

Animal-based research will be hampered, if additional bureaucratic burden is implemented

by an additional EU co-ordination office that has to consider:

- a compliance check
- a supporting opinion from a local ethical evaluation and
- a non-specified deadline.

GFBF aims to achieve a balance

between a properly regulated animal-based biomedical research **and** the freedom of research without undue delays, bureaucracy and hindrance.

With such a structure it will not be possible to have experiments authorised within the initial trial period.

The biomedical research community itself provides powerful tools of self-control. This facilitates the ability to effectively guarantee the scientific and moral self-commitment of animal protection as defined in the Declaration of Helsinki.

This is especially relevant with respect to the principles of the Declaration of Helsinki, requesting that clinical research is based on prior adequate animal-based research.

We ask you to support our arguments, to consider these in your decision making with respect to the Revision of Directive 86/609, **and** to implement the necessary changes and corrections.

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Gesellschaft zur Förderung der
biomedizinischen Forschung e.V.

Society for the Advancement of
Biomedical Research, Germany

Revision of the EU-Directive 86/609
- **Our Position** -
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Animal-based research will be hampered when new diseases emerge, especially projects

aiming to explore and develop

- **vaccines against human epidemics**

if

- the use of non-human primates (NHPs) is prohibited or
- when only second generation (F2) non human primates may be used.

There is presently no sufficient supply of second generation (F2) primate offspring and it is unlikely to be seen in the foreseeable future.

Animal-based research will especially be hampered in studies related to chronic diseases, like

projects aiming to analyse and/or cure

- **chronic arthritis**
- **cancer**
- **infections**
- **metabolic disorders**

if

- long-lasting experiments are inevitable and it is unavoidable that animals may suffer from considerable distress.

Approximately 50% of all projects, previously and currently being authorised in Germany, would in future most probably be rejected.

As a result, biomedical research would solely depend on human studies with all limitations and ethical issues involved.

Background

Medical research to maintain or reconstitute human health is strongly dependent on biomedical research, using animal models, organ and tissues cultures, all of which are indispensable for the development of new therapeutic strategies.

The EU ETS 123 and Directive 86/609 set out the framework for this biomedical research. Type of animals and procedures, collection of data and their report to appropriate authorities, animal care and accommodation are defined, aiming to avoid distress and unnecessary pain to the experimental animals.

In 2001 the European Commission initiated a full revision of Directive 86/609. In 2007 the DG Environment has presented a draft version, its wording was preliminary and open to discussion (internet consultation).

We are concerned that the current draft does not consider the needs and perspectives of biomedical research. If these basic requirements are neglected, future research in prevention, diagnosis and treatment of human diseases may seriously be hampered.

The Society for the Advancement of Biomedical Research, Germany, represents members, who are involved and depend on this type of research. It strongly disapproves certain parts of the current draft of the Revision of Directive 86/609.