

## AnimalTestInfo Database

FAQ to the BfR of 1 November 2014

German law has given the Federal Institute for Risk Assessment (BfR) the legal mandate to anonymously publish non-technical summaries of authorised animal testing projects in Germany. The AnimalTestInfo database provides non-technical project summaries to the general public. It contains information about all projects which have been applied by research departments of universities, industry and the federal government, and subsequently have been authorised by the competent authorities in the federal states. The applicants are responsible for the content of the project summaries published by the BfR.

The BfR is home to ZEBET (Centre for Documentation and Evaluation of Alternatives to Animal Experiments). The goal of the BfR is to reduce the use of animals for scientific purposes to an indispensable amount and to develop alternatives to animal testing.

### **Why does the BfR publish the database [www.animaltestinfo.de](http://www.animaltestinfo.de)?**

German law has given the BfR the mandate to publish non-technical project summaries of authorised animal testing projects in Germany in an anonymised way. This is regulated in § 41 of the German Animal Welfare - Laboratory Animal Regulation.

### **What purpose does the database serve?**

The purpose of the database is to keep the public informed about authorised animal testing projects in Germany.

The database thereby fulfils a requirement of the EU-law. In the recitals of EU Directive 2010/63/EU, recital (41) states: "To ensure that the public is informed, it is important that objective information concerning projects using live animals is made publicly available. ....". This goal is outlined in Article 43 of the directive.

Directive 2010/63/EU was transposed into German law with the Animal Welfare Act of 4 July 2013 (TierSchG) along with the Animal Welfare - Laboratory Animal Regulation of 12 August 2013 (TierSchVersV). The latter stipulates that every application for the authorisation of an animal testing project must be accompanied by a summary in which the project is described in generally understandable language. Article 43 of Directive 2010/63/EU (Fn. 1) refers to a "non-technical project summary".

### **What details are contained in the project summaries intended for the general public?**

The applicants provide information about the purpose of the animal experiments, what kind of experiments are planned, what benefits they will have and what harm and/or stress can be expected for the animals used. The number and species of the animals scheduled for use (mice, rats etc.) must also be stated along with all measures taken to 1.) Avoid the use of animals in advance (replacement), 2.) Reduce their number in the experiment (reduction), and 3.) Improve their wellbeing (refinement).

### **What can I research in the database?**

You can search for the species (e.g. mice) and number (magnitude) of test animals used, for the legally defined purpose of the project (e.g. fundamental research), for the year of publishing in the database and of course for keywords, which you can choose freely.

More information is contained in the operating instructions.

### **Does the database contain all animal testing projects in Germany?**

The database contains all animal testing projects requiring authorisation, which have been applied for by research departments of universities, industry and the federal government, and which have subsequently been authorised by the competent authorities in the federal states.

The database does not contain notifiable testing projects (§ 8a, Para. 1 TierSchG). Notifiable animal tests include such tasks as the testing of vaccines within the scope of batch testing (§ 8a, Para. 1, Number 2, Letter b TierSchG). Furthermore, if animals are killed exclusively so that their organs or tissue can be used for scientific purposes, this is not regarded as animal testing (§ 7, Para. 2, Sentence 3 TierSchG). Accordingly, no summary has to be published.

### **Why are the project summaries on animal testing published anonymously?**

Anonymous publication is prescribed by law. This is already stipulated in Directive 2010/63/EU on the protection of animals used for scientific purposes. Recital (41) states: *[Publication] should not violate proprietary rights or expose confidential information. Therefore, users should provide anonymous non-technical summaries of those projects, which Member States should publish. The published details should not breach the anonymity of the users.* This is addressed in Article 43, Para. 1, Sentence 2 of the Directive.

### **Can it be seen from the summaries who and/or which institution applied for the respective animal experiment?**

No. This must be ensured by the applicant because the law prescribes an anonymous publication. Since the data is already anonymised when the BfR receives it, the institute does not know who the applicants are.

### **Can I find out from the BfR in which federal state the project was applied for?**

No. The BfR cannot give any information on this since the law prescribes anonymous publication, thus making it impossible to trace the applicant. The regulations on the protection of intellectual property and of company and trade secrets remain unaffected too (§ 41, Para. 1, Sentences 3 and 4 TierSchVersV).

### **Who is responsible for the content of the summaries?**

The applicant has sole responsibility for the content of the project summary.

### **How long does it take until a project summary is published after the authorisation has been granted?**

The law allows up to 15 months until publication: 3 months for the forwarding of the summary from the competent authority to the BfR and an additional 12 months for publication. The BfR usually publishes the summaries of authorised animal test projects within 3 months.

### **How up-to-date is the database?**

After publication, the summaries remain accessible in the database for 5 years, thus complying with the maximum duration of an animal testing project. This guarantees that the database entries are up-to-date. With projects of shorter duration it can happen that they are still shown in the database although the tests have already been completed. Even if authorised animal testing projects are not ultimately conducted, they remain in the database. The BfR has no knowledge of whether projects have been conducted or not.

**What are the differences to the statistics on the number of animals used for experimental and other scientific purposes published every year by the Federal Ministry for Food and Agriculture (BMEL)?**

Laboratory animal statistics retrospectively record the actual number of animals (including those killed for the removal of organs or used for training purposes) used per calendar year, irrespective of the individual test project. In this way, the actual total number of animals used per year for specific purposes or rough areas of research (e.g. cancer) can be established.

The summaries published in the AnimalTestInfo database, on the other hand, relate to animal testing projects planned by the applicants. In addition to this, more information on each individual animal testing project can be taken from the summaries. This includes the purpose, the benefits and measures to reduce the suffering of the animals.