

April 21th, 2009

## Position

**of science and industry on the proposal of the EU Commission for a directive of the European Parliament and of the council on the protection of animals used for scientific purposes (KOM(2008) 543 final)**

Dear Ladies and Gentlemen,

The signing representatives of German research organisations, representatives from industry involved in research, and representatives from other organisations welcome the efforts of the European Commission to revise the directive on the use of laboratory animals from 1986. Important from our point of view is, above all, the goal of further inner-European harmonisation of the basic conditions for the use of laboratory animals.

We support a revision of the directive that ensures an ethically acceptable balance between animal welfare and research interests and the cornerstones of which are founded on scientific knowledge. We advocate pragmatic approaches that contribute to the high importance of both basic research and applied research for advances in the life sciences, pharmacology and toxicology and that do not create administrative hurdles without positive effects on animal welfare.

Experiments on animals are an unavoidable necessity for progress in basic research in the life sciences, for topics in applied research and in pharmacology as well as in toxicology. We call for an objective discussion on the importance of animals in situations where their use for experimentation purposes is dependent on a scientific and ethical review. These assessments should be performed by independent experts. We reject a scientifically unjustified reevaluation of certain species or development stages.

In particular, we expect that the new regulations will not result in any unnecessary hurdles for European research that would impair the global competitiveness of European research institutions in academia or industry.

It is our opinion that the draft put forth by the European Commission must urgently be examined and adapted in the five following key areas:

- 1) **Extension of the scope of application to include fetuses, embryos and larvae (Art. 2.2.a and Art. 2.3):** The inclusion of these development forms in the scope of application of the law will result in an explosive increase in the number of laboratory animals without any resulting benefit to animal welfare since, for example, incubated eggs used for the production of vaccines or embryos used for the creation of transgenic lines of mice are counted as animals. We argue that the scope of application be restricted to mammalian fetuses and mammalian embryos in which the capability to sense pain has been scientifically documented.
- 2) **Classification of the severity level of procedures and the prohibition of "severe" procedures (Art. 15):** The severity level of procedures must be defined together with the entry into force of the directive, as a corresponding assessment of experiments under free interpretation of the directive text would be counterproductive, if not dangerous. The planned prohibition of extremely strain-inducing experiments with no possibility for special exceptions according

to ethical considerations is, for all practical purposes, a ban on research of the most severe human illnesses and their therapies (such as for illnesses related to tumours or arthritis).

- 3) Reuse of laboratory animals (Art. 16):** The objective of distributing the strain over as many animals as possible stands contrary to a reduction in the number of animals, typically achieved in practice by reusing animals after recovery and veterinary examinations. Reuse should be determined on a case-by-case basis under observation of the 3R principle. We rely here on a strengthened ethical review system which, in addition to the strain on the individual animal, also takes into consideration the number of additional animals necessary for the new experiment.
- 4) Use of non-human primates (Art. 8, 10):** We recognise that, from the viewpoint of broad classes of society, these animals deserve a particularly high level of protection on account of their genetic proximity to humans. Given the high political sensitivity of this topic, we argue that only scientifically documented facts should serve as the basis for political decisions. We therefore demand that an implementation of the findings presented in the recently published SCHER report "The need for non-human primates in biomedical research, production and testing of products and devices" be included in the revision of the directive text.
- 5) Bureaucratisation.** Excessive bureaucratisation may jeopardise Europe's international competitiveness without a benefit to animal welfare. Overlapping responsibilities of ethics commissions, animal protection officers and officials charged with granting approvals (**Art. 24.2; Art. 25; Art. 37.3; Art. 37.4**), delays in the approval of experiments due to lack of decision deadlines for the officials, (**Art. 43**) and the discontinuation of the announcement procedure for legally required animal experiments, as stipulated by the draft of the directive (**Art. 35ff.** henceforth subjects all uses of animals for scientific purposes to prior authorisation), result in considerable disadvantages for research and, thus, affect the competitiveness of Europe as a research location. The draft must promote the international, regulatory acknowledgement of alternative methods of animal experiments.

In the interest of research in Europe, we implore you to work towards an appropriate change to the proposed directive. The leading Committee on Agriculture and Rural Development (AGRI) and the Committees on Environment, Public Health and Food Safety (ENVI) and Industry, Research and Energy (ITRE) have already expressed themselves in this regard. Their balanced position aims to strengthen animal welfare as well as ensure that animal experiments can be performed in the future in Europe.

We urge you to support the revisions proposed by the AGRI, ENVI and ITRE committees.

Sincerely

**Alexander von Humboldt Foundation**

Jean-Paul-Straße 12, 53173 Bonn

**FhG – Fraunhofer Gesellschaft**

Hansastraße 27 C, 80686 München

**DAAD - German Academic Exchange Service**

Kennedyallee 50, 53175 Bonn

**German Academy of Sciences Leopoldina  
National Academy of Sciences**

Emil-Abderhalden-Straße 37, 06108 Halle/Saale

**HRK – German Rectors' Conference**

Ahrstraße 39, 53175 Bonn

**DFG – German Research Foundation**

Kennedyallee 40, 53175 Bonn

**Helmholtz Association of  
German Research Centres**

Anna-Louisa-Karsch-Straße 2, 10178 Berlin

**WGL – Leibniz-Gemeinschaft**

Eduard-Pflüger-Straße 55, 53113 Bonn

**MPG – Max-Planck Society**

Hofgartenstraße 8, 80539 München

**Wissenschaftsrat –  
German Council of Science and Humanities**

Brohler Straße 11, 50968 Köln

**Acting on behalf of the German Science  
Organisations mentioned above**

Prof. Dr. Jürgen Mlynek  
President of the Helmholtz Association



**VCI**

Verband der  
Chemischen  
Industrie e.V.

Dr. Gerd Romanowski  
Geschäftsführer



Dr. Ricardo M. Gent  
Geschäftsführer



Prof. Dr. Dr. W. Kirch  
Direktor  
Institut für Klinische Pharmakologie  
Medizinische Fakultät der TU Dresden

**vfa.** Die forschenden  
Pharma-Unternehmen

Dr. Siegfried Throm  
Geschäftsführer Forschung, Entwicklung,  
Innovation

 Vitale  
Gesellschaft  
**BDI initiativ**

Ivor Parvanov  
Geschäftsführer BDI initiativ-Vitale Gesellschaft

**BIO DEUTSCHLAND**

Dr. Viola Bronsema  
Geschäftsführerin

Bundesverband der  
Pharmazeutischen  
Industrie e.V.  
**BPI**

Dr. Norbert Gerbsch  
Stv. Hauptgeschäftsführer

**DVG**

Dr. Heinz Brandstetter  
Leiter der Fachgruppe Versuchstierkunde  
Deutsche Veterinärmedizinische Gesellschaft