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

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Animal experiments are carried out to answer scientific questions, but not every scientific question justifies an animal experiment. The Animal Welfare Act specifies the purposes for which animal experiments may be carried out, the organisational and technical requirements that must be met, and the requirements for the qualifications of the personnel.

The permissible purposes of an animal experiment include, in particular, basic research, the diagnosis and treatment of diseases in humans and animals, and the safety testing of medicines and chemicals. However, the 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.

Wherever reliable alternative methods exist, these must be used instead of animal experiments. The German Centre for the Protection of Laboratory Animals (Bf3R) at the Federal Institute for Risk Assessment (BfR) promotes the development, validation and use of such alternative methods to animal experiments. The Federal Ministry of Food and Agriculture (BMEL) previously recorded the annual number of animals used in experimental projects in Germany and published these figures on its website. Since 2015, the BMEL also transmitted these figures to the European Commission. With the amended Experimental Animal Reporting Ordinance of 11.8.2021, this legal task was transferred to the BfR. Accompanying this, the BfR will publish the figures from 2020 onwards on its website.

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

What are animal experiments?

Animal experiments within the meaning of the German Animal Welfare Act are interventions or treatments on animals which serve to answer a scientific question and which may involve pain, suffering or harm to these animals or their offspring. Likewise, the modification of the genetic make-up of animals and the breeding of genetically modified animal lines fall under the concept of animal experimentation if the offspring may experience pain, suffering or harm as a result of the genetic modifications. Interventions and treatments on animals that do not directly serve to answer a scientific question are also considered animal experiments if they are carried out to produce substances and products (e.g. antibodies) or to propagate organisms (e.g. parasites) that are subsequently used to address scientific questions. Animal experiments also include the removal of organs or tissues for transplantation, the creation of a culture, the examination of isolated organs or tissues for scientific purposes, the attachment of tracking devices to wild animals, as well as interventions and treatments on live animals for the purposes of education, training or higher education.

Who is allowed to carry out animal experiments?

The Animal Welfare Act stipulates that animal experiments may only be carried out by persons who have the necessary knowledge and skills. As a rule, this requires a university degree in veterinary medicine, medicine or dentistry. Animal experiments without surgical intervention may also be carried out by persons who have completed university studies in the natural sciences, provided they can demonstrate they have the necessary knowledge and skills, and by persons who have acquired the necessary knowledge and skills within the framework

of completed vocational training (e.g. animal caretakers, biology laboratory assistants). The acquisition of the required knowledge and skills must be demonstrated to the competent authority before the start of participation in an experimental project.

When may an animal experiment be conducted?
In principle, an animal experiment may only be conducted if it has been approved by the competent authority. The prerequisite for a permit is that the animal experiment project is to be carried out for a purpose that can be approved under the Animal Welfare Act and is indispensable for this purpose. The scientific question must not already have been answered and it must not be possible to answer it by a method other than animal experimentation. In an animal experiment, the pain, suffering or harm inflicted on the animal must be reduced to an irreducible level. All persons involved in the conduct of the experiments or the care of the animals must have the necessary qualifications.

Applications for animal experiments are only approved, among other things, if it is plausibly justified that the expected pain, suffering or harm to the animals is ethically justifiable with regard to the purpose of the experiment. This also includes compliance with the 3Rs principle (Replacement, Reduction, Refinement). The 3Rs principle was established as early as 1959 by the British scientists William Russell and Rex Burch and is used in the approval process to the extent that pain, suffering and harm may only be inflicted on the animals to the extent that it is indispensable for the purpose pursued, and the experiments cannot be replaced by alternative methods (replacement), reduced in scope (reduction) or the stress on the animals reduced (refinement).

What is the difference between "approved" and "used" laboratory animals?
In principle, a distinction must be made between the number of animals approved for experiments and the number of animals actually used in experiments:
Every animal experimentation project must go through an official approval process before it is carried out. The application to be submitted must also state the number of animals expected to be used in the experimental project. An animal experiment project is usually planned for a longer period, but approved for a maximum of five years. This means that the approved number of animals is spread over several years. An approved animal experiment project therefore states the total number of animals planned for the project. This figure is based on a statistical estimate of how many animals are needed for the experiments. However, it often happens that fewer animals are used than originally planned because, for example, scientific knowledge has changed in the meantime and animal experiments that were actually planned are no longer necessary as a result. However, if it becomes apparent in the course of the research that more animals are needed than originally approved, another application must be submitted for this. In the breeding of genetically modified animals, too, the number of approved experimental animals is often significantly higher than those that were actually used. The numbers of approved and used laboratory animals can therefore sometimes differ significantly.

How many animal experiments are carried out in Germany each year?
No exact figures are available on the number of individual animal experiments. Naturally, it is far below the number of laboratory animals used. The AnimalTestInfo database (www.animaltestinfo.de) provides an overview of approved animal experiments and approved laboratory animals in Germany. Since 2013, approved animal testing projects have been systematically recorded in this database by means of generally understandable, so-called non-technical project summaries (NTP).

How many and which laboratory animals are used in Germany?
The detailed laboratory animal statistics for the years 2009 to 2019 were published annually by the BMEL in German (https://www.bmel.de/DE/themen/tiere/tierschutz/versuchstierzahlen2019.html#doc85090bodyText11). From 2020 onwards, the annual figures will be published by the BfR and can be viewed here.

Why were fewer laboratory animals used in 2020 than in the previous year?
The reasons for this drop can be many and varied. On the one hand, the decreasing numbers could speak for the increased and successful use of suitable alternative methods. On the other hand, there was a particularly sharp drop in fish, with approximately 120,000 fewer animals used in 2020 than in the previous year.

However, the decline in the number of laboratory animals is not limited to Germany. For example, the number of laboratory animals used in the UK also dropped by 15% in 2020 (https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2020/annual-statistics-of-scientific-procedures-on-living-animals-great-britain-2020). The coming years will show whether the trend of decreasing numbers of laboratory animals will continue.

For what purposes are animal experiments carried out in Germany?
Broken down by purpose, in 2020 a total of 58% of animals were used in basic research, 13% for research into human and animal diseases, 19% for the production or quality control of medical products or for toxicological safety tests, and 10% for other purposes such as education, training and further education or for the breeding of genetically modified animals.

What regulations apply to the collection of laboratory animal numbers?
The EU Experimental Animals Directive 2010/63/EU came into force on 9 November 2010. Its transposition into national law in 2013 also necessitated a revision of the Laboratory Animal Reporting Ordinance with an extension of the reporting obligation on the use of laboratory animals. Since then, the use of cephalopods (e.g. squid and octopuses), larvae of vertebrates from the time they are able to feed on their own, and the breeding of genetically modified animals must also be reported. In addition, the severity of pain, suffering or harm (mild, moderate, severe) to which the animals were subjected by the use as a whole shall also be reported. In addition, the animals on which experiments were performed 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.

How does the Federal Institute for Risk Assessment (BfR) collect the annual numbers of laboratory animals for Germany?
Scientists conducting animal experiments in Germany are obliged to report the number of laboratory animals used and other information on the experiments (including the type and origin of the animals used, the purpose of the animal experiments, the severity of the exposure) to the competent state authority in accordance with the Laboratory Animal Reporting Ordinance (in German). Each year, the competent authorities then send a compilation of all reports made within a federal state in anonymised form to the BfR. The BfR checks the plausibility of the figures received from all federal states, using software provided by the European Commission as a support. Once this check has been completed, the BfR sends the figures to the European Commission.

Are laboratory animal numbers also collected for the entire European area?
The European Commission is required under Article 54 of the EU Experimental Animals Directive to establish and maintain a searchable, freely accessible database. This database is to contain statistical data on the use of laboratory animals and make it publicly available on an annual basis. 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 are "surplus animals"?
"Surplus animals" are animals that are bred and killed in connection with animal experiments but were not used in the experiment. Among other things, this concerns the offspring in a breeding programme of genetically modified animals that do not have the characteristics desired for the experiment. The figures for the reporting year 2020 are not available to the BfR. In 2021, the BfR will receive reports of surplus animals from the federal states for the first time together with the laboratory animal figures of the same year. These figures are submitted to the European Commission every five years. The next time this takes place is in 2023 with the transmission of the animal experiment figures collected for the year 2022.

What legal regulations apply to animal experiments?
Animal experiments in Germany are regulated by the Animal Welfare Act (in German), which since 2002 has been constitutionally based on the state objective of animal welfare under Article 20a of the German Basic Law. 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 through the revision of the Animal Welfare Act. At the same time, the new Ordinance on the Protection of Experimental Animals came into force. It concretises the framework conditions laid down in the Animal Welfare Act. The Animal Protection Act stipulates, for example, that a person conducting animal experiments must have the appropriate knowledge and skills. The Animal Welfare Experiments Ordinance (in German) describes the required qualifications in more detail. The same also applies, for example, to the content of records that must be kept about an animal experiment. The Animal Protection Act is divided into twelve sections. Section 5 "Animal Experiments" of the Animal Protection Act (§§ 7-9) (in German)stipulates that animal experiments must be limited to what is indispensable with regard to the pain and suffering inflicted and the number of animals used, and may only be carried out if they are indispensable for a specific purpose. Animal experiments on vertebrates or cephalopods are generally subject to authorisation.

What legal regulations for animal experiments apply to chemicals in addition to the Animal Welfare Act?
The European chemicals regulation REACH (*Registration, Evaluation, Authorisation and Restriction of Chemicals*, 1907/2006/EG) regulates the registration, evaluation, authorisation and restriction of chemicals in the European Union (https://europa.eu/youreurope/business/product-requirements/chemicals/registering-chemicals-reach/index_de.htm). REACH is based on the principle that manufacturers and users of chemicals must ensure that the chemical substances do not harm human health or the environment. To minimise the need for extensive animal studies for this purpose, animal testing should be avoided as far as possible and non-animal methods should be used and developed. Experiments on vertebrate animals should only be carried out as a last resort. Corresponding studies must not be repeated, but should be shared by different manufacturers.

In addition to the Animal Welfare Act, what legal regulations for animal testing apply to plant protection products and biocides?
EU Regulation No. 1107/2009 concerning the placing of plant protection products on the market and EU Regulation No. 528/2012 concerning the making available 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. Within this context, the regulations provide for minimising the required animal testing within the framework of the authorisation of plant protection products and biocides. Here, too, tests on vertebrate animals are to be carried out only as a last resort. Corresponding studies must not be repeated, but should be shared by different manufacturers.

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

Animal testing in connection with cosmetics is 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. The placing on the market of cosmetic products tested on animals and cosmetic products whose ingredients have been tested on animals is also prohibited. Cosmetic products are substances or mixtures of substances intended to come into contact externally with the parts of the human body (skin, hair, nails, etc.) or with the teeth and mucous membranes of the oral cavity solely or mainly for the purpose of cleansing them, perfuming them, changing their appearance, protecting them, keeping them in good condition or influencing body odour.

In addition to the Animal Welfare Act, what legal regulations for animal testing apply to medicinal products for humans?

So-called finished medicinal products for humans, which are intended for distribution to consumers and are manufactured in advance, may only be placed on the market if they are authorised by the competent higher federal authority (Federal Institute for Drugs and Medical Devices, BfArM) or if the European Community or the European Union has granted a marketing authorisation for them. This authorisation requirement is laid down in the Medicines Act (AMG) § 21 paragraph 1. When a medicinal product is authorised, the quality, safety and efficacy of the new medicinal product must be proven.

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

If an animal testing project has been approved, the competent authorities have been sending the BfR the associated non-technical project summary (NTP) since the revision of the Animal Protection Act came into force in 2013. The NTP is a generally comprehensible summary of approved experimental projects that describes, among other things, the purpose and benefits of the experiments, but also the pain, suffering and harm to which the animals were subjected. The BfR publishes the NTPs on the website (www.animaltestinfo.de) within twelve months. The publication serves to make information on approved animal experimentation projects publicly available. The BfR has compiled detailed questions and answers on the AnimalTestInfo database here (in German) Since 2021, BfR has been transmitting the NTPs to the central database of the European Commission, in which the NTPs of all European Member States are published.

What is the Federal Republic of Germany doing to reduce animal testing?

The Federal Republic of Germany strives to reduce the number of animals used in experiments. For this reason, various projects are initiated and supported 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 Experimental Animals (Bf3R) by the Federal Ministry of Food and Agriculture (BMEL), research funding by the BfR, 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 BMEL's Animal Protection Research Prize. The Bf3R also conducts research on the development of methods to replace and reduce animal experiments. In addition, it conducts research projects

to improve the welfare of laboratory animals. The BfR has compiled additional questions and answers on the subject of Bf3R here.

What tasks does the Federal Institute for Risk Assessment (BfR) perform to protect laboratory animals?
In 2015, the German Centre for the Protection of Laboratory Animals (Bf3R) was opened at the BfR. The Central Office for the Recording and Evaluation of Alternative and Complementary Methods to Animal Experiments (ZEBET), founded in 1989, is part of the new centre. Bf3R co-ordinates nationwide activities that serve to restrict animal experiments to only those which are considered essential, and guarantee the best possible protection for laboratory animals. Furthermore, the Centre's work intends to stimulate research activities nationally and internationally and to promote scientific dialogue. The Centre has the following tasks:

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

The BfR has compiled questions and answers on this subject here.

What is meant by alternative methods?
Alternative methods to animal experiments are all procedures that can replace animal experiments, reduce the number of animals used in experiments or reduce the suffering of animals used in experiments. The generally accepted scientific basis for the development of alternative methods is the so-called "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 animals used in experiments is reduced.
- *Refinement*: Suffering or pain of the test animals is reduced.

Alternative methods include, for example, in vitro procedures with isolated human or animal cells, computer simulations and imaging techniques 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 through the EU Directive 86/609/EEC on the protection of laboratory animals.

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 tests. In order to prove that an alternative method can replace a regulatory animal test, i.e. that it provides equally good or better results than the animal test and leads to the same results in all laboratories, the method must be scientifically validated. Since the transferability of results from animal experiments to humans is sometimes limited due to species differences, alternative methods may even be able to make more reliable statements about the effects of chemical substances on humans. For this reason, the development of cell models of human origin in particular has great potential. Since alternative methods usually only represent individual biological aspects due to their reduced complexity, combinations of different alternative methods are often necessary to achieve a reliable test result. The development of test strategies and evaluation concepts in which the data from several alternative methods are integrated into a final evaluation of a chemical substance is a focus of international research activities.

How do scientists find out whether there is an alternative to an animal test?
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. In order 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: https://publications.jrc.ec.europa.eu/repository/handle/JRC88200. The Search Guide provides information on the wide variety of possible sources of information that can be used for a search 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 major role in the development of the guide.

Which alternative methods has ZEBET been able to establish so far?
Since 1989, ZEBET has supported the development, validation and implementation of alternative methods, which 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, ZEBET has developed a non-animal test for phototoxic skin damage (redness, swelling or blistering). The test is now routinely used worldwide for safety testing of medicines, chemicals and cosmetics that could be exposed to sunlight and thereby alter their effects. This alternative method has largely replaced stressful animal testing on mice, rats, guinea pigs and rabbits for phototoxicity testing and is also more informative for human health than animal testing. The test was recognised in 2004 under the OECD Test Guidelines Programme (TG 432) and is thus used for testing chemicals worldwide. In addition, the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) have also approved this test for testing pharmaceuticals. Testing for skin corrosive and irritant properties on rabbits could also be replaced by alternative methods. Within this context, ZEBET was partly in charge of and coordinated the validation of reconstructed models of human skin and promoted regulatory acceptance. As a result, these models have been accepted as OCED test methods for the detection of skin irritating (TG 439, 2010) or corrosive effects (TG 431, 2004), so that the skin compatibility of chemicals in the EU is now only tested on human skin models.

Is the development of alternative methods promoted internationally?
ZEBET is the world's first governmental research institution with the mission to replace animal testing. 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, similar facilities to ZEBET exist 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 EURL-ECVAM Scientific Centre. The US National Institutes of Health (NIH) has been funding a major priority programme (*Toxicology in the 21st Century*) since 2008, which aims to predict adverse effects of drugs and other chemicals on humans without animal testing. The OECD is the main international organisation for the recognition of alternative methods to animal testing in the field of toxicological testing of chemical substances. The legally agreed *mutual acceptance of data* from alternative methods is the basis for the international application of alternative methods.

How is the development of new alternative methods supported financially in Germany?
For the research funding of new alternative methods at German universities and research institutes, the Federal Ministry of Food and Agriculture (BMEL) provides the BfR with an annual budget of currently about 400,000 euros. Since the start of the funding programme in 1990, more than 170 research projects have been supported so far. ZEBET funds about ten working groups per year, each with a duration of one to three years. In addition, the Federal Ministry of Education and Research (BMBF) has been funding the development of alternative methods since 1980, so far in more than 600 projects with about 190 million euros in funding.

Why does the Federal Institute for Risk Assessment (BfR) now publish the annual numbers of laboratory animals?
Until now, the BMEL recorded the annual number of animals used in experimental projects in Germany and published these figures on its website. Since 2015, the BMEL also transmitted these figures to the European Commission. With the amended Experimental Animal Reporting Ordinance of 11.8.2021, this legal task was transferred to the BfR. Accompanying this, the BfR will publish the figures from 2020 onwards on its website.

Does the Federal Institute for Risk Assessment (BfR) also approve animal experiments?
The BfR does not approve animal experiments. In Germany, the authorities of the federal states are responsible for the enforcement of animal protection regulations and thus also for the approval of animal experiments. This includes:

- the examination/processing of animal experiment applications
- the approval of animal experiment applications
- monitoring compliance with animal protection regulations in the keeping and use of laboratory animals

The BfR advises the approval authorities on alternative methods in accordance with § 46 of the German Animal Welfare Experimental Animal Ordinance. Further information can be found here: https://www.bf3r.de/en/bf3r-homepage.html.

Does the Federal Institute for Risk Assessment (BfR) also conduct animal experiments?
The German Federal Institute for Risk Assessment (BfR) performs animal experiments 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. On the other hand, animal experiments are carried out at the German Centre for the Protection of Laboratory Animals (Bf3R) at the BfR. Possible ways of reducing stress for animals in experiments (refinement) are investigated at the centre. The scientific goal is to establish better management and experimental conditions which can be used 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.

Further information on the subject from the BfR website

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

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

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