



Position Paper on Securing Efficient Biomedical Research While Maintaining the Highest Animal Welfare Standards

Recommendations Proposed by the DFG's
Permanent Senate Commission on Animal
Protection and Experimentation

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1 Theses

Science and innovation are cornerstones of progress and prosperity in our society and as such, they also enable resilience and crisis response capability, as was recently exemplified in the coronavirus pandemic. In order to continue to safeguard the future viability of biomedical research while maintaining the highest standards of animal welfare, a long-term and sustainable strategy for securing and further developing free, knowledge-driven research is needed, based on the following theses:

- 1) *Biomedical research is necessary and ethically required in order to ensure responsible scientific and medical progress. Scientists take their high ethical responsibility seriously when using animals for the purpose of research. Due to the special need to protect animals – while at the same time ensuring scientific progress – the use of animal experiments are always kept to a minimum.*
- 2) *In addition to the freedom of science as enshrined in the German constitution, the necessary resources have to be provided, long-term perspectives have to be secured, and bureaucratic hurdles and administrative burdens need to be removed in order for excellent research to flourish.*
- 3) *Free access to technologies, promotion of methodological development and the technological sovereignty this gives rise to are essential requirements for scientific innovation to meet future challenges for human beings, animals and nature.*
- 4) *Full-scale education, training and professional development of those working in human and veterinary medicine, in the life and natural sciences, and all other persons involved in the handling of laboratory animals requires the use of animals. This ensures responsible handling of laboratory animals with regard to animal welfare and guarantees continuous improvement in the quality of treatment, a highly reliable patient care as well as optimal and legally compliant use of new methods and techniques.*

- 5) *The choice of method in research is based on the best possible suitability of a method or model for answering a scientific hypothesis (scientific validity). The optimal use of a broad, interdisciplinary spectrum of methods overcomes the limitations of isolated methodological approaches.*
- 6) *The use of animals in research is an essential part of the spectrum of research methods and is therefore an indispensable building block in terms of ensuring outstanding scientific findings and medical applications. In scientific research, the separation between research “with” and “without” animals does not exist.*
- 7) *The 3Rs principle (Replacement, Reduction, Refinement) and scientific validity are the key guidelines for ensuring the highest level of animal welfare and quality in research. Without simultaneous consideration of the progress of scientific knowledge, the number of animals used for scientific purposes does not constitute a benchmark for the quality of animal welfare in research.*
- 8) *Transparent and fact-based communication about science is an obligation towards society and provides the basis for forming societal and political opinion.*
- 9) *Any fundamental ban on animal research does not automatically put an end to the need for the use of animals in research but endangers Germany and the EU with regard of their innovation potential and status as research hubs: it increases dependence on biomedical innovation from non-European sources, reduces sovereignty and the ability to act independently in the face of future challenges, and removes control over animal welfare from Germany and the EU.*

2 Politically Motivated Activities Seeking to Ban Animal Research

Animal experiments are currently part of the diverse range of techniques used in life science research. Due to the special protection of animals as enshrined in the German constitution and also at EU level, researchers have a particular ethical responsibility when conducting animal research, and one of the ways they assume this responsibility is by engaging in dialogue. Despite rigorous legal frameworks attaching great importance to animal welfare, animal research remains controversial both socially and politically. Activities pursued by politicians at national and European level demanding so-called phase-out plans to end the use of animals in research are viewed with concern by the scientific community. EU Directive 2010/63/EU aims in the long term at the possibility of abandoning the use of animals in research “as soon as it is scientifically possible to do so.”¹ The Directive explicitly emphasises the importance of the scientific feasibility of such a move. At the same time, it deliberately does not formulate any specific timelines or other milestones.² A fundamental ban on research using animals constitutes a maximum encroachment on the constitutionally protected freedom of research and science, which also includes the free choice of methods. It restricts the agile use of a broad spectrum of technologies, which is necessary for scientific innovation, in such a rigorous way that the generation of future knowledge and the progress in the life sciences that this gives rise to, as well as the possible transfer of science to medical applications, are jeopardised. Thus, the implementation of strategic plans and recommendations for the development of biotechnology and health research in Germany as formulated by the Federal

1 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes; [to document on eur-lex.europa.eu](https://eur-lex.europa.eu/uri/lexuri-srv?uri=celex:32010L0063).

2 See also EU Commission response to “Resolution on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education”, 2021/2784(RSP).

Government and currently still in force^{3,4} would also be restricted by a ban on research methods using animal for scientific purposes. One goal of the Federal Ministry of Education and Research's current High-Tech Strategy is to make use of innovation potential by promoting key technologies in order to meet societal challenges and, among other things, to ensure that medical progress finds its way to patients more quickly. A phase-out scenario for animal research would, for example, run counter to the goals of the "*Nationale Dekade gegen Krebs*" (engl. "National Decade against Cancer") set out in the High-Tech Strategy, since animal research is a key contributing factor in this branch of research.

The desire to end the use of animals for scientific purposes by pursuing an action plan that contains binding timelines and goals with regard to scientific content is based on fundamental misconceptions of how knowledge-driven research works and how essential it is to have a broad, interdisciplinary spectrum of methods that includes both animal experiments and non-animal methods in equal measure. For this reason, there can be no underlying justification for any such short-term scheduled plan to phase out research with animals as this would endanger Germany's science and innovative strength.

When considering the opportunities and limitations of a technology transfer towards animal-free methods, it is imperative to distinguish between knowledge-driven research⁵ and research for regulatory purposes⁶, since the objectives and the development potential are fundamentally distinct. While basic research serves to generate new findings and increase knowledge, making

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- 3 Federal Ministry of Education and Research (2018): Research and innovation that benefit the people – the High-Tech Strategy 2025; [to document on bmbf.de](#).
 - 4 Commission of Experts for Research and Innovation (2021): Report on Research, Innovation and Technological Performance in Germany 2021; [to document on e-fi.de](#).
 - 5 Knowledge-driven research also includes translation, i.e. the transfer of basic scientific research results to areas of application.
 - 6 Research for regulatory purposes includes the use of animals for regulatory compliance procedures, for example in statutory safety and risk assessments.

use of a flexible, creative spectrum of methods, the standardisation of processes and the establishment of fixed technology pipelines play a key role in research for regulatory purposes. This may also include the validation of alternative methods to animal testing for standardised processes.

In this paper, the DFG's Permanent Senate Commission on Animal Protection and Experimentation (hereafter referred to as the Senate Commission) will focus on the aspects of knowledge-driven research (including translation and teaching).

There is a legitimate desire in science, society and politics to further strengthen animal welfare in research. In this paper, the Senate Commission therefore elaborates ideas on how animal welfare in research can be guaranteed while at the same time ensuring scientific quality in research projects. The paper focuses on information about the framework conditions that must be in place for efficient biological and biomedical basic research in order to maintain the innovative strength of research in Germany and the EU. It describes the link between animal welfare measures and scientific validity and then goes on to address ideas to the various stakeholders from science, politics, administration and society. By means of participation and communication, the framework conditions for animal welfare and research are to be improved, and a shift is to be initiated in the discourse towards a holistic understanding of biomedical research methods.

3 Legal and Ethical Foundations of Animal Research to Maintain the Highest Standards of Animal Welfare and Ensure the Highest Quality in Research

Comments on Theses 1, 2, 4 and 5

The anchoring of animal protection in German Basic Law⁷ and EU Directive 2010/63/EU provides a strict framework for the approval of animal research. According to this, animal experiments can only be carried out if no non-animal methods are available to answer a scientific question in order to achieve the same research objective⁸. Every animal experiment must be approved in advance in an extensive procedure carried out by the relevant authorities. This includes a harm-benefit analysis in which an assessment is carried out of whether an experimental project is suitable, necessary and appropriate to achieve the desired gain of knowledge. The 3Rs principle (Replacement, Reduction, Refinement) serves as a guideline for animal welfare in research, and the assessment of this forms part of the approval procedure. Here, it is necessary to demonstrate that the desired gain of knowledge cannot be achieved without using sentient animals (Replace), with fewer animals (Reduce) or using methods causing less harm (Refine). In addition to the use of methods without laboratory animals (so-called alternative methods), an assessment has to be made as to whether animals considered to be less sentient can be used (“relative replacement”).

However, consideration of the 3Rs principle in isolation without scientific context can have a negative impact on the quality of research projects. For this reason, in addition to the 3Rs principle, scientific validity is an important requirement for the planning and implementation of experiments. Measures that promote animal welfare in accordance with the 3Rs principle must always be

7 Art. 20a. Basic Law (GG).

8 Animal Protection Act (TierSchG) § 7 and § 7a (status: 23.03.2022).

considered in the light of scientific validity. This applies, for example, to such aspects as the selection of non-suitable models or insufficient sample sizes in order to reduce the number of animals used. If animal welfare measures limit scientific validity, the experimental design and thus also the overall project has to be questioned from both an ethical and a resource-saving perspective⁹.

The 3Rs principle must also be anchored in teaching and training in the field of animal research: here it is crucial to ensure full initial education, training and professional development involving animals so as to ensure responsible, professional handling of laboratory animals in practice.

Recommendation and notes

- ▶ *Only by interlinking animal welfare measures with simultaneous consideration of the different aspects of scientific validity (construct validity, internal validity and external validity) is it possible to ensure sound animal welfare while maintaining the scientific quality of research projects¹⁰.*
- ▶ *Due to the particular ethical responsibility of science in the use of animals in experiments, both aspects – animal welfare measures and scientific validity – must be taken into account to the same extent in every experimental design and execution and be recognised by the authorities.*
- ▶ *The implementation of animal welfare measures as an intrinsic part of scientific project planning must be more firmly anchored in the context of teaching and training.*

9 Deutsche Forschungsgemeinschaft (2019): Animal Experimentation in Research: The 3Rs Principle and the Validity of Scientific Research; [to document on dfg.de](#).

10 Ibid.

- ▶ *In addition to the requirements of the 3Rs, regulatory decisions by the authorities must take into account the scientific validity of the outcomes to be achieved.*

- ▶ *At federal and state government level, responsibilities for animal welfare and research lie with different ministries and authorities. Thus, within the framework of legislative procedures and/or subsequent legislative and executive steps, care must be taken to ensure that both aspects are given equal consideration through participation, inter-ministerial communication and cooperation.*

4 Use and Promotion of a Diverse Range of Methods as a Fundamental Requirement

Comments on Theses 2, 3, 4, 5 and 6

The aim of the life sciences is to understand the structures and interrelationships of living organisms, including the underlying physiological and pathophysiological processes. The scientific approach is hypothesis-oriented and the choice of methods and models is based on the scientific question to be answered. The spectrum of methods used is highly diverse and interdisciplinary. It includes so-called *ex vivo* or *in vitro* methods such as cell cultures and organoids, *in silico* or theoretical approaches (for example computer-based modelling), *in vivo* models (animal models) and human studies. In veterinary medicine and organismic biology, animals themselves are the focus of scientific interest.

The selection of methods and models is largely based on whether they are well suited to answering the research question (construct validity). However, all methods – both animal models and animal-free approaches – are subject to limitations, and the results require validation by complementary methods. Generally speaking, a combination of methods – animal models and non-animal approaches – is needed to answer complex questions. It is not uncommon for far-reaching cooperation to take place between different research groups in order to make optimal and creative use of methodological expertise. Non-animal methods are often used at the beginning of a research strategy to generate fundamental insights. *In vivo* models are only used if no other *in vitro* methods are available for the further pursuit of the research question. It is not uncommon for insights gained from animal research to lead to a return to animal-free methods at a later stage. For example, computer models often draw on data generated by animal experiments.

Methods and models are thus optimised, improved and newly developed from the point of view of which method is best suited to answering a scientific question. In the long run, those methods prevail that prove to be most suitable and feasible.

Animal-free training methods are available for education, training and professional development. Nevertheless, training on animals is also necessary because this is the only way to ensure responsible handling of laboratory animals according to animal welfare standards based on appropriate training, as well as ensuring the optimal use of methods and techniques.

In the course of the great methodological progress achieved in the life sciences, there has also been a significant increase in expertise in the development and improvement of animal-free technologies, offering new potential for research without the use of animals. This methodological advancement is an essential part of research. It occurs as new biological/biomedical questions arise and is intrinsically motivated by them, without these methods being directly classified as alternative methods. In knowledge-driven research, the often postulated separation into research using alternative methods and research using animals for scientific purpose does not exist.

To forego the possibility of validating results in animal models and of generating new questions that can currently only be addressed by means of animal research constitutes a massive intervention in the fundamentals of scientific research. It limits the agile and creative use of existing technological potential and prevents new innovations in Germany and the EU. In addition, any such ban could limit scientific validity with regard to reproducibility and generalisability of results in cases where mutual model validation is required.

Recommendations and Notes

- ▶ *In order to be able to conduct research in the life sciences at the highest international level in the future, it is vital to ensure that the choice of methods is oriented towards the research question. Here, the most suitable method should be prioritised over an adaptation of the question to a less suitable method (construct validity) and this method should be freely available.*
- ▶ *The use of less suitable, animal-free methods and of less valid animal models or insufficient sample sizes would limit the quality of research and are therefore not justifiable, whether ethically or in terms of sustainability. For this reason, scientific validity must be a key factor in fundamental experimental design and implementation and must not be subject to limitation by authorities.*
- ▶ *At the same time, progress in life science research promotes the development of new methods and the innovations that these give rise to. In knowledge-driven research, however, methodological progress is not recognised and published in the same way as advancements in the knowledge of biological and biomedical processes.*
- ▶ *Methodological development must receive greater recognition and support. Awareness of innovation potential must be trained and enhanced, also with regard to the 3Rs principle.*
- ▶ *Mechanisms for appropriate method transfer in the scientific community need to be developed so as to ensure innovations find more widespread practical application.*
- ▶ *The explicit promotion and development of non-animal alternative methods must be practice-oriented with a view to translation into everyday research work. Methodological progress should not be allowed to develop in a parallel structure without exploiting the relevant application potential.*

- ▶ *Information networks between individual disciplines must be further expanded and collaborative participation between more methodologically oriented and knowledge-driven research areas must be intensified so as to improve and accelerate the knowledge transfer and transformation process.*

From Fundamental Research to Application Based on the Example of Checkpoint Inhibitors

Checkpoint inhibitors (CI) are a new class of drugs that have been revolutionising the treatment of tumour patients for several years. CI work by activating the body's immune response against the tumour. Without CI, the immune response against tumours is inhibited, and it can be said that CI suspend this inhibition.

The development of CI began in the 1980s with the aim of answering fundamental questions about the immune system: in addition to aspects of the development of T lymphocytes (a group of white blood cells that are essential to the body's immune response), the aim was to clarify which signals control activation of T lymphocytes.

The researchers used a wide range of methods to answer these questions. For example, cell culture experiments on T cell activation were used to first understand more precisely the effect or function of various molecules that seemed to be involved here, before subsequently investigating *in vivo* – i.e. using animal experiments – whether these molecules function the same way in living organisms. An important aspect of this was the use of mice that had been genetically manipulated (gene targeting) such that the molecules to be investigated were not present (so-called knockout mice).



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It was found that the knockout mice developed the most severe signs of autoimmune disease. This meant that without these specific molecules, the T lymphocytes acted unchecked and uncontrolled, also triggering unwanted immune responses to organs in their own bodies. In turn, it was possible to conclude that the molecules under investigation had an inhibiting effect on the T lymphocytes.

Two complementary strands of translational research emerged from these findings: I) the attempt to restrain inhibitory molecules so as to increase the body's immune response and target tumours, and II) the attempt to stimulate these inhibitory molecules so as to curb the body's immune response and thus be able to treat patients suffering from autoimmune diseases. Here, the research also relied on the use of various complementary methods, in particular animal models and cell culture experiments, in order to specifically transfer the knowledge gained from basic research to application. For the inhibitory approach (I), different tumour diseases were imitated in mice to test the effect of the molecules in different tumours. Based on these results, it was possible to conduct clinical trials that confirmed the effectiveness of the approach, thereby resulting in its approval as a new clinical application. For some years now, various drugs have been available that are based on the principle of inhibitory molecules and have become established as an essential pillar of therapy for tumour patients. Translational research relating to approach (II) led to the development of a drug to treat rheumatoid arthritis, for example.¹¹

11 Kamradt, T. (2017): Wie aus Grundlagenforschung im Tier ein neues Therapiekonzept für Tumorpatienten entstand. Trillium 1: 18–23; [to document on trillium.de](https://www.trillium.de).

5 The 3Rs Principle in the Context of Scientific Validity as a Benchmark for Animal Welfare in Research

Comments on Thesis 7

The annual statistics on the use of laboratory animals are used by politicians and the public as an important benchmark for the success of animal welfare measures in research. Any decrease in the numbers of laboratory animals used is seen as an improvement in animal welfare and vice versa. From a scientific point of view, this view is misguided because it is too short-sighted. Mere numbers say nothing about the quality of animal welfare and protection applied within the research projects carried out. The same applies in other areas of animal use.

The idea of animal welfare in research essentially follows the 3Rs principle, which in addition to the replacement of animal experiments also includes reduction (using fewer animals or obtaining more information with the same number of animals) and refinement (improvements in the handling of the experimental animals during the experiment and husbandry). 3R strategies depend fundamentally on the type of experimental animal and the inherent differences in husbandry, care, physiological and psychological needs, as well as on the technologies used. The further development of technologies in the conduct of research (for example, imaging procedures) or improvement of animal husbandry and handling of laboratory animals are important contributions to animal welfare in the area of refinement and replacement. Refinement measures in particular cannot be measured based on a decrease in the numbers of animals used. In addition, compliance with the guidelines for ensuring good scientific practice – in particular the aspects of free data availability (open science, data sharing, FAIR principles) and unbiased reporting – contributes to the implementation of the 3Rs principle.

However, as described above, it is essential for the 3R measures always to be considered in the light of scientific validity. In principle, an animal exper-

iment is only worthwhile and compliant with animal protection requirements if the resulting outcomes are scientifically valid and serve to advance knowledge. As such, a 3R strategy cannot be an end in itself: it is only effective if viewed in the context of scientific validity. So when looking at numbers of animals used, as well as other animal welfare measures, it is crucial not to disregard this intrinsic link to scientific quality.

Just as the mere tracking of the number of animals used does not provide any indication of effective animal welfare measures in research, gain of knowledge cannot be measured by a simple quantitative benchmark. The metrics of research achievements (total number of publications and citations for individuals or journal impact factor for journals etc.) to measure the relevance and quality of research results is an intensely and controversially debated topic in science and science management¹². Quantitative assessment of success in animal welfare and scientific progress is therefore not possible. Thus, only a few examples of projects can be cited here to demonstrate how key scientific findings have emerged as a result of animal research. These are often based on decades of research: during this time, a broad spectrum of methods was used and animal research methods also underwent further scientific progress. One current example is the rapid development of vaccines to combat the coronavirus pandemic, which resulted from many years of work in the field of cancer research, not least using animal research. Advances in transplant medicine also vividly illustrate the evolution of animal research – from genetically modified animals and xenotransplantation research through to medical application in human beings. The key point about these examples is not that animal numbers have increased or decreased, but that animal research has continuously developed and ultimately, after decades of research, has resulted in significant medical application which benefits people. In addition, examples of research projects can be mentioned in which 3R measures have led to an increase in

12 Deutsche Forschungsgemeinschaft (2022): Academic Publishing as a Foundation and Area of Leverage for Research Assessment; [to document on dfg.de](https://www.dfg.de/en/foerderung/foerderungsberechtigten/foerderungsberechtigten-2022).

animal welfare in experiments and/or a reduction in animal numbers – while at the same time maintaining high standards of scientific quality.

Recommendations and Notes

- ▶ *The numbers of animals used in experiments cannot be regarded as a benchmark of quality for animal welfare in research without simultaneous consideration of the progress of scientific knowledge.*
- ▶ *The 3Rs principle can only serve as a benchmark for increasing animal welfare in research in the context of scientific validity.*
- ▶ *Refinement and reduction must be perceived as equally important animal welfare measures and must be incorporated in a communication strategy that is not limited to replacement.*
- ▶ *Reduction and refinement approaches must be taken into account when implementing 3R funding measures.*
- ▶ *When promoting new non-animal alternative methods, the verification of validity must also be considered and promoted. In order to reduce the risk of transformation failure, it is also important to consider and promote cooperation between “developers” and “users”.*
- ▶ *Research results must be processed and made available in accordance with the FAIR principles (“Findable, Accessible, Interoperable and Re-usable”).*

What is Refinement?

In laboratory animal science, refinement refers to all measures that lead to an improvement in the living conditions of the animals, thereby reducing the overall burden they are exposed to when used for research purposes. Refinement methods are diverse, ranging from simple changes in cage design to the technically complex use of imaging techniques. As such, refinement is itself an important field of research in which new improvements are continuously developed and evaluated.

The following areas of refinement are of particular importance:

Improvement of husbandry conditions:

Experimental animals spend most of their lives in housing systems that are guided by aspects such as hygienic standards and the practical demands of experimental feasibility. Possible improvements for housing conditions concern cage size, equipment elements and opportunities for activity to counteract boredom, for example.

Improvement of experimental conditions:

Certain experimental designs and test procedures have been scientifically established for many years. However, science is also a constant process of change and progress, so animal experiments, in particular those which are considered to be severe, are constantly being questioned. For example, modern video analysis systems based on artificial intelligence can record the behaviour of animals in their home cages. This avoids stressors caused by moving the animals to special experimental apparatus.

Improvement of the handling of laboratory animals:

The health and welfare of laboratory animals is a human responsibility and includes cleaning of housing systems and daily inspection. The interactions that take place between humans and animals offer great potential

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for improvement. For example, it has been shown that mice that are removed from the cage with the help of a tube show less stress than when they are grasped by the tail root. Intensive training and gradual habituation to the experimental apparatus can optimally prepare research animals for the experiment. This not only improves the welfare of the animals, but also the well-being of the people involved, even leading to better experimental results.

Reduction of the amount of burden in the experiment itself:

Animal research can involve pain, suffering or harm, for example in surgical procedures. Better procedures of severity assessment and the resulting optimised administration of analgesics and anaesthetics can significantly reduce burden.

6 Animal Research in Public and Political Perception

Comments on Thesis 8

The use of animals in knowledge-driven research occupies a special position in the context of the ethical debate on how far the use of animals for humans can be legitimised. There is frequently no direct link between the scientific gain in knowledge and the resulting benefit to human beings. Scientific breakthroughs which could not be foreseen at the start often arise after decades of research. In the context of the harm-benefit analysis, the scientific gain in knowledge is weighted against the expected harm on the animals in the experiment, but in public perception the significance of scientific findings can be classified as less relevant if no direct progress for humans, animals and nature can be seen. On the other hand, the suffering of animals in research is obviously a highly emotional factor. Science is therefore faced with the challenge of communicating the importance of basic research for the future viability of society while at the same time ensuring acceptance for the justifiability of animal research. In the progress report on its High-Tech Strategy 2025¹³, the Federal Government says that “*die Partizipation der Gesellschaft an Erkenntnissen und Erfolgen der Wissenschaft*” (engl. “the participation of society in the findings and accomplishments of science”) is one of its strategic guiding objectives under the Research Framework Programme. The aim is “*die Wissenschaftskommunikation zu stärken, um die Aufgeschlossenheit der Gesellschaft gegenüber der Wissenschaft zu erhöhen und die Basis für gemeinsame Diskussion um Forschung und Innovation zu verbreitern*” (engl. “to strengthen science communication in order to increase society’s openness towards science and broaden the basis for joint discussion around research and innovation”). It was in 2015 that the Alliance of Science Organisations in Germany set up the information platform “*Tierversuche verstehen*”¹⁴ (engl.

13 Federal Ministry of Education and Research (2019): Fortschrittsbericht zur High-tech-Strategie 2025; [to document on bmbf.de](#).

14 [Initiative „Tierversuche verstehen“ \(tierversuche-verstehen.de\)](#)

“understanding animal research”); this was followed by the launch of the *“Initiative Transparente Tierversuche”*¹⁵ (engl. “initiative transparent animal research”) in July 2021. The aim of this latest initiative is to call on academic institutions and research-based industry to provide the public with transparent information about the research on animals taking place at these institutions and to engage in dialogue. In addition to the researchers themselves and their institutions, a commitment and willingness to engage in transparent dialogue of this kind is also desirable among other stakeholders. For example, in translational research, in the pharmaceutical industry and in biomedicine (including the medical profession and pharmacy) hardly any information is provided about the fact that the products, procedures, medication and medical therapies used are largely based on research outcomes that also involved the use of animals. Furthermore, media coverage of innovations, scientific awards and research achievements generally tend not to mention the use of laboratory animals. Similarly, the Federal Government’s strategy papers lack a clear commitment as to the basis and methods to be used in achieving strategic goals in the field of health research (cf. National Decade against Cancer and *“Wirkstoffe entwickeln, Infektionen bekämpfen und Forschung zu globaler Gesundheit stärken”* (engl. “developing active substances, fighting infections and strengthening research on global health”¹⁶)). Only by maintaining transparency it is possible to ensure that public and political decision-makers are informed about the widespread use of animals in research and create a knowledge-based foundation that also allows the impact to be assessed of any possible animal experiment ban on the future of the innovation potential and status of a research hub.

Recommendations and Notes

- ▶ *Transparent communication about the use of animal in science and research should be part of the institutional self-image of all stake-*

15 [.Initiative Transparente Tierversuche“ \(initiative-transparente-tierversuche.de\)](https://www.initiative-transparente-tierversuche.de)

16 Federal Ministry of Education and Research (2018): Research and innovation that benefit the people – The High-Tech Strategy 2025; [to document on bmbf.de](#).

holders involved, providing the basis for a dialogue geared towards facts and for social and political acceptance.

- o On the part of science itself, such a cultural change must be supported by the research institutions, with communication strategies to this effect being developed – not least so as to provide researchers with the necessary support, especially if they personally become the target of animal research critics. The initiative “Tierversuche verstehen” of the Alliance of Science Organisations in Germany and the “Initiative Transparente Tierversuche” aim to support this change.*
 - o On the part of “technology users” in industry and business, medicine and the medical profession, there should be a clear commitment regarding the use of products that have been developed based on animal research in order to transparently underpin the importance of animal research, including examples from application and practice.*
 - o In media reporting on research and innovation, the use of animals in research should also be referred to transparently. In this way, reporting would act as a multiplier, broadening the circle of the informed public.*
 - o Such transparency is called for on the part of politicians and the executive, too. For example, strategy papers, planned funding programmes etc. should mention the use of animal for scientific purposes to the same extent as other methodological approaches. In the case of cross-departmental issues, a consensus should be reached concerning strategic orientation and joint communication.*
- In addition to communicating the research methods used, a realistic impression should be provided of the opportunities and limitations of new scientific findings. This applies to statements about future promises of cures produced by knowledge-driven research, and equally to the promise that new alternative methods would make animal research obsolete in the near future.*

7 Future Safeguarding of Technological Sovereignty in Biological and Biomedical Research

Comments on Thesis 9

A mandated ban on the use of animals for scientific purposes does not automatically mean the end of the need to use animals in research per se. Rather, a ban endangers Germany and the EU in terms of their innovation potential and standing as a research location: it increases the potential dependence on biomedical innovation from other research locations, reduces the ability to act independently in the face of future challenges, and leads to a relocation of relevant research projects to non-European countries. At the same time, Germany and the EU would lose sovereignty over the animal welfare standards desired by society. With its directive, the EU has issued strict framework conditions for research on animals which have been translated into national legislation and allow the authorities to act in the interests of animal welfare. In Germany, research involving animals is one of the most heavily regulated areas of animal use. These legal and regulatory frameworks lose their validity as soon as Germany or the EU prohibit research using animals and become dependent on innovations resulting from animal research conducted outside the EU.

The need for sovereignty in the field of biological and biomedical research was recognised by the Federal Government and highlighted in an impulse paper, using the example of vaccine development¹⁷. In order to preserve this sovereignty, it seems counterproductive to no longer allow researchers in Germany and the EU to conduct research using animals. Rather, the political objective must be to consider excellent science and animal welfare in research together and to optimise the framework conditions in such a way that the two consti-

17 Federal Ministry of Education and Research (2021): Technologisch souverän die Zukunft gestalten – BMBF-Impulspapier zur technologischen Souveränität; [to document on bmbf.de](https://www.bmbf.de/document-on-bmbf.de).

tionally protected assets (freedom of science and animal welfare) are safeguarded as effectively as possible, while further promoting sovereignty and innovative strength in research and method development. A crucial aspect is to bring about a cultural change in which the perceived contradiction between animal welfare and animal research is resolved and collaborative strategies are developed that take equal account of the quality of research and animal welfare. In view of the distribution of responsibilities in the federal ministries and the relevant state governments, such an approach requires horizontal and vertical coordination of policies in order to jointly align future strategies and optimise administrative and bureaucratic processes with regard to these two valuable assets – freedom of science and animal welfare. In addition to this call for a shift in discourse, the Senate Commission endorses much of the Commission of Experts for Research and Innovation (EFI) report¹⁸ in its assessment of the Federal Government's long-term research and innovation policy. In particular, it supports the proposed measures and recommendations to exploit the potential of gene editing and CRISPR/Cas from the perspective of animal research. All in all, innovation strategies and funding measures must therefore be designed in such a way that they always aim to optimise animal welfare and research quality. Administrative procedures adopted by public authorities should support this process so as to create an ideal foundation for future innovation. In order to initiate a cultural change towards a holistic view of animal welfare and research quality and to anchor this in strategic plans, there is a need for policy coordination that always involves the relevant departments at an early stage and on an equal footing, such as the ministries concerned and inter-ministerial working groups as well as state, federal and EU stakeholders.

18 Commission of Experts for Research and Innovation (2021): Report on Research, Innovation and Technological Performance in Germany 2021; [to document on e-fi.de](https://www.efi.de/en/our-work/research-and-innovation-report-2021).

Recommendations and Notes

- ▶ *The reduction in bureaucracy mentioned frequently throughout the coalition agreement¹⁹ must be noticeably implemented in the area of science, too: the legally prescribed project authorisation must be designed in such a way that, while strictly adhering to the ethical justifiability of animal research, the administrative burden for researchers is reduced. This includes the harmonisation of authorisation procedures across Germany and the EU, thereby providing legal certainty for researchers.*
- ▶ *With regard to the internationalisation of research and development, care must be taken to ensure that research remains globally competitive in the area of technology. For example, in spite of the common EU Directive harmonising animal welfare in research across the EU, the administrative burden and the duration of approval procedures in EU countries vary so much that Germany currently suffers a significant competitive disadvantage.*
- ▶ *The “reduction strategy” for animal experiments also proposed in the coalition agreement must be preceded by an impact assessment report that takes into account the positions of all relevant stakeholders; this should be coordinated and taken into account by the Federal Government across departments and ministries.*
- ▶ *Following the recommendation of the EFI report, a German 3R centre should be set up to take on the role of a competence centre for 3R measures and their transfer to basic and translational research for the purpose of advising researchers and promoting networking between the various stakeholder groups.*

19 [Coalition agreement \(bundesregierung.de\)](https://www.bundesregierung.de)

8 Appendix

Members of the DFG's Permanent Senate Commission for Animal Protection and Experimentation (DFG)

Professor Dr. Brigitte Vollmar, Rostock (Chair)

Professor Dr. Anja-Katrin Bosserhoff, Erlangen

Professor Dr. Petra Dersch, Münster

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