

### 1. Project evaluation before Directive 2010/63/EU

The ethical review was a mandatory part of the project evaluation process. The application of a project should be reviewed in first place by an institutional Animal Welfare Officer (a veterinarian, medical doctor or zoologist), before it was submitted to the competent authority. A regional committee advised the government authority in the project evaluation process.

The regional committees should be composed by:

- Scientists (scientists must be involved, but it is not specified whether these should use animals or not),
- Animal welfare/protection society members (these members must make up one-third of the commission).

### 2. Implementation of Directive 2010/63/EU

The Directive is already transposed into the national legislation. Therefore the German Animal Welfare Act ("Tierschutzgesetz") was amended changed and a supplementary regulation ("Tierschutz-Versuchstierverordnung") was created. The German Animal Welfare Act and the new regulation are available at: <http://www.gesetze-im-internet.de/tierschg/BJNR012770972.html> and <http://www.gesetze-im-internet.de/tierschversv/index.html>.

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

The Directive introduced the following changes in the project evaluation process:

- Extension of the definition of animal experiments
- Definition of the end of the procedure
- Classification of severity of procedures
- Special regulations for primates
- Animal welfare body
- Retrospective assessment
- Publication of project summaries

### 4. Regulation and authorisation process: main actors

**4.1. Ministry:** Federal Ministry of Food and Agriculture

**4.2. Entity responsible for the project evaluation and authorisation:** authorities responsible under "Land" law<sup>1</sup>  
(with advice from regional/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 applications must be submitted to the competent authority. They have to contain a review of the institutional Animal Welfare Officer ["Tierschutzbeauftragter", a designated veterinarian with expertise in laboratory animal medicine who helps in the design of the applications in the requesting research institute]. The competent authority has to send presented applications to the regional/local ethics committees ("Tierversuchskommission"), who assists the authority in the project evaluation process. The competent authority proofs the application and decides on the planned projects (this process should not take more than 40 days). Who decides about the applications in each competent authority is regulated by the specific "Land" law and is partly different in the 16 "Lands".

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<sup>1</sup> Germany has 16 states ("Länder") and each "Land" has public authorities that are responsible for the project authorisation and notification. Each relevant authority has its own ethic committee.

The legally-required applications or those who have educational purposes must be notified to the competent authority. These projects can start 20 working days after notification to the competent authority.

[In the field of the German Federal Armed Forces the relevant agencies of the Federal Armed Forces shall be responsible for implementing the German Welfare Act and the ordinances issued on the basis thereof. The Federal Ministry of Defence shall appoint a commission to assist the competent agencies in deciding whether to authorise planned experiments.]

## **5.2. Evaluators**

The evaluation is conducted by the competent authority. A regional ethics committee assists the competent authority in the evaluation process. Each relevant authority has its own ethic committee, reason why we defined the scope of these committees as regional.

### **5.2.1. Committees' composition**

The majority of the commission members must possess the specialist knowledge in veterinary medicine, medicine or any other discipline of natural science needed to assess experiments on animals. The commissions shall also include members from nominee lists of animal welfare organizations and with the experience needed to assess animal welfare issues; these members must make up one-third of the commission.

## **5.3. Protocol submission**

There is an example for a standard form, in German, available at

<http://www.regierung.oberbayern.bayern.de/formulare/gesundheit/tier/> .

## **5.4. Fees**

The fees depend on the aim of the institution that applies for project evaluation ("profit vs. "non-profit" aim).

## **5.5. Guidelines for project evaluation**

There are no guidelines for the ethics committees on how to conduct the project evaluation.

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

This responsibility is regulated by the specific "Land" law and is partly different in the 16 "Lands".