



Alternatives to Animal Experiments

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Alternatives to Animal Experiments

The Department of Experimental Toxicology and ZEBET at the BfR has already been working on alternative methods to animal experiments for many years. The founding of the German Centre for the Protection of Laboratory Animals (Bf3R) in 2015 signalled even more intensive research into alternative methods. The Centre coordinates all activities in Germany aimed at reducing animal experiments to an absolute minimum and offering the best possible protection to laboratory animals. The Bf3R was created within the framework of the initiative entitled “A Question of Attitude – New Ways to Improve Animal Welfare” and launched by the Federal Ministry of Food and Agriculture. The work of the Centre inspires research activities all over the world and facilitates scientific dialogue. In this interview, department head Professor Dr. Gilbert Schönfelder talks about the remit and goals of the Bf3R and what it has achieved to date.

**Interview with
head of department
Professor Dr.
Gilbert Schönfelder**



Professor Schönfelder, what does the work of the “German Centre for the Protection of Laboratory Animals” (Bf3R) involve?

The Bf3R is the only governmental institution of its kind in the world and is entrusted with stepping up research into alternative methods as well as advising authorities and scientific institutions on this issue. It promotes research projects to advance the development of alternative methods on both national and international level, and informs both the public and the scientific community about topics in the area of animal welfare relating to laboratory animals. ZEBET and the National Committee for the Protection of Laboratory Animals are now areas of competence at the Bf3R.

Why was it necessary to create the Bf3R?

There is widespread interest in society in limiting animal experiments. Some people are even calling for the complete banning of these experiments. Despite this, the number of laboratory animals used in basic research has still not fallen to any great degree. A further argument in

support of more intensive research into alternative methods is the current debate as to which animal experiments enable us to draw conclusions regarding certain processes in humans, thereby paving the way for the development of medical therapy concepts. Then there are the efforts to develop models which possibly supply more robust results, such as 3D models of organs made from human cells. All these aspects together outline the need to ensure better protection of laboratory animals. This does not mean that animal experiments should be completely prohibited. Wherever they are indispensable, it will still be necessary to conduct these experiments until suitable alternative methods have been developed.

Why is this further development only taking place now?

ZEBET was set up back at the end of the 1980s, and the situation then was totally different. We shouldn't forget that the review of safety has only been stipulated in the German Medicines Act since the early 1970s – in response to the “thalidomide scandal”. In the endeavour to ensure the safety of medicines and other products, the focus was initially on animal experiments as the most suitable method. Even back then, some organisations were demanding that animal experiments be restricted and laboratory animals be protected as effectively as possible. At that time, however, science was not sufficiently advanced to provide answers to the pressing questions. The Centre we now have is the only entity of its kind in Europe: Germany is the only country with an official centre for the protection of laboratory animals that can comprehensively demonstrate expertise in the relevant areas and that is independent in its activities; in other words, the work of the Bf3R is not influenced by political, economic or social interests. →

Every single animal that doesn't have to be used in an experiment is an animal that experiences less suffering and less pain.

What does the abbreviation “Bf3R” stand for?

The abbreviation expresses the affiliation with the BfR and also makes reference to the “3R principle” according to Russell and Burch. These three Rs stand for “Replace”, “Reduce” and “Refine” – “Replace” is geared towards completely replacing animal experiments, “Reduce” towards reduction in overall the number of experiments, and “Refine” at the mitigation of the pain or suffering of animals used in experiments.

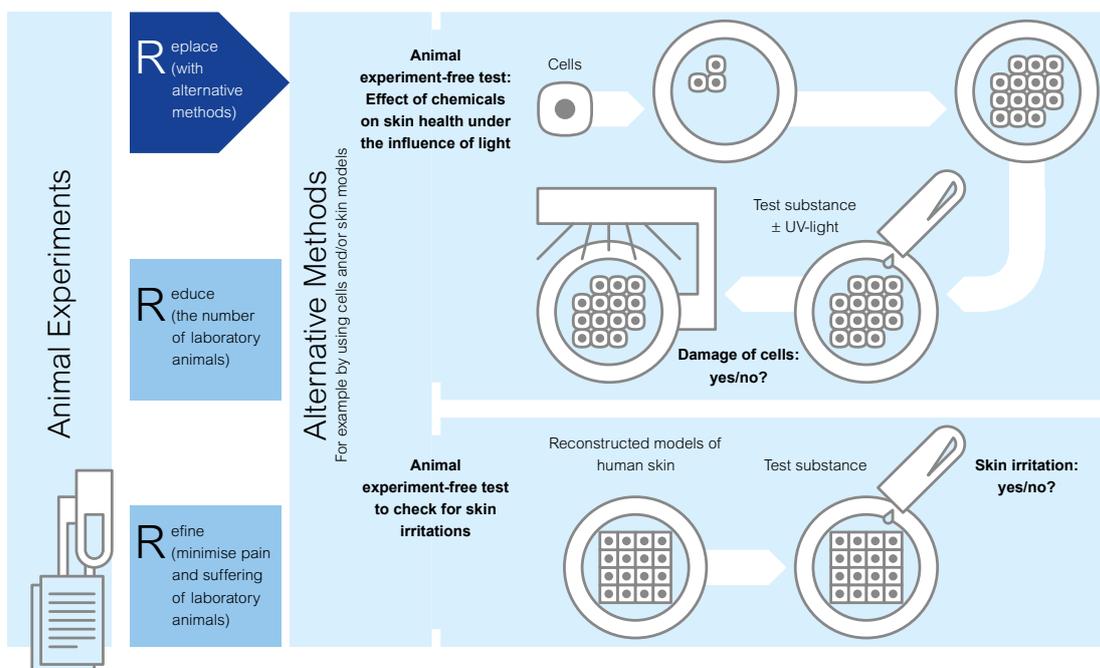
The number of animal experiments can be reduced with the help of alternative methods, but also through the painstaking biometric planning of animal experiments

and through systematic analysis of literature before conducting any experiments. If it is still necessary to expose animals to pain and suffering in an experiment that is absolutely essential, then all measures must be taken to reduce this pain and suffering to a minimum.

What is the background of the employees of the Bf3R?

The Bf3R makes the BfR even more interdisciplinary, with representatives of the natural sciences, veterinary medicine, human medicine, engineering and law all working closely together.

3R Principle for Alternative Methods



Why do you need legal experts?

The practical implementation of legal requirements is not always defined in detail. The concept of harm is a good example: pain, suffering and harm are basic elements used in the definition of an animal experiment. While the legal interpretation of the concepts of pain and suffering are relatively clear-cut, it is unclear how to apply the concept of harm in relation to laboratory animals. This is where interdisciplinary cooperation incorporating legal expertise is of particular importance.

On what issues does the Bf3R advise authorities and research institutions?

The amendment of the German Animal Welfare Act in 2013 outlined the legal requirements. If someone wants to conduct an animal experiment, they have to submit an application for the experiment to the approval authorities. We are often consulted to carry out a review to determine whether there isn't an alternative to the animal experiment after all. The task of the National Committee, on the other hand, is to advise authorities and animal welfare bodies on the acquisition, breeding, accommodation, care and use of laboratory animals. The issues are therefore not confined to alternative methods but also extend to questions relating to interpretation of the law. The recommendations of the National Committee are particularly important when it comes to complex legal matters.

Will there come a day when animals are no longer used for experiments?

I don't think this will happen in the foreseeable future. Of course, our long-term goal is to replace animal experiments altogether, but we haven't yet reached the level of science that would make this possible. It's important to emphasise that every single animal experiment that doesn't have to be conducted makes a difference. Every single animal that doesn't have to be used in an experiment is an animal that experiences less suffering and less pain.

How can the public obtain information on animal experiments?

In Europe, it has been mandatory to publicly document every animal experiment since 2013. The "non-technical project summary" required for this purpose supplies information on the purpose for which an application was approved, which animal species is to be used and how many animals are to be used. We already developed the internet-based AnimalTestInfo database in 2014. All interested parties can access the database to view all non-technical project summaries from Germany. The database is unique throughout the world and guarantees a high level of transparency. →



The development of OECD test methods for the toxicological assessment of substances is coordinated by the BfR in Germany.

The BfR developed the "AnimalTestInfo" database in close cooperation with the authorities of the federal states ("Laender") responsible for the approval of animal experiment projects and published it on the internet in December 2014. It is the first Web-based database solution for the publication of project summaries on animal experiments in Europe. AnimalTestInfo contains information on all approved animal experiment projects of scientific research institutes of the universities, industry and the government in Germany.

i The BfR reported on AnimalTestInfo in the special-interest journal "Nature":
www.nature.com/nature/journal/v519/n7541/full/519033d.html?WT.ec_id=NATURE-20150305

More information (in German) at: www.animaltestinfo.de

What financial resources are available to the Bf3R?

We have received around six million euros for the purchase of research equipment. We also receive continuous research funding of just under one million euros a year and have been assigned additional staff.

The Bf3R has already bought new research equipment. What will this equipment enable you to do?

One of our research goals is to obtain information on the optical level, in order to better understand the ultrastructure of cells and tissue. It's easy to imagine a room the size of an office – perhaps with a desk, a chair and a computer. But if you try to imagine this room in a size as small as a thousandth of a pinhead, it's impossible. Human beings are heavily dependent on their spatial perception skills. But information on rooms as tiny as the one I mentioned can help us to understand how complex organs work, something that is particularly beneficial in the field of research into alternative methods. Nowadays, areas of this kind can be depicted spatially with the help of high resolution imaging methods. We bought the relevant equipment so that we can use this gigantic technical advance for our purposes. In this way, we can investigate processes on a cellular level in organs and develop cell and tissue culture methods with which animal experiments can be substituted or reduced.

Does the Bf3R award research funds to projects for the development of alternative methods?

ZEBET has been inviting bids for project funding for more than 20 years. Promoting research in this way is of major importance in Germany, as it provides start-up finance in the field of alternative method research. Funding is available to scientists who have promising ideas but cannot point to the kind of scientific findings that would pique the interest of the big funders of research. Our start-up finance concept enables the scientists to generate data for two to three years so that they can subsequently apply for larger-scale funding.

What alternatives exist; what has already been achieved?

A wide range of different technologies (cell culture models, omics technologies, imaging techniques etc.) are already being used in the many biomedical research laboratories around the world that do without animal experiments and generate new knowledge and insights in the field of basic research.

In the field of application-focused science, there are already several OECD-audited and validated methods which can be used, for example, to test the irritant potential of chemicals on skin models. As a result, the number of animal experiments in this field is lower than it otherwise would be. There are also cases in which an animal experiment is funded – in cases where there is uncertainty regarding the results obtained by other means, for example.

Why is the number of animal experiments on the rise?

The implementation of the EU Directive on the protection of laboratory animals into national law in 2013 also necessitated a new version of the regulation on the statistical reporting of laboratory animals with an extension of the obligation to report the use of laboratory animals. Accordingly, the use of cephalopods (e.g. squid, octopus), the larvae of vertebrates and the breeding of genetically modified animals have to be reported.

Has the Bf3R already achieved any success?

In my opinion, absolutely. During the short time since it was founded, the Bf3R has drawn up the first ever international proposal for the assessment of the severity of genetically altered fish (bony fish, teleostei), thereby creating a common basis for the categorisation of severity of fish by the authorities, researchers and legal experts. There are still a few gaps that need to be closed by biological research, but this kind of consensus is necessary, even if it is only of a preliminary nature.

The AnimalTestInfo database is a further success story, because it is the only database of its kind in the world. It is unique because it provides the public with transparent information on animal experiments, and because it supplies new and detailed information on animal experiments in Germany that enables us to more effectively identify research fields for the development of new alternative methods. The database not only supports our own research, but also helps us to provide scientific advice on promotion measures in the field of alternative method research in Germany and Europe.

Last but not least, there is the scientific article entitled “The ‘reasonable cause’, for killing excess animals, a classic question of animal welfare law in the context of biomedical research”. The concept of the “reasonable cause” is one of the most difficult and most frequently discussed problems in the German animal welfare law. This article illustrated the potential conflict between modern biomedical research and the concerns of animal welfare, and outlined solution approaches. ||

 Publications of the Bf3R

The animal experimentation quandary: stuck between legislation and scientific freedom.

In: EMBO reports (DOI: 10.15252/embr.201642354)

Considerations for a European animal welfare standard to evaluate adverse phenotypes in teleost fish.

In: The EMBO Journal (DOI: 10.15252/embj.201694448)

Laboratory animals: German initiative opens up animal data.

In: Nature (DOI: 10.1038/519033d)

Der “vernünftige Grund“ zur Tötung von überzähligen Tieren (The “reasonable cause” for killing excess animals).

In: Natur und Recht (DOI: 10.1007/s10357-015-2903-9)



More information on the Bf3R at:
www.bfr.bund.de/en > **The Institute**
> **German Centre for the Protection of Laboratory Animals (Bf3R)**



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