

Questions and answers on animal experiments at the German Federal Institute for Risk Assessment (BfR)

BfR FAQ from 23 April 2020

The German Federal Institute for Risk Assessment (BfR) performs animal experiments as part of its statutory duty. For which scientific purposes are animals used at the Institute, which species are used and how is it guaranteed that the animals suffer as little as possible? The BfR has summarised and answered these and other questions below.

For what purpose does the BfR perform animal experiments?

Animal experiments are performed at the BfR as part of its statutory duty. Firstly, this involves research into the safety of food and feed. The goal of these experiments is to recognise and assess risks for humans and livestock. Secondly, animal experiments are performed at the German Centre for the Protection of Laboratory Animals (Bf3R) which is part of the BfR. Possible ways of reducing stress for animals in experiments (refinement) are investigated at the centre. The scientific goal is to establish better housing and experimental conditions, which can be applied worldwide.

How many animals are used in animal experiments at the BfR?

In 2018, 133 animals were used in experiments at the BfR. 180 animals were used in 2019.

Which animal species are used in BfR animal experiments?

Mice, rats, guinea pigs, rabbits, chickens, turkeys, sheep, goats, cattle, mussels, shrimp, farmed fish, and zebra danios (zebrafish) are currently kept in the BfR laboratory animal house and used for scientific issues.

Which types of animal experiments are there at the BfR?

Reference material: The statutory duties of the BfR include developing and refining detection methods for pathogens which are transmissible to humans via foods, and unwanted or prohibited substances in foods. The National Reference Laboratories also regularly inspect the methodical expertise of food safety laboratories. Animal reference material is required for this. This either originates from untreated animals which have been proven to be free from the pathogens or substances in question, or animals which have specifically been infected with certain pathogens or treated with substances. Depending on the method, faeces, spontaneous urine, fur or feathers, eggs, milk, blood or meat can act as reference material.

Training: The German Animal Welfare Act and the German Laboratory Animal Welfare Directive state that only persons with proven expertise in the care of laboratory animals and animal experiments may be involved. Expertise must be gained through continued education. The BfR therefore trains animal keepers in the field of research and clinical practice, and trains employed scientists in planned animal experiments in accordance with legal guidelines. Several training methods are used for this, such as training sessions, teaching videos, working with artificial models and practical instruction in day-to-day work. These procedures are only used on living animals when the described theoretical methods have been exhausted, so that they can be applied safely in experiments and the laboratory animals suffer from as little stress as possible.

Refinement: In accordance with Article 4 of EU Directive 2010/63/EU on the protection of animals used for scientific purposes, there is a particular emphasis on 'refinement' by the member states. This means that any possible pain, suffering, stress or long-term damage must be avoided or reduced as much as possible for animals. The 'Laboratory Animal Science' unit at

the BfR explores how stress in laboratory animals can be recorded as objectively as possible and reduced. The goal is to establish better management and experimental conditions. Experiments which cannot be avoided in the foreseeable future must be performed under the best possible animal welfare conditions.

Who authorises animal experiments at the BfR?

The Regional Office for Health and Social Affairs (LAGeSo) is responsible for inspecting and authorising animal experiments in the German federal state ("Land") of Berlin. Each experiment planned at the BfR contains a written application which is submitted to the LAGeSo. Each experimental project is extensively discussed and planned internally within the BfR with animal welfare officers beforehand. We adhere strictly to the '3R' principle in this regard: First, checks are performed to see whether the goal of the experiment can also be achieved with methods not involving animal experiments ('replace'). If this is not the case, the number of animals to be used is selected in order to ensure that as few animals as possible are used ('reduce'). This is achieved by means of careful statistical calculation while planning animal experiments. Care is also taken to ensure that the experimental conditions are designed in a way that reduces pain, suffering and damage to the absolute minimum ('refine'). Examples of this are the continuous improvement of the conditions under which the animals are kept, the design of their environment and the handling of the animals. Habituation of the laboratory animals to certain measures reduces stress, leading to a lower burden. If painful procedures are performed, the relevant painkillers are administered.

Experiments may only be performed by people with the appropriate training. This is stated in the application. The LAGeSo checks the application documents for completeness and comprehensibility and is advised by an independent animal testing commission. All questions arising about the experimental procedure are answered in writing and then checked again by the LAGeSo. When all questions have been sufficiently answered, an authorisation notice can be issued for this proposed experiment for a maximum of five years.

Who is responsible for ensuring that animal experiments at the BfR are performed appropriately?

The authorising authorities are responsible for monitoring animal experiments; in Berlin, it is the Regional Office for Health and Social Affairs (LAGeSo). The LAGeSo monitors experiments with announced or unannounced visits. All animal experiments are accompanied internally by the BfR animal welfare officer. As well as veterinary training, they also possess a specific qualification in the field of laboratory animal science. Performing experiments properly is in the interests of all parties involved in the experiment and is documented accordingly.

Where do the animals in the BfR animal experiments come from?

Some animal species are specifically bred at the BfR for in-house experiments. Other animals are purchased from specialist laboratory animal breeders or selected agricultural enterprises, in accordance with legal guidelines.

How does the BfR ensure that the suffering of animals is kept as low as possible?

Applications for animal experiments define the maximum degree of distress for the animals. This specifies all measures for keeping stress as low as possible. These include suitable painkillers, as well as sufficient rest periods and an environment designed to be species-appropriated (including factors such as suitable toys or lighting conditions). The current German Animal Welfare Act stipulates that animals must be constantly monitored during animal ex-

periments. The animals are therefore systematically and regularly monitored for signs of distress. When a defined stress limit is reached, the experiment is stopped for the affected animal. The monitoring of the signs and the limit above which the animal must be excluded from the experiment is authorised by the competent authority beforehand. All parties involved in animal experiments are obliged to apply veterinary and care measures to improve the welfare of the animals and to reduce any distress.

What happens to the animals after the experiment?

What happens to the animals after the experiment essentially depends on the type of experiment. For some experimental purposes, the animal must be slaughtered or killed in accordance with animal welfare law, so that further investigations can be performed on its organs. If it is possible for the animals to survive without impairment of their well-being, and without them presenting a hazard to humans or other animals and the environment, they either remain at the BfR or attempts are made to hand the animals over to knowledgeable private individuals.

Which other statutory duties and initiatives does the BfR follow with regards to animal welfare?

German Centre for the Protection of Laboratory Animals (Bf3R) was founded at the BfR in 2015 as part of the animal welfare initiative of the German Federal Ministry of Food and Agriculture (BMEL). The centre coordinates all activities nationwide with the goals of restricting animal experiments to only those, which are considered essential, and guaranteeing the best possible protection for laboratory animals.

You can find selected questions and answers regarding this here:

- <https://www.bfr.bund.de/cm/349/questions-and-answers-on-the-german-centre-for-the-protection-of-laboratory-animals-bf3r.pdf>

On 7 January 2019, the German Laboratory Animal Welfare Centre at the BfR started the digital animal experiment register www.animalstudyregistry.org. The register was set up as a reaction to the reproducibility crisis and offers scientists a platform to register a detailed study plan before beginning their experiments, thereby preventing selective reporting.

Our FAQ provides more detailed information on this:

- <https://www.bfr.bund.de/cm/343/ausgewaehlte-fragen-und-antworten-zum-digitalen-tierversuchsregister.pdf>

The legislator has also assigned the BfR the task of publishing anonymised summaries of authorised animal experimentation projects in Germany. The database www.animal-testinfo.de is for this purpose.

You can find explanatory background information on this here:

- <https://www.bfr.bund.de/cm/349/animaltestinfo-database.pdf>