of the organisation. They are Veterinary practitioners or PhD scientists. All staff has received appropriate training in the conduct of project evaluation. After the evaluation, administrative personnel upload the approved NTPS reports to the website.

5.2.1. Committees' composition

In the "Guide to Ethics Committee Assessment of Project Applications under Directive 2010/63/EU and S.I. No. 543 of 2012", the HPRA describes several recommendations for the composition of the ethics committees (but these are not mandatory). The recommendations are:

1. The committee must have at least 6 persons ("but preferably substantially more to provide more robust scrutiny of proposed projects and to allow for occasional absences of members"). "All persons involved in the ethics committee are expected to be familiar with, and be able to provide evidence (e.g. signed and dated records of having read and understood relevant documents and reading material) that they fully understand the 3R principles" (p.5).
2. Members should be appointed for 3 years (renewable).
3. There must be a chairperson and a vice-chair. "The chairperson should be a person of standing or with significant responsibilities in the institution, such as a president or vice-president of research, dean, professor, director or senior executive with a demonstrable track record in dealing with complex issues and able to chair meetings where different perspectives are being sought, while able to forge consensus" (p.6)
4. "The expertise that an ethics committee would be expected to include are:

- The designated veterinarian who is charged with advisory duties in relation to the well-being and treatment of the animals,
- The animal care and welfare officer who is responsible for overseeing the welfare and care of the animals in the user establishment,
- One or more representative(s) of the research community, or those with current or recent experience in the conduct of procedures in animals,
- A public interest representative independent of the research being conducted at the user establishment (i.e. a 'lay' person)
- A statistician or person with expertise in statistical analysis (where relevant).

It is recommended that additional participants are included to enhance the value of the ethics committee's assessment. Such members might include:

- An ethicist or member of an ethical review group for clinical trials in humans
- A patient representative,
- A specialist in a particular animals species being investigated, or suitably qualified expert and
- Additional animal technicians or members of the research community" (p.5).

5.3. Protocol submission

As described in the guide “Project Applications under Scientific Animal Protection Legislation” (p.19), “the HPRA provides a secure online system to enable submission of applications and data. This system is known as CESP – the Common European Submission Platform. Applications can also be submitted by standard e-mail to sapsubmit@hpra.ie. If the application cannot be submitted electronically, applications will be accepted in hard copy by post”. Forms for project applications, establishment applications and individual personnel applications (as well as guidelines on how to complete them) are available on the HPRA website, at: www.hpra.ie .

5.4. Fees

Since 1 January 2015, the HPRA does not charge for project fees, except in the following cases:

- For projects without ethical approval: 2.000€
- For fast track applications - within 21 days: 2.000€.

5.5. Guidelines for project evaluation

In the chapter 6 of the “Guide to Ethics Committee Assessment of Project Applications under Directive 2010/63/EU and S.I. No. 543 of 2012”, the HPRA provides some guidelines for the harm-benefit assessment. These are the only guidelines available for the committees regarding how to conduct the project evaluation.

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

The HPRA is responsible for the follow-up of the project authorisation. They do this through a number of mechanisms, including compliance inspections (the committees’ functioning is also supervised by the HPRA inspections). The inspections to the user establishments also have fees, namely:

- Per day, per member of the inspection team: 1.489€
- Part of day (per hour, per member of the inspection team): 213€

6. Changes expected to occur in 2015

There are no changes in the project evaluation process expected to occur in 2015.