Member state: Portugal

1. Project evaluation before Directive 2010/63/EU

The project review and approval was conducted on national level, done by the central competent authority "Direção Geral de Alimentação e Veterinária" - DGAV. This process involved an advisory board including representatives of the competent authority (2), the state laboratories of veterinary medicine (1), animal reproduction and breeding (1), zootechnics (1) human health (1) of the faculties of veterinary medicine (1), medicine (1), sciences (1) and pharmacology (1) and representatives of non-governmental research institutions (1) and of animal protection NGOs (1).

2. Implementation of Directive 2010/63/EU

The directive is already transposed to the Portuguese national legislation through the Law Decree nº 113/2013 from 7th August and the Order nº 2880/2015 from 20th March.

3. Regulation and authorization process: main actors

3.1. Ministry: Ministry of Agriculture and the Sea

3.2. Competent authority: Direcção Geral de Alimentação e Veterinária - DGAV

3.3. Entity responsible for the project authorization: Direcção Geral de Alimentação e Veterinária – DGAV, with advice from the Animal Welfare Bodies.

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

4.1. Geographical organization of the project evaluation process

A national authority (Portuguese National Authority for Food and Animal Health – "Direcção Geral de Alimentação e Veterinária") is responsible for the projects' authorization. However, the applications will have to be accompanied by a recommendation from the institutional Animal Welfare Bodies (AWB).

The National Committee for the Protection of Animals Used in Research ("Comissão Nacional para a Protecção dos Animais Utilizados para Fins Científicos") could be consulted for advice when appropriate.

4.2. Evaluators

The evaluation is conducted by the AWB and by officers at DGAV.

4.2.1. Committees' composition

According to the Order n.º 2880/2015, an AWB should be composed by:

- The person responsible for the establishment
- The person(s) persons responsible for the welfare and care of the animals,
- The designated veterinarian,
- A scientific member.

Additionally, it could integrate a i) representative for the animal care/laboratory animal technicians, ii) an expert in statistics or experimental design, iii) an independent person with expertise in laboratory animal science without any juridical, contractual or other relation with the establishment; iv) a representative from an health or clinical research ethics committee from the same institution/establishment; or v) a representative from civil society to provide the public perspective.

4.3. Protocol submission

The applications must be submitted to DGAV through a standard form, available at: http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=197212&cboui=197212 . This is an old version of the form; a new and completely revised application form is expected.

4.4. Fees

The license fee for project evaluation is 400 euros per research project.

4.5. Guidelines for project evaluation

There are no specific guidelines for the DGAV and the AWB conduct the project evaluation.

5. Other institutions involved

There is also the National Committee for the Protection of Animals Used in Research, who as an advisory role. This committee must take into account specific knowledge in the fields of: 1) scientific area in which the research will be conducted – including the 3 R's; 2) research/experimental design, including statistics where appropriate, 3) veterinary practice with laboratory animals (and, if appropriate, the veterinary practice with wild animals) and 4) husbandry and care or the animal species that will be used.