

FAQ

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Questions and answers on animal experiments, alternative methods and animal experiment numbers

→ Changes compared to the version from 11 December 2024: addition of questions on legal regulations for animal experiments on medicinal products; history and role of the Bf3R

Animal experiments are carried out to answer scientific questions, but not every scientific question justifies an animal experiment. The German Animal Welfare Act (Tierschutzgesetz, TierSchG) specifies the purposes for which animal experiments may be conducted, the organisational and technical requirements that must be met, and the qualification requirements placed on personnel.

Permissible purposes of animal experiments include, in particular, basic research, the diagnosis and treatment of diseases in humans and animals, and safety testing for drugs and chemicals. However, the German Animal Welfare Act stipulates that animal experiments may only be carried out if they are essential to answer the scientific question and appear ethically justifiable in the balance of interests between the expected gain in knowledge and the expected suffering of the animals.

If reliable alternative methods are available, these must be used instead of animal experiments. The German Centre for the Protection of Laboratory Animals (Bf3R) at the German Federal Institute for Risk Assessment (BfR) promotes the development, validation, and use of such alternative methods to animal experiments. Until 2019, the German Federal Ministry of Food and Agriculture (BMLEH) collected the annual number of animals used in experimental projects in Germany and published these figures on its website. Since 2015, these figures have also been communicated to the European Commission. With the amended German Laboratory Animal Reporting Ordinance of 11 August 2021, this legal task was transferred to the BfR. Accordingly, the BfR has published the figures on its Bf3R website (www.bf3r.de/en/) since 2020.

The BfR has compiled a selection of questions and answers on animal experiments, alternative methods, and the annual reporting of laboratory animal numbers.

General questions about animal experiments and their legal regulations

What are animal experiments?

Animal experiments within the meaning of the German Animal Welfare Act are interventions or treatments performed on animals which serve to answer a scientific question and which may involve pain, suffering or lasting harm to these animals or their offspring. The modification of the genome of animals and the breeding of genetically modified animal lines also fall under the definition of animal experiments if the offspring may experience pain, suffering or lasting harm as a result of the genetic modifications. Interventions and treatments performed on animals that do not directly serve to answer a scientific question are also considered animal experiments if they are carried out in order to produce substances and products (e.g. antibodies) or to reproduce organisms (e.g. parasites) that are subsequently used to answer scientific questions. Animal experiments also include, for example, removing organs or tissues for transplantation, creating cultures, examining isolated organs or tissues for scientific purposes, attaching of tracking transmitters to wild animals as well as interventions and treatments for education, training, and further education on live animals.

Who is authorised to carry out animal experiments?

The German Animal Welfare Act stipulates that animal experiments may only be carried out by persons who have the necessary knowledge and skills. This generally requires a university degree in veterinary medicine, medicine or dentistry. Animal experiments without surgical intervention may also be carried out by persons who have a university degree in natural sciences, provided they have the necessary knowledge and skills, as well as by persons who have acquired the necessary knowledge and skills as part of a completed vocational training programme. In any case, the required knowledge and skills must be demonstrated to the competent authority before the start of collaboration in an experimental project.

When may an animal experiment be carried out?

In principle, an animal experiment may only be carried out if authorisation has been granted by the competent authority. The prerequisite for authorisation is that the animal experiment is to be carried out for a purpose that can be approved under the German Animal Welfare Act and is essential for that purpose. The scientific question must not already have been answered and it must not be possible to answer it using a method other than animal experiments. In an animal experiment, the pain, suffering or lasting harm inflicted on the animal must be minimised to an irreducible level. All persons involved in conducting the experiments or caring for the animals must have the necessary qualifications.

Applications for animal experiments are only approved if, among other things, it is plausibly rationalised that the expected pain, suffering or lasting harm to the animals is ethically justifiable with regard to the purpose of the experiment. This also includes compliance with the 3R principle (replacement, reduction, refinement). The 3R principle was established back in 1959 by the British scientists William Russell and Rex Burch. In the authorisation process, it is applied to ensure that the animals may only be subjected to pain, suffering and lasting harm to the extent that it is essential for the purpose pursued and that there are no

alternative methods (replacement). In addition, the number of animals used must be kept to the absolute minimum necessary (reduction) and the suffering of the animals must be minimised (refinement).

What legal regulations apply for animal experiments?

Animal experiments in Germany are regulated by the German Animal Welfare Act, which has been constitutionally based on the state objective of animal welfare in accordance with Article 20a of German Basic Law since 2002. In 2010, the EU Directive 2010/63/EU on the protection of animals used for scientific purposes was adopted. In 2013, the regulations enshrined therein were transposed into German law by revising the German Animal Welfare Act. At the same time, the new Animal Welfare Experiments Ordinance came into force. It further specifies the framework conditions laid down in the German Animal Welfare Act. For example, the German Animal Welfare Act stipulates that a person conducting animal experiments must have the appropriate knowledge and skills. The German Ordinance on the Protection of Animals used for Experiments and other Scientific Purposes describes the required qualifications in more detail. The same applies, for example, to the content of records that must be kept about a given animal experiment. The German Animal Welfare Act is divided into twelve sections. Division 5 “Animal experiments” of the German Animal Welfare Act (Sections 7–9) stipulates that animal experiments must be minimised in terms of the pain and suffering inflicted and the number of animals used and may only be carried out if they are essential for a specific purpose. Animal experiments on vertebrates or cephalopods generally require authorisation.

What legal regulations apply for animal experiments for chemicals in addition to the German Animal Welfare Act?

The European chemicals regulation REACH (*Registration, Evaluation, Authorisation and Restriction of Chemicals, 1907/2006/EC*) regulates the registration, assessment, authorisation and restriction of chemicals in the European Union. REACH is based on the principle that manufacturers and users of chemicals must ensure that the chemical substances do not impair human health or harm the environment. According to the standard information requirements for chemicals set out in Annexes VII-X of the REACH Regulation, animal experiments may sometimes be required. In order to minimise the need for extensive animal studies for this purpose, animal experiments should be avoided as far as possible and animal-free methods should be used and developed. Tests on vertebrates should only be carried out as a last resort. Corresponding studies must not be repeated or carried out separately by different manufacturers. Instead, the results of a particular study should be shared between different manufacturers.

What legal regulations apply for animal experiments for plant protection products and biocides in addition to the German Animal Welfare Act?

EU Regulation No 1107/2009 concerning the placing of plant protection products on the market and EU Regulation No 528/2012 concerning placement on the market and use of biocidal products regulate the authorisation requirements for plant protection products, biocides, and their active substances within the European Union. The regulations aim to minimise the animal experiments required for the authorisation of plant protection products and biocides. Here, too, tests on vertebrates should only be carried out as a last resort.

Corresponding studies may not be repeated, but should instead be used jointly by different manufacturers.

What legal regulations apply for animal experiments for cosmetics in addition to the German Animal Welfare Act?

Animal experiments in connection with cosmetics are generally prohibited within the European Union by Regulation No. 1223/2009. The ban applies to finished cosmetic products as well as to ingredients and combinations of ingredients. Placing cosmetic products tested on animals and cosmetic products whose ingredients have been tested on animals on the market is also prohibited. Cosmetic products are substances or mixtures intended to come into external contact with parts of the human body (skin, hair, nails, etc.) or with the teeth and mucous membranes of the oral cavity for the sole or main purpose of cleaning, perfuming, altering the appearance, protecting or maintaining them in good condition, or influencing body odour. However, if the animal experiments were required under another statutory European regulation, e.g. the testing of individual components of cosmetics with an annual tonnage of over one tonne as chemicals in accordance with the standard requirements under REACH (see *Which legal regulations for animal experiments apply for chemicals in addition to the German Animal Welfare Act?*), the results may be used for the safety assessment of the cosmetic product. However, this does not apply if the animal experiments, for example in third countries, were carried out for marketing in non-EU countries.

What legal regulations apply for animal experiments for medicinal products for humans in addition to the German Animal Welfare Act?

Finished medicinal products intended for human use may only be placed on the market within the scope of the German Medicinal Products Act (AMG) if they have been authorised by the competent higher federal authority or if they have been granted a marketing authorisation by the European Community or the European Union in accordance with Regulation (EC) No. 726/2004. The competent higher federal authority is the German Federal Institute for Drugs and Medical Devices (BfArM) in accordance with AMG Section 77 (1), unless the Paul Ehrlich Institute (PEI) is responsible. The PEI is responsible for sera, vaccines, blood preparations, tissue preparations, tissues, allergens, advanced therapy medicinal products, xenogeneic medicinal products and genetically engineered blood components in accordance with AMG Section 77 (2). Xenogeneic medicinal products are or contain living animal tissue or cells.

This authorisation requirement is regulated in the German Medicinal Products Act (AMG). As part of the authorisation process, the quality, safety and efficacy of the new medicinal product must be demonstrated. Animal experiments as well as alternative, animal-free methods that are carried out for this purpose are described in the Pharmaceuticals Testing Directive Regulation, Regulation (EU) 2019/5, Directive 2001/83/EC and the German and European Pharmacopoeia.

What legal regulations apply for animal experiments for veterinary medicinal products in addition to the German Animal Welfare Act?

Veterinary medicinal products within the meaning of Regulation (EU) 2019/6 and veterinary medicinal products within the meaning of Section 3 may only be placed on the market within the scope of the Veterinary Medicinal Products Marketing Act and the national

implementation of the provisions stipulated by the European Union Veterinary Medicinal Products Legislation (German Veterinary Medicinal Products Act – TAMG) if they have been authorised by the competent higher federal authority.

In accordance with TAMG Section 75, the competent higher federal authority for immunological veterinary drugs, in the field of immunotherapy for monoclonal antibodies and veterinary drugs for advanced therapies as well as for animal allergens is the Paul Ehrlich Institute (PEI). For the remaining area, the German Federal Office of Consumer Protection and Food Safety (BVL) is the competent federal authority.

This authorisation requirement is regulated in the TAMG in the following sections or subsections:

- Implementing provisions for authorisation (Subsection 3)
- Implementing provisions for the authorisation of veterinary medicinal products; authorisations to issue ordinances (Section 9)
- Supplementary provisions for clinical trials and residue trials (Subsection 4)
- Authorisation of applications to conduct a clinical trial and a residue trial (Section 10)

In addition, the first subsection of the TAMG regulates the authorisation of veterinary medicinal products outside the scope of Regulation (EU) 2019/6 and of veterinary medicinal products. Section 22 (Authorisation procedure) and Section 23 (Clinical trials) must be observed here in particular.

According to the TAMG, the quality, efficacy and safety of veterinary medicinal products and veterinary medical products must be ensured during authorisation. Animal experiments carried out for this purpose are regulated, among other things, in Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary drugs.

Does the German Federal Institute for Risk Assessment (BfR) also authorise animal experiments?

The BfR does not authorise animal experiments. In Germany, the competent authorities of the federal states (“Laender”) are responsible for the enforcement of animal welfare regulations and thus also for the authorisation of animal experiments. This includes

- reviewing/processing animal testing applications,
- authorising animal testing applications, and
- monitoring compliance with animal welfare regulations in the keeping and use of laboratory animals.

The BfR advises the authorising authorities on alternative methods in accordance with Section 46 of the German Animal Welfare Experiments Ordinance. [You can find further information here.](#)

Does the German Federal Institute for Risk Assessment (BfR) also conduct animal experiments?

As part of its legal mandate, the German Federal Institute for Risk Assessment (BfR) conducts animal experiments. On the one hand, this concerns research into the safety of food and feed. The aim of these tests is to recognise and assess health risks for humans and livestock. On the other hand, animal experiments are carried out at the German Centre for the Protection of Laboratory Animals (Bf3R) at the BfR. This centre investigates ways of reducing the suffering of animals in experiments (refinement). The scientific goal is to establish better husbandry and experimental conditions that can be applied worldwide. Various research projects are continuously planned and carried out at the BfR in order to develop alternatives to animal experiments. The BfR has compiled detailed questions and answers [here](#).

Questions on laboratory animal numbers and their collection and publication

How many and what kinds of laboratory animals are used in Germany?

The detailed laboratory animal statistics for the years 2009 to 2019 were published annually by the BMLEH ([source \(in German\)](#)). Since 2020, the annual [figures have been published by the BfR](#). The current figures for 2023 [can be viewed here](#).

Why were fewer laboratory animals used in 2023 than in the previous year?

The number of animal experiments carried out in each reporting year is subject to project-specific fluctuations. As a result, there are small changes in the number of laboratory animals used from year to year. However, looking at the past five years, the number of animal experiments is continuously decreasing in almost all areas. The only exceptions are experiments on species conservation, which usually involve wild animals. The number of these experiments is comparatively low and has remained almost constant over the past few years. By contrast, the decline in regulatory uses and routine production, for example of animal reagents for clinical use, is particularly clear. Other areas, such as the breeding and maintenance of new genetically modified lines, as well as basic research and translational (applied) research, have fluctuated more strongly over the past five years, but have all decreased substantially compared to 2022.

What is the difference between “authorised” and “used” laboratory animals?

A basic distinction must be made between the number of animals authorised for experiments and the number of animals actually used in experiments.

Every animal experiment project must undergo an official authorisation process before it can be carried out. The application to be submitted must also specify the number of animals expected to be used in the experimental project. An animal experiment project is usually planned for a longer period of time, but is authorised for a maximum of five years. This means that the authorised number of laboratory animals can be spread over several years. However, an approved animal experiment project specifies the total number of animals planned for the project for the entire period. This number is usually based on a statistical estimate. However, it is often the case that fewer animals are used than originally planned, for example because scientific findings have changed in the meantime and animal experiments that were already planned are therefore not conducted at all. However, if it becomes apparent in the course of the research that more animals are required than

originally authorised, a further application must be submitted to the authorities. When breeding genetically modified animals, the number of authorised laboratory animals is also often much higher than those actually used. The number of authorised laboratory animals is therefore sometimes significantly higher than the number of animals actually used.

An overview of the animal experiment projects authorised in Germany can be found on the website www.animaltestinfo.de (see also the question “How many animal experiment projects are conducted in Germany each year?”). The ALURES NTP database of the European Commission provides information on the [animal testing projects authorised within the EU](#).

Statistics on the laboratory animals used in Germany can be found on the [Bf3R website](#). The statistics for the entire EU can be [found here](#).

What regulations apply to the recording of laboratory animal numbers?

The EU Directive 2010/63/EU protecting animals used for scientific purposes came into force on 9 November 2010. Its transposition into national law in 2013 also necessitated a new version of the German Laboratory Animal Reporting Ordinance with an extension of the obligation to report the use of laboratory animals. Since then, the use of cephalopods (e.g. squid and octopuses), vertebrate larvae from the point at which they can feed on their own, and the breeding of genetically modified animals must also be reported. In addition, the severity of pain, suffering or harm (minor, moderate, severe) to which the animals were exposed as a result of use must also be reported. In addition, the animals on which experiments were carried out under deep anaesthesia from which they were not resuscitated (no restoration of vital function) are recorded. The use of animals in animal experiments was recorded for the first time in 2014 in accordance with the new requirements.

The details of the reporting are regulated in the implementing decision for [Directive 2010/63/EU](#) establishing a common reporting format. In 2020, the updated [Implementing Decision \(EU\) 2020/569](#) came into force, which was accompanied by an amendment to the German Laboratory Animal Reporting Ordinance in 2021.

What has changed in laboratory animal reporting since 2021?

New categories have been introduced for the declaration of laboratory animals since 2021. The reason for this is the amended [Implementing Decision \(EU\) 2020/569](#). Firstly, the category “higher education or training for the acquisition, maintenance or improvement of vocational skills” was split into “higher education” and “training for the acquisition, maintenance or improvement of vocational skills”, and secondly, the new category “developmental biology” was introduced in basic research and the new category “animal nutrition” in translational and applied research. Within the “routine production” category, a distinction has been made since the 2021 reporting year between “monoclonal antibody(ies) only in the ascites procedure” and “monoclonal and polyclonal antibodies (excluding ascites methods)” in the production of antibodies. In addition, the animal species “other fish” are further subdivided into “sea bass”, “salmon, trout, char and graylings” and “guppy, swordtail, molly, platy”. The group “turkey” has also been added. Under “other species of non-human primates”, a distinction is now made between “other species of New World monkeys” and “other species of Old World monkeys”. In addition, the number of non-human primates originating from self-sustaining colonies is now shown regardless of the

breeding generation. The new categories are taken into account when preparing the reports on the laboratory animals used each year.

Since 2021, the figures for animals bred for scientific purposes but not used and killed for such purposes have also been recorded (see also the question “What are unused, killed or ‘surplus’ laboratory animals?”). The BfR now publishes these figures annually alongside the other figures in the laboratory animal report. In addition, these figures are submitted to the European Commission once every five years. The last transmission took place in 2023 for the reporting year 2022.

How does the German Federal Institute for Risk Assessment (BfR) collect the annual numbers of laboratory animals for Germany?

Scientists conducting animal experiments in Germany are obliged to submit the number of laboratory animals used and other information on the experiments (including the species and origin of the animals used, purpose of the animal experiments, severity) to the competent state authority in accordance with the German Laboratory Reporting Ordinance (in German). The competent authorities of the federal states (“Laender”) then send all reports made in a calendar year to the BfR in anonymised form. The BfR checks the plausibility of the figures received from all German federal states (“Laender”) using software provided by the European Commission. Once this check has been completed, the BfR forwards the figures to the European Commission.

Are laboratory animal numbers also collected for Europe as a whole?

According to Article 54 of the EU Directive on the protection of animals used for scientific purposes, the European Commission is obliged to create and maintain a searchable, freely accessible database. This database is to contain annual statistical data on the use of laboratory animals within the European Union and make it publicly accessible. The ALURES database can be accessed via this link. An explanatory video is also published there, which provides detailed information on how to use the database.

What is meant by first-time use animals and reuse animals when reporting the use of laboratory animals?

When reporting the laboratory animals used, a distinction is made between animals used for the *first time* and *reused* animals. *First-time* use means that the animals have never been used in an experimental project before. *Reuse* describes that an animal has already been used in an experimental project and was subsequently used in another experimental project. It is important that the first experimental project has already been completed and that the second animal experiment is not related to the first use of the animal. A prerequisite for reuse is that the previous experimental project was not severely harmful for the animal, that the animal’s health and well-being have been fully restored, and that the reuse is not associated with severe suffering. There must be a veterinary recommendation that reuse is possible.

If an animal is used, does that automatically mean that it is killed?

When reporting laboratory animals used in animal experiments, the whereabouts of the animals after the end of the experiment are not queried. In many cases, it is possible that animals survive an experiment and are subsequently kept, passed on to private individuals or used again for other scientific purposes. This applies in particular to animals that have

been used in animal experiments with a maximum of low severity. However, even low-severe animal experiments can end with the laboratory animals being killed in accordance with animal welfare regulations. In practice, the proportion of animals that live on after the animal experiment is completed will vary greatly depending on the species reported.

What is meant by “severity” in animal experiments?

In accordance with [Article 15 of Directive 2010/63/EU](#) on the protection of animals used for scientific purposes and [Section 31 para. 1 no. 2 lit. b of the German Animal Welfare Experiments Ordinance](#), animal experiments must be classified into one of four severity categories in the application for authorisation of an experimental project. The severity category is a classification of the suffering to which the animals are likely to be exposed during the experiment. A distinction is made between “no restoration of vital function” (see question “What regulations apply to the recording of laboratory animal numbers?”), “low”, “moderate” and “severe”. A definition as well as classification criteria and illustrative examples for the individual severity levels can be found in [Annex VIII of Directive 2010/63/EU](#).

What are unused, killed or “surplus” laboratory animals?

The group of unused, killed laboratory animals largely comprises offspring from the breeding of genetically modified animals that do not have the desired characteristics for the experiment. However, the category also includes laboratory animals that were killed, for example, for hygiene monitoring of breeding colonies. It also includes animals that could not be used scientifically for other reasons, for example because they were too old or not the right sex for the experiment. These laboratory animals, which were bred for scientific purposes but not used for such purposes, are in many cases killed as not used. Colloquially, the animals are also referred to as “surplus” laboratory animals.

The BfR first recorded these figures for the 2021 reporting year and published them on its website. These figures are also sent to the European Commission once every five years. This was last done in 2023 with the transmission of the laboratory animal figures collected for 2022.

A team of scientists from the German Centre for the Protection of Laboratory Animals (Bf3R) conducted a legal analysis of the fate of unused laboratory animals and published two articles on this topic in the legal journal *Natur und Recht* in 2023 (<https://link.springer.com/content/pdf/10.1007/s10357-022-4102-9.pdf> and <https://link.springer.com/article/10.1007/s10357-022-4103-8>). In addition, the BfR organised the public BfR stakeholder forum “Unused laboratory animals – ‘surplus’ or necessity?” on 15 December 2023. The recordings of the presentations are available on the [BfR YouTube channel](#).

What is meant by “housing capacity”?

Any facility wishing to keep laboratory animals for the purpose of animal experiments requires official authorisation in accordance with [Section 11 of the German Animal Welfare Act](#). The application for a licence to keep laboratory animals must specify, among other things, the animal species and the housing capacity, i.e. the maximum number of animals that can be kept in the facility per animal species. These figures, which must be reapplied for every five years in accordance with the current requirements for keeping laboratory

animals, describe the maximum number of animals per species that may be kept in suitable rooms and stables at the same time. The actual numbers of animals kept and used in animal experiments are based on the projects and the numbers approved as essential for the individual animal experiments. At no time may these be higher than the authorised total number for the property.

How can the public find out about authorised animal testing projects?

Once an animal experiment project has been authorised, the competent authorities submit the associated non-technical project summary (NTP) to the BfR. This has been the case since the revision of the German Animal Welfare Act came into force in 2013. The NTP is a generally understandable summary of an authorised experimental project, in which, among other things, the purpose and benefits of the experiments are set out, as well as the pain, suffering and lasting harm to which the animals could be exposed. The authorities responsible for authorising animal experiments submit the corresponding NTP of the experimental project to the BfR within three months of authorisation being granted. The BfR usually publishes the NTPs on the website (www.animaltestinfo.de) one month after submission by the competent authority. The purpose of the publication is to make information on authorised animal research projects publicly accessible. The BfR has [compiled](#) detailed questions and answers on the AnimalTestInfo database [here](#). The German Centre for the Protection of Laboratory Animals (Bf3R) has also created animated videos to help scientists write good NTPs. The videos can be viewed [here](#).

Since 2021, the BfR has also been transmitting the NTPs to the European Commission's central [database](#) ALURES, in which the NTPs of all European Member States are published.

Questions about alternative methods to animal experiments

What is the Federal Government doing to reduce animal experiments?

The Federal Government of the Federal Republic of Germany strives to reduce the number of laboratory animals. For this reason, various projects are being initiated and funded with the aim of replacing animal experiments with alternative methods as quickly as possible.

These include the establishment and operation of the German Centre for the Protection of Laboratory Animals (Bf3R) at the German Federal Institute for Risk Assessment (BfR) by the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH), Bf3R research funding, support for the Foundation for the Promotion of Research into Alternative and Complementary Methods to Limit Animal Experiments (SET), and the annual awarding of the BMLEH's Animal Protection Research Prize.

The Bf3R develops replacement and supplementary methods for animal experiments. It also researches ways to improve the well-being of laboratory animals.

Within the remit of the German Federal Ministry of Research, Technology and Space (BMFTR), the ["Federal Network 3Rs"](#) promotes the transfer of knowledge for research and technology development on alternative methods through exchange, dialogue and networking. It acts as a central hub for effective knowledge transfer.

The aim of German Federal Ministry of Research, Technology and Space (BMFTR) [funding programme "Alternative methods to animal experiments"](#) (in German) is to develop

alternative methods, in particular to close existing gaps in their application. Established methods are to be standardised and disseminated in order to make them ready for practical application. The funding programme supports projects with a 3R concept.

What tasks does the German Centre for the Protection of Laboratory Animals (Bf3R) perform to protect laboratory animals?

In 2015, the German Centre for the Protection of Laboratory Animals (Bf3R) was founded at the BfR. The Central Office for the Recording and Evaluation of Alternative and Complementary Methods to Animal Experiments (ZEBET), which was founded in 1989, is part of the new centre. The Bf3R 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. The Centre's tasks are to

- intensify research into alternative methods,
- provide advice to authorities and research institutions,
- harmonise alternative methods at the international level,
- promote and coordinate research into alternative methods, and
- inform the public.

Further questions and answers on the Bf3R are [summarised here](#).

How did the German Centre for the Protection of Laboratory Animals (Bf3R) come to be and why is it an integral part of the BfR?

The history of the Centre began in 1986 with EU Directive 86/609, according to which all Member States of the European Union undertook to ensure the protection of laboratory animals and to promote the development and validation of alternative methods. The German Animal Welfare Act was amended accordingly for the first time after 1972 and promulgated on 18 August 1986. The Federal Government at the time made it clear that it wanted to improve the protection of laboratory animals without neglecting the interests of humans. In 1988, the departments involved in animal experiments agreed to set up the world's first institution for the protection of laboratory animals at the German Federal Health Agency (BGA), the Centre for the Recording and Evaluation of Alternative and Complementary Methods to Animal Experiments (ZEBET). The ZEBET was tasked with recording and evaluating alternative and complementary methods and developing them to such an extent that they could be used by industry or authorities and could also be prescribed in legal regulations.

The decision to locate ZEBET at the BGA was a logical one, as the BGA was the central German authority for public health. It had the required technical expertise and legal responsibilities. For example, the BGA authorised and registered drugs and researched drug effects. The Max von Pettenkofer Institute at the BGA was dedicated to consumer health protection and the authorisation of plant protection products. The assessment centre under the German Chemicals Act was also located there. The Robert Koch Institute, responsible for infectious diseases and genetic engineering, and the Robert von Ostertag Institute for Veterinary Medicine, which answered questions on the hygiene of animal foodstuffs and conducted residue research, were also part of the BGA.

The German Central Healthcare Institutions Reorganisation Act (GNG) of 1994 dissolved the BGA. Three independent higher federal authorities were established: the Robert Koch Institute, the German Federal Institute for Drugs and Medical Devices (BfArM) and the German Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV). The BgVV combined the functions of an authority and a scientific institution and thus fulfilled a large number of legal tasks that were essentially associated with consumer health protection. These included, for example, testing the quality and safety of substances and products (chemicals, plant protection products, wood preservatives and pesticides, veterinary drugs and additives in animal feed, food including food additives, tobacco products, cosmetic products and consumer goods). The BgVV was also entrusted with the protection against zoonoses and animal welfare. ZEBET thus became part of the BgVV.

ZEBET remained part of the BgVV for eight years. In 2002, the BgVV was reorganised to become the BfR and the German Federal Office of Consumer Protection and Food Safety (BVL).

ZEBET became part of the BfR. As a scientific institution of the Federal Republic of Germany for the refinement of consumer health protection and food safety, the BfR prepares expert opinions and draws up opinions on food and feed safety as well as on the safety of chemicals and products, and conducts research in the respective fields. ZEBET was able to seamlessly build on the founding idea from 1988. It now utilises the expertise of the individual BfR departments, particularly in the field of toxicology.

As a result of the amendment to the German Animal Welfare Act in 2013, the BfR was assigned further legal tasks in the protection of laboratory animals. The German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH) launched the initiative “A question of husbandry – new ways for more animal welfare” and opened the German Centre for the Protection of Laboratory Animals (Bf3R) at the BfR in 2015. ZEBET was integrated into the Bf3R. This makes the Bf3R the first “3R Centre” in Europe that is part of an authority. The BfR is independent in its scientific communication, assessment and research.

What is meant by alternative methods?

Alternative methods to animal experiments are all procedures that can replace animal experiments, reduce the number of laboratory animals or minimise the suffering of laboratory animals. The generally recognised scientific basis for the development of alternative methods is the “3R” principle, which was published by the English scientists W.M.S. Russell and R.L. Burch in 1959. According to this principle, an alternative method must fulfil at least one of the following three requirements:

- *Replacement*: animal experiments are replaced by non-animal methods
- *Reduction*: the number of laboratory animals is reduced
- *Refinement*: suffering or pain of the laboratory animals is reduced

Alternative methods include, for example, *in vitro* procedures with isolated human or animal cells, computer simulations, and imaging procedures such as magnetic resonance imaging or ultrasound. The Member States of the European Union have been obliged to promote the development and validation of alternative methods in their countries since 1986 by EU Directive 86/609/EEC on the protection of animals used for scientific purposes.

What requirements must alternative methods fulfil in order to be able to replace animal experiments for safety toxicological tests?

Alternative methods are only recognised by the regulatory authorities for safety toxicological testing of chemical substances if their results are as reliable as animal experiments. The method must be scientifically validated in order to show that an alternative method can replace an animal experiment prescribed by the authorities, i.e. that it provides equally good or better results than the animal experiment and leads to the same results in all laboratories. As the transferability of results from animal experiments to humans can be limited due to species differences, alternative methods can provide supplementary and comparative information, e.g. on the mechanism, which allows an improved assessment of the effect of chemical substances on humans. For this reason, the development of cell models of human origin in particular has great potential. As alternative methods generally only depict individual biological aspects due to their reduced complexity, combinations of different alternative methods are often necessary in order to achieve a reliable test result in relation to the desired research question. The development of test strategies and assessment concepts, in which the data from several alternative methods are taken into account in a final assessment of a chemical substance, is a focus of international research activities.

How do scientists find out whether there is an alternative to an animal experiment?

In order to assess the indispensability of an animal experiment, the applicant of an animal experiment project is obliged to systematically exhaust all relevant sources of information. To make systematic research easier for them, but also for animal welfare officers and approval authorities, the European Centre for the Validation of Alternative Methods (ECVAM) published an English-language reference work entitled “ECVAM Search Guide – Good Search Practice on Animal Alternatives” in 2013. [It is available here](#). The Search Guide provides information on the wide variety of possible sources of information that can be used for research on alternative methods to animal experiments and the rules for making this variety accessible. The BfR contributed its expertise in the field of information searches for alternative methods and played a key role in the development of the guide. In addition, the Bf3R trains scientists in such research techniques as part of laboratory animal science courses and has developed a search engine that can be used specifically for searching for alternative methods. “SMAFIRA” (SMARt Feature based Interactive RANking) uses artificial intelligence to help with searches in scientific databases and is available here: <https://smafira.bf3r.de>.

What alternative methods has the Bf3R been able to establish so far?

The Bf3R is continuing the work of ZEBET, which has been supporting the development, validation and implementation of alternative methods since 1989. Various methods are now internationally recognised and established as official test methods (*Test Guideline*, TG) in the EU and at the Organisation for Economic Cooperation and Development (OECD). Among other things, an animal-free test for phototoxic or light-dependent skin damage was developed, which was recognised as an OECD test guideline (TG 432) in 2004. The test is now routinely used worldwide for the safety testing of pharmaceuticals, chemicals and cosmetic ingredients that could be exposed to sunlight and thereby alter their effects. In addition, the test for skin corrosive and irritant properties on rabbits could be replaced by alternative methods. The BfR played a leading role in the validation of reconstructed models

of human skin and coordinated and promoted regulatory acceptance, so that these models were published as OECD test methods for the detection of skin-irritating (TG 439, 2010) or corrosive effects (TG 431, 2004). Subsequently, a testing and assessment strategy was developed under the leadership of the BfR and published as an OECD guideline in 2014, so that the skin compatibility of chemicals in the EU is now largely tested on human skin models. Finally, the Bf3R supports the recognition of various methods as OECD test methods by submitting them as projects in the OECD Test Guideline Programme and actively participating in expert groups. For example, the Bf3R was able to support the recognition of the first test strategies with defined evaluation processes, known as “defined approaches”, in the field of skin sensitisation as test method TG 497 and ensure the regulatory recognition of further methods for the detection of sensitising activities.

Is the development of alternative methods being promoted internationally?

ZEBET, now an integral part of the Bf3R, was the world’s first governmental research institution tasked with replacing animal experiments. When it was founded in 1989, there were only a few non-animal toxicological test methods that were accepted by authorities worldwide for testing chemical substances or products. Today, there are similar facilities in other European countries as well as in Japan, South Korea and the USA. The European Union directly promotes the development of alternative methods through Directive 2010/63/EU on the protection of animals used for scientific purposes and the use of alternative methods through cosmetics and chemicals legislation. In addition, the EU coordinates the validation of alternative methods through the scientific centre EURL-ECVAM and is advised by the Member States as part of PARERE, an EU-wide network. The Bf3R acts as the national contact point in the PARERE network. However, the OECD is the most important international organisation for the recognition of alternative methods to animal experiments in the field of toxicological testing of substances. The legally agreed *mutual acceptance of data* is of particular significance for the international recognition and application of alternative methods.

How is the development of new alternative methods supported financially in Germany?

The BMLEH currently provides the Bf3R with an annual budget of around 400,000 euros to fund research into new alternative methods at German universities and research institutions. Each year, the Bf3R uses this to fund around ten research projects, each lasting between one and three years ([information on Bf3R research funding can be found here](#)). Since the start of the funding programme in 1990, more than 183 3R projects have been supported. The Bf3R also provides financial support and advice to the SET Foundation to promote research into alternative and supplementary methods to limit animal experiments. In addition, the German Federal Ministry of Education and Research (BMBF) has been funding the development of alternative methods since 1980. So far, this has included more than 620 projects with around 200 million euros in funding ([source](#)). Research work that helps to replace animal experiments or reduce their number can also be honoured. From 2025, the BMLEH’s Animal Welfare Research Prize will be awarded annually in three prize categories and is endowed with a total of 220,000 euros. In addition to the federal government, many German federal states (“Laender”) also award funding and research prizes for 3R-relevant research.

Further information on the Bf3R website on animal experiments

Website of the German Centre for the Protection of Laboratory Animals (Bf3R):

<https://www.bf3r.de/en/bf3r-homepage.html>

Recording of laboratory animal numbers in Germany:

https://www.bf3r.de/en/laboratory_animal_numbers-310547.html

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Agriculture, Food and Regional Identity (BMLEH) in Germany. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemicals and product safety. The BfR conducts independent research on topics that are closely linked 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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