

Animal Research in Germany - What, Where and How Much?

- Scientists use animals in medical, veterinary and basic research to develop treatments and diagnostic tools for humans and animals and to understand the biological processes associated with health and disease. This takes place across a range of institutions including medical and veterinary colleges, universities, teaching hospitals, pharmaceutical companies and other research facilities.
- There are many comparable physiological processes in humans and animals. These similarities mean that scientists can study animals as models of human biological processes and the diseases which affect them while, at the same time, taking into account dissimilarities.
- Genetically modified (GM) animals, usually mice, rats and fish, help scientists understand the function of particular genes and genetic factors that cause diseases.
- Animal research programs benefit from a team of people, including veterinarians, animal technicians and scientists, who together manage the day-to-day welfare needs of the animals.
- In 2015 the number of procedures conducted on animals in Germany was 2,799,961. The most common species used were mice (73%), rats (12%), fish (7%) and rabbits (4%). Dogs, cats and primates, together, accounted for less than 0.4% of procedures on animals.
- It is illegal to test cosmetic products or their ingredients on animals anywhere in the EU. It is also illegal to sell new cosmetic products that have undergone animal tests.

Why is Animal Research Necessary?

- Basic research aims to address fundamental biological questions about humans and animals. This contrasts with applied research, which focuses on a specific disease or treatment. Without basic research and the use of living organisms we would not have much of the knowledge that underpins the development of new medical and veterinary treatments and diagnostic tools.
- New medical treatments are required by law to be tested on animals before they can enter human clinical trials. Safety regulations to protect patients also require that batches of certain drugs be screened in animals.

When are Animal Studies Allowed?

- Biomedical research is one of the most strictly regulated industries in Germany. It is regulated under the Animal Welfare Act (1972), Animal Protection Laboratory Animal Regulations (2013), and European Directive 2010/63/EU. All facilities are subject to inspections by the designated authority. These inspections must be done at least every 3 years for facilities conducting animal experiments and every year for facilities conducting procedures on primates.
- Every breeder, supplier and institution that uses animals for research must set up an animal-welfare body (*Tierschutzgremium*), consisting of at least one person/s responsible for the welfare and care of animals (*Tierschutzbeauftragte/r*). "Tierschutzbeauftragte" must be present in institutions using animals or their organs/tissues for scientific purposes, or breeding animals for research. The animal-welfare body must support staff in the accommodation, care and use of animals, and the application of the 3 Rs throughout the duration of all experiments.
- The "3 Rs" – Replacement, Reduction and Refinement – guide the ethical use of animals in science. Researchers must *replace* animal studies with other research methods wherever possible; employ strategies that will *reduce* the number of animals as far as possible while maintaining scientific rigor; and *refine* experimental and husbandry procedures to minimize potential pain or distress for the animals. Better animal welfare improves the quality of science.
- Special protections are provided to non-human primates to ensure that they can only be used if the researchers first show why they cannot use another species instead. EU law prohibits the use of great apes (e.g. chimpanzees and gorillas) except in exceptional circumstances.

Where Does the Scientific Community and General Public Stand on Animal Research?

- Surveys consistently show that a vast majority of scientists support the use of animals in research, but there has always been a small minority that is sceptical of its utility. Similarly, the majority of the German public support the use of animals like mice to improve understanding of human health issues.

Do we Need Animals to Develop New Medical Treatments?

Animal research has played a part in the overwhelming majority of medical advances, often through the basic research needed to understand diseases. Animal testing is also a crucial safety screening process in the development of new treatments. Although safety screening does not directly lead to medical advances, it has ruled out many treatments that would have posed a threat to human health. Ultimately, all new medicines are approved as safe based on clinical trials in humans.

Are Results of Animal Experiments Relevant to Human Health?

Specific animals are chosen for experiments because they are similar to humans in a particular way, e.g., susceptibility to a certain disease. Genetically modified animals, usually mice, are bred to increase those similarities. Screening drugs in animals identifies dangerous side effects that may also harm people. At the same time, many drugs originally developed for people are then used to treat animals with conditions such as heart disease, diabetes, arthritis, and cancer.

Pain and Distress

According to European Directive 2010/63/EU a regulated procedure is any which “may cause the animal a level of pain [...] equivalent to, or higher than, that caused by the introduction of a needle [...]”. Such procedures are subject to ethical review where its purpose, substitutability and necessity have to be reviewed by a committee and weighed against the potential suffering or distress to the animal. The researcher must justify both the decision to use an animal and explain why they could not use a species of animal which would suffer less. Animal experiments must only be conducted by trained personnel.

In German law, animal experiments are evaluated to take account of the number of animals, any pain or distress involved, and the capacity of the used species to suffer from the experiment. This is then weighed against the potential benefits of the research.

Non-Animal Research Methods

In accordance with the European Directive 2010/63/EU, “The use of animals for scientific or educational purposes should [...] only be considered where a non-animal alternative is unavailable”. Various non-animal research methods are used together with animal studies to reduce the number of animals needed. These methods include stem cells, tissue cultures and computer models. Non-animal methods account for the majority of biomedical research. Nevertheless, there are important research questions that still require animals. For example, in drug development, a large initial group of chemical candidates may be screened using non-animal methods, and only the most promising ones are taken through animal testing and human clinical trials. Before animal studies can go forward, investigators must detail how they have considered non-animal methods, and why they are not appropriate for answering their research question.

Secrecy

Activists have claimed that the animal research visible to the public only represents a sanitized fraction of what is actually going on. While it is true that the legacy of extremism makes some researchers cautious, institutions are increasingly giving journalists access to their facilities.

What Does the Future Hold for Animal Research?

The need for animal research changes as technology advances, new scientific questions arise and new diseases emerge. The research community continues to find ways to reduce the potential for pain and distress in research animals; much of this work is done under the 3Rs umbrella – Replacement, Reduction and Refinement. New scientific methods, such as organ-on-a-chip, have the potential to reduce the number of animals used in certain experimental areas, however there are limits to all technologies and it is unlikely animal research will be completely replaced in the foreseeable future.

Links to further information:

Official statistics for the number of animals used in research in Germany

<http://www.bmel.de/DE/Tier/Tierschutz/texte/TierschutzTierforschung.html>

German Animal Protection Act (1972) // Tierschutzgesetz (TierSchG).

<http://www.gesetze-im-internet.de/bundesrecht/tierschg/gesamt.pdf> (in German)

Animal Protection Laboratory Animal Regulations (2013) // Tierschutz-Versuchstierverordnung.

<http://www.gesetze-im-internet.de/bundesrecht/tierschversv/gesamt.pdf> (in German)

European Directive 2010/63/EU, which regulates animal research across the EU.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF> // <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:de:PDF>

Speaking of Research (SR) provides accurate scientific information on the role of animals in research. It also offers extensive links to other organisations also focused on animal research.

www.speakingofresearch.com

The European Animal Research Association is a communications and advocacy organisation that work to explain animal research across the EU.

www.eara.eu // www.eara.eu/deutsch

AnimalResearch.info is a collaboration of scientists and expert contributors who provide information about the contribution of animals to scientific advances.

www.animalresearch.info // www.animalresearch.info/de

Public opinion on animal research according to the Eurobarometer Survey

http://ec.europa.eu/public_opinion/archives/ebs/ebs_340_en.pdf // http://ec.europa.eu/public_opinion/archives/ebs/ebs_340_de.pdf

A 2011 poll of biomedical scientists, conducted by the journal *Nature*, including questions regarding whether animal research is necessary for science.

www.nature.com/news/2011/110223/full/470452a/box/1.html (Graphic summary)
www.nature.com/nature/newspdf/animal_research.xls (Data)

Pro-Test Deutschland is an initiative by students and scientists aimed at explaining animal research and furthering an open, informed, realistic public debate in Germany.

<http://www.pro-test-deutschland.de/>