Bf3R
German Centre for the Protection of Laboratory Animals

BfR
German Federal Institute for Risk Assessment

FAQ

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

As part of its statutory remit, the German Federal Institute for Risk Assessment (BfR) also carries out animal experiments. For what scientific purposes are animals used at the Institute, which animal species are used, and how is it ensured that the animals suffer as little as possible? The BfR has compiled and answered these and other questions below.

Why does the BfR carry out animal experiments?

As part of its statutory responsibilities, animals are used at the BfR to develop alternative methods for animal experiments and to establish better welfare and testing conditions that can be applied internationally. The second major area of activity for the use of animals in experiments is research into the safety of food and animal feed. The aim of these experiments is to identify and assess risks to humans as well as animals used for food production.

As the headquarters of the German Centre for the Protection of Laboratory Animals (Bf3R), the BfR applies with particular rigour the principle – which is also required by law – of avoiding the use of living animals, using the smallest possible number of animals to carry out the task, and in doing so ensuring the greatest possible level of animal welfare and reducing stress as far as possible. This principle is also known as the "3R" principle (see ‘What is the "3R" principle?’ below). For this reason, all animal testing projects are comprehensively assessed prior to commencement to determine whether alternative methods (replacement) can be used instead of live animals. If this is not possible, complex statistical methods are used to determine the smallest number of animals necessary to answer the research question (reduction). All animals at the BfR are kept and cared for under the best possible conditions before, during and, where applicable, after their use in an animal experiment, in order to meet their species-specific needs and improve their welfare (refinement).

Which animal species are used in BfR animal experiments?

In accordance with its broad range of activities the BfR keeps mice, rats, guinea pigs, hamsters, rabbits, as well as chickens, pigs, sheep, goats, cattle, prawns, farmed fish and zebrafish and uses them for scientific research.

For what purposes does the BfR conduct animal experiments?

Refinement: In accordance with Article 4 of European Directive 2010/63/EU on the protection of animals used for scientific purposes, 'refinement' is particularly emphasised by the Member States. This means that any pain, suffering, distress or lasting harm to the animal must be avoided or minimised as far as possible. The BfR's unit 'Behaviour of Laboratory Animals and Refinement' and its animal facility are researching how to assess and reduce the distress of laboratory animals as objectively as possible. The aim is to establish and promote better welfare, adaption and testing conditions.

Food and feed safety: As part of its statutory responsibilities, the BfR conducts animal experiments to assess the safety of and potential contamination in animal food products. In these experiments, cattle, pigs, chickens or fish are used to determine, for example, whether substances from the environment or feed are absorbed by these animals and can be detected in the food products derived from them.

Preparation of reference material: The BfR's statutory responsibilities include developing and improving detection methods for pathogens that are transmissible to humans via food, as well as for undesirable or prohibited substances in food. In addition, the National Reference Laboratories regularly verify the methodological competence of the official testing authorities. This necessitates animal reference material. It is either taken from untreated animals proven to be free of the pathogens or substances in question, or from animals that have been specifically infected with certain pathogens or treated with substances. Depending on the specific method, faeces, spontaneous urine, hair or feathers, eggs, milk, blood or meat are used as reference material.

Training: The German Animal Welfare Act and the Ordinance on the Protection of Laboratory Animals stipulate that only persons with proven expertise may be involved in the care of laboratory animals and in animal experiments. For this reason, the BfR trains animal caretakers specialising in research and clinical settings and participates in the Berlin training association for this specialisation. Initially, many different training methods are used that do not require the use of animals, such as theoretical instructions, training videos, working with artificial models, and practical training in day-to-day tasks. Only when these methods have reached their limit, certain procedures are allowed to be practised on live animals, so that they can be applied safely in experiments and the laboratory animals are exposed to as little stress as possible.

How many animals were used in animal experiments at the BfR in 2025?

In 2025, 69 animals were used at the BfR in experiments completed in the same year. A total of 28 mice, 13 rabbits, 22 chickens, 2 pigs, 1 sheep and 3 cattle were used in a total of eight approved projects. All projects involved minimal distress to the animals. In addition to the animals used in animal experiments, 48 mice were killed so that their organs could be used to develop alternative methods to animal experiments. These animals were not subjected to

any distress prior to their death and were killed painlessly. This also applies to 64 zebrafish, which were used for breeding and killed at an advanced age to avoid distress and suffering.

What capacity does the BfR have for keeping laboratory animals?

The BfR has been granted permission by the Berlin State Office for Health and Social Affairs (LAGeSo) to keep up to 70 cattle, 90 sheep, 60 goats, 65 turkeys, 300 chickens, 170 pigs, 50 rabbits, 20 guinea pigs, 10 hamsters, 100 rats, 1,000 mice, 600 edible fish, 2,500 zebrafish and 70 cephalopods on its premises.

These numbers, which need to be reapplied for every five years in accordance with the current rules on keeping laboratory animals, are the maximum permissible number of each species of animal that may be kept in suitable rooms and pens at the same time. The actual numbers of animals that are kept and used in animal experiments depend on the projects and the numbers deemed essential for the individual animal experiments. At no time may these exceed the approved total number for the premises.

The Berlin State Office for Health and Social Affairs provides further information on the requirements for keeping laboratory animals on its website:
https://www.berlin.de/lageso/gesundheit/veterinaerwesen/tierschutz/versuchstierhaltung/

What is the "3R" principle?

The 3R principle was published in 1959 by the British scientists William Russell and Rex Burch and enshrined in law in the 2010 European Directive 2010/63/EU on the protection of animals used for scientific purposes. The aim of the 3R principle is to completely avoid animal experiments (replacement) or to limit the number of animals (reduction) and their suffering (refinement) in experiments to the absolute minimum. All persons and organisations that carry out animal experiments are legally obliged to act in accordance with this principle.

Further information on the "3R" principle can be found on the Bf3R website:
https://www.bf3r.de/en/

What research is the BfR carrying out to replace animal experiments?

Various research projects are being planned and carried out continuously at the BfR to replace animal experiments. On the one hand, this involves the development of cell or tissue culture-based testing methods to create new, animal-free alternative methods for basic research and toxicological assessment. On the other hand, it involves the development of state-of-the-art, partly AI-based search engines to help scientists identify animal-free alternative models and methods, thereby promoting the implementation of these tools.

In addition, the BfR is involved in several international projects within which alternative methods are being developed, such as PARC and RISK-HUNT3R.

Further information on research into alternative methods at the BfR can be found here:
https://www.bf3r.de/en/research/replace/.

What research is the BfR carrying out to reduce the use of laboratory animals?

Various research projects are being planned and carried out continuously at the BfR to reduce the number of laboratory animals used in experiments. Some examples are given below. The list is by no means exhaustive.

For example, in order to find ways of reducing the number of laboratory animals used in research, the BfR is researching new statistical and bioinformatic analysis models. The aim is to use them to determine which methodological and institutional changes to research and the publication process could contribute to fewer animal experiments being carried out. At the same time, the BfR is using new biometric approaches to make the statistical planning of experiments more efficient with and without the use of laboratory animals. This should reduce to the minimum the number of animals required for planned research projects involving laboratory animals.

Further information on the projects can be found on the Bf3R website: https://www.bf3r.de/en/research/reduce/.

What research is the BfR carrying out to reduce pain or suffering in laboratory animals?

Various research projects are being planned and carried out continuously at the BfR to minimise the pain and suffering of laboratory animals.

In order to reduce aspects such as pain, suffering or distress in laboratory animals and thereby also improve the quality of experimental results, measures to reduce stress and improve welfare are being researched. In addition, assessment criteria for evaluating the degree of stress are being developed. A key focus is on the refinement of the housing conditions of laboratory animals and investigating the impact of alternative housing systems with enriched environments on the animals, with the aim of reducing the stress they experience. The assessment of stress is always carried out from the animals' perspective.

Further information on the projects can be found on the Bf3R website: https://www.bf3r.de/en/research/refine/.

Who authorises animal experiments at the BfR?

The Berlin State Office for Health and Social Affairs is responsible for the inspection and authorisation of animal experiments in the German federal state ("Land") of Berlin. Every experiment planned at the BfR requires a written application which is submitted to the Berlin State Office for Health and Social Affairs. Beforehand, the BfR discusses and plans each experimental project in detail internally with the animal welfare officers, and the BfR Animal Welfare Committee is also involved. We adhere strictly to the 3R principle: First of all, we check whether the objective of the experiment can also be achieved using animal-free methods ('replace'). If this is not the case, the number of animals to be used is selected to ensure that the lowest possible number of animals is used ('reduce'). This is achieved by careful statistical calculation when planning the animal experiments. In addition, the experimental conditions are intentionally designed such that pain, suffering and harm are reduced to the absolute minimum ('refinement'). Examples include the continuous improvement of the conditions in which the animals are kept, the design of their environment and the handling of the animals. Training laboratory animals for certain procedures reduces stress and results in less pressure. If painful procedures are carried out, an appropriate painkiller is administered.

The experiments may only be carried out by specifically trained staff. These staff members are named in the application. The Berlin State Office for Health and Social Affairs checks the application documents for completeness and clarity and consultation is provided by an independent commission for animal experiments. All questions about the experimental project that are brought up during this process are answered in writing and checked again by the Berlin State Office for Health and Social Affairs. Once all of the questions have been adequately answered, a notice of authorisation can be issued for the requested experiment for a maximum of five years.

Who monitors that animal experiments at the BfR are carried out in accordance with the regulations?

The authorising authority, in Berlin the State Office for Health and Social Affairs, is responsible for monitoring animal experiments. The Berlin State Office for Health and Social Affairs monitors the experiments by making announced or unannounced visits. Internally, all animal experiments are monitored by the BfR's animal welfare officers. In addition to their veterinary training, these officers have a specific qualification in the field of laboratory animal science. It is in the interest of all persons involved in the experiment that the experiments are carried out in accordance with the regulations and are documented accordingly. The BfR's Animal Welfare Committee discusses ongoing and completed animal experiments with the project leaders and all persons involved in the experiment and makes recommendations for future projects, in particular to improve animal welfare. It also continuously checks whether the living conditions of the animals and their welfare can be improved both during and outside of animal experiments.

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

Some species are bred specifically at the BfR for its own experiments. Other animals are purchased from specialised laboratory animal breeders or from selected farms according to legal requirements.

How does the BfR ensure that animal suffering is minimised?

When an application is made to conduct an animal experiment, the maximum level of stress that the experiment may cause an animal is determined. All procedures are defined to minimise the stress as far as possible. This includes suitable painkillers as well as sufficient recovery time and a species-appropriate environment (including factors such as suitable toys or lighting conditions). The German Animal Welfare Act requires animals to be constantly monitored during the experiment. The animals are systematically and regularly examined for signs of distress. When a defined stress limit is reached, the experiment is discontinued for the animal affected. The monitoring of signs and the point at which the animal needs to be removed from the experiment are authorised in advance by the competent authority, which checks compliance. All those involved in the animal experiment are required to continually apply veterinary and care measures to improve the well-being of the animals and to reduce any stress.

What happens to the animals after the experiment?

What happens to the animals after the experiment depends mainly on the type of experiment. For some experimental purposes, it is necessary to euthanise the animal in accordance with animal welfare regulations to be able to carry out further examinations of

the organs. If it is possible for animals to live on without impairments to their welfare and without posing a hazard for humans, other animals or the environment, they either remain at the BfR or an attempt is made to place the animals with competent private individuals.

What other legal tasks and initiatives does the BfR work on within the field of laboratory animal welfare in research?

As part of the German Animal Welfare Initiative of the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH), the German Centre for the Protection of Laboratory Animals (Bf3R) was founded at the BfR in 2015. The centre coordinates nationwide activities with the aim of limiting animal experiments to the minimum necessary and ensuring the best possible protection for laboratory animals.

Further details on the mission and objectives of the German Centre for the Protection of Laboratory Animals can be found here: https://www.bf3r.de/en/about-the-bf3r/our-mission/.

On 7 January 2019, the German Centre for the Protection of Laboratory Animals at the BfR launched the **digital animal study registry** www.animalstudyregistry.org. The registry was set up in response to the reproducibility crisis and gives scientists a platform for registering an exact study plan before starting their studies and thus prevents selective reporting. In addition, more transparency is provided worldwide by the animalstudyregistry.org. New fields of research and development for greater animal welfare can thus be identified.

Further information on this can be found in our FAQs:
https://www.animalstudyregistry.org/asr_web/asr.web.static.action?name=asr.links.faq

The legislator has also assigned the BfR the task of publishing generally understandable project summaries (NTP) of approved animal experiments projects in Germany in anonymised form. The investigators submit these summaries to the competent authorities together with the authorisation application. The BfR publishes them in the online database **AnimalTestInfo** (www.animaltestinfo.de), to inform the public about animal experiments. In addition, the BfR sends NTPs to the European database ALURES.

Explanatory background information on this can be found here:

https://www.bfr.bund.de/en/service/frequently-asked-questions/topic/animaltestinfo-database/ or https://www.bf3r.de/en/offers/for-private-citizens/animaltestinfo/

In accordance with Section 15a of the German Animal Welfare Act, the BfR also performs the role of the '**National Committee for the Protection of Animals Used for Scientific Purposes**' – or National Committee for short – for the Federal Republic of Germany. The National Committee advises the competent German authorities and animal welfare committees on matters relating to the acquisition, breeding, housing, care and use of animals in procedures according to the German Animal Welfare Act. It ensures that there is an exchange of best practice in Germany and also shares information with other national committees within the European Union on the functioning of animal welfare committees, project assessment and best practice.

More background information as well as the statements and recommendations of the National Committee can be found here:

https://www.bf3r.de/en/offers/for-national-authorities/national-committee/.

In 2021, the BfR was commissioned by the BMLEH to **report the number of laboratory animals** used annually. The data collected annually by laboratory animal facilities and submitted to the BfR by the relevant authorities was published on the Bf3R website for the first time for the reporting year 2020. The BfR's legal mandate has since been enshrined in the German Laboratory Animal Reporting Ordinance (Section 2 VersTierMeldV). In this context, the BfR also sends the German laboratory animal numbers to the European Commission.

Current laboratory animal numbers can be found on the Bf3R website: https://www.bf3r.de/en/offers/laboratory-animal-numbers/ .

Does the BfR support the "Transparent Animal Experiments Initiative"?

The "Transparent Animal Experiments Initiative" is a joint project of the Senate Commission for Animal Experimentation Research of the German Research Foundation (DFG) and the "Understanding Animal Experiments" initiative of the Alliance of Science Organisations, which was launched on 1 July 2021.

The BfR not only supports this initiative, but was also one of its founding signatories. The declared goals include transparent information and open communication regarding animal experiments in research. The BfR and its German Centre for the Protection of Laboratory Animals (Bf3R) have been active in this area for many years. The BfR is committed to ensuring that animal experiments are transparent to the public. The BfR's AnimalTestInfo and AnimalStudyRegistry databases are intended to help make studies more comprehensible and avoid unnecessary animal experiments.

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH). It protects people's health preventively in the fields of public health and veterinary public health. The BfR provides advice to the Federal Government as well as the Federal States ('Laender') on questions related to food, feed, chemical and product safety. The BfR conducts its own research on topics closely related to its assessment tasks.

About the Bf3R

The German Centre for the Protection of Laboratory Animals (Bf3R) was founded in 2015 and is an integral part of the German Federal Institute for Risk Assessment (BfR). It co-ordinates nationwide activities with the goals of restricting animal experiments to only those which are considered essential, and safeguarding the best possible protection for laboratory animals. Moreover, it intends to stimulate research activities and encourage scientific dialogue.

This text version is a translation of the original German text which is the only legally binding version.

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