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Statement by the German National Academy of Sciences Leopoldina, acatech – the German Academy of Science and Engineering – and the BBAW (Berlin-Brandenburg Academy of Sciences and Humanities, representing the Union of the German Academies of Sciences and Humanities) on the

Revision of EU Directive 86/609/EEC on the protection of animals used for scientific purposes

On the occasion of the revision of the EU Directive 86/609/EEC on the protection of animals used for scientific purposes, the three Academies would like to highlight certain points requiring consideration during discussion on the draft Directive to ensure that European research functions properly and thus retains its potential to make vital contributions to human health and wellbeing. The aim of the Directive – to establish a high standard of protection for animals used in experiments in the EU – receives the scientists' full and unequivocal support. So far, however, certain aspects relating to research have received too little consideration; in its current form, the Directive would mean a drastic decline in conditions for biomedical research. In economically challenging times, research and innovation are Europe's most valuable resources. Progress in our society is critically dependent on the results of biomedical research, especially when it comes to lifelong good health. For this reason, the three Academies call on the negotiating parties (the European Parliament, the EU Council of Ministers, the European Commission) to ensure that the Directive finely balances the concerns of animal protection, on the one hand, and, on the other, the needs and requirements of research, if effective health protection is to be achieved.

1. Taking into account the interests of research and health

The blanket bans in the Directive need to be replaced by the consideration of individual cases, allowing decisions to be made on whether laboratory animals' suffering is justified by the value of the expected results.

2. The necessity of basic research

The regulations must not discriminate against basic research in favour of applied research.

3. Special treatment of certain groups of animals

The use of non-human primates for scientific purposes must be regulated in a manner which considers the purposes of the experiment and does not impede biomedical research and the development of medicines.

4. Experiments involving prolonged, severe suffering

There cannot be a blanket ban on prolonged, severe suffering as described in Article 15 (2) of the draft amendments and adopted by the European Parliament in first reading. This must be replaced with weighing up the detriments and benefits, bearing in mind how crucial the purpose of the experiment is.

5. Research using endangered species

Steps must be taken to ensure that animals from endangered species which are bred for use in procedures are excluded from the restrictive regulations of Articles 7 and 8 (1A).

6. Legal uncertainties, imprecise definitions and lengthy procedures

In the interest of targeted, efficient research, care must be taken to avoid legal uncertainties, imprecise definitions and lengthy procedures when the Directive is transposed into national law.

Details of individual points:

re 1. Taking into account the interests of research and health: The use of animals for human purposes – research is just one relatively small part of a range of different uses – is part of human culture. Accordingly, societies in Europe and around the world place human wellbeing at the centre of ethical considerations. Thus, international agreements (such as the World Medical Association's Declaration of Helsinki) stipulate that research on human beings is to be avoided as far as possible, and that the risk for human test subjects must be reduced to a minimum. Based on these considerations, the revision of the Directive must not merely take into account aspects relating to animal protection: it must also allow for other legally protected rights and interests, such as scientific freedom and the protection of human health. This is required in order to respect the basic rights which were set out in the Charter of Fundamental Rights and became written European law by means of the Treaty of Lisbon. Blanket bans and drastic restrictions on biomedical research alike conflict with the Community's duty to ensure that its citizens' health is well protected. All in all, without this research there would be no advances in the struggle against disease. When grappling with protecting people's health, with maintaining freedom of research and with the legitimate concern of avoiding animal suffering and pain, a fine balance must be kept.

→ The blanket bans in the Directive must be replaced with weighing up the facts in individual cases. This allows decisions to be made on whether laboratory animals' suffering is justified by the value of the expected results.

re 2. The necessity of basic research: Not only is basic research – striving towards insights – a human cultural asset, the freedom it creates also opens up unexpected routes for science and technology. Discoveries such as penicillin or x-rays, or the development of bionic technology, e.g. using the lotus effect, are examples of how pioneering developments of huge practical and social benefit often result as an accidental side-effect of basic research. They show that basic research is necessary for innovation. No-one can say in advance which research will lead to new developments – who could have guessed with the discovery of the transistor that the introduction of computers and communications technology would change our society as it has? Various regulations relating to permissible purposes for using laboratory animals for basic and applied research (Articles 7, 8, 50) are highly problematic due to the way they are interlinked.

→The regulations must not discriminate against basic research in favour of applied research.

re 3. Special treatment of certain groups of animals: To achieve the declared aim of the Directive – to reduce animal suffering – legal regulations must be based on solid scientific insights into animals' specific needs. To substantiate the restrictions on research using non-human primates (Article 8 (1)), the ban on basic research using protected primate species (Article 8 (1A)) and the ban on research using great apes (Article 8 (2)), the Directive cites the animals' highly developed social and cognitive skills and their genetic proximity to human beings. Genetic proximity is not an adequate measure of whether primates feel pain in a similar way to human beings or can suffer in the same way as us. Equally, the characteristic of "intelligence" does not depend on genetic proximity to human beings, as demonstrated by the well-developed cognitive skills of the crow or octopus families. The latest findings in epigenetics and interfering RNA about the activation of certain genes show that the mere existence of genes does not allow any conclusions to be drawn about their functioning.

When animals are kept and handled, their social and cognitive skills need to be taken into account. Limits on suffering must be judged separately for each specific experiment. Other mammals are far more sensitive to certain stresses than the primates addressed in the Directive, which can quickly be accustomed to certain test conditions and do not perceive them as stressful.

Moreover, blanket bans on specific fields of research when using non-human primates do not take into account medical reality. Despite advances in testing the safety of medicines using in-vitro systems and cell cultures, the use of animals cannot be avoided, and not all animal models are equally suitable for all research purposes. Where there are no tried-and-tested alternative procedures, categorical prohibitions run the risk of research having to be carried out using unsuitable models. In the field of pharmacological

research, to guarantee the safety of human test subjects, preclinical tests need to be carried out using appropriate animal models with results that apply to human beings. In the fields of neurobiology, reproductive biology and immunology, in particular, non-human primates are in some cases the only suitable animal models. For example, in most cases the safety of new therapies using monoclonal antibodies can only be tested on non-human primates, and sometimes even only on chimpanzees. Blanket bans in the field of research on non-human primates or great apes do not take this into account.

→ The use of non-human primates for scientific purposes must be regulated in a manner which is geared towards the purposes of the experiment and does not impede biomedical research and the development of medicines.

re 4. Experiments involving prolonged, severe suffering: There are major problems with the ban on prolonged experiments exceeding an upper limit of suffering on the part of the laboratory animal. How much an animal actually suffers depends on the specific conditions of an experiment and can only be defined roughly, at best, using the examples listed in Annex IX of the Directive. This means that there is no clear definition of the upper limit for suffering. This lack of clarity does not provide sufficient criteria to allow planned experiments to be authorised, posing a major obstruction to research into severe chronic illnesses such as organ failure, polyarthritis, cancer or Parkinson's disease. Diseases such as these, which currently cannot yet be cured, cause great suffering to human patients, whose only hope for possible treatment comes from advances in research. Thus, the great stresses placed on laboratory animals must not be seen in isolation, but in relation to the purpose of the experiments. The safeguard clause in Article 50 does not do this and, for the reasons named above, is not a suitable regulation to cover exceptions.

→ There cannot be a blanket ban on prolonged, severe suffering as described in Article 15 (2) of the proposed amendments and adopted by the European Parliament in first reading. This must be replaced by weighing up the detriments and benefits, bearing in mind how crucial the purpose of the experiment is.

re 5. Research using endangered species: Research using animals must not be allowed to endanger the continued existence of a species. To protect endangered species it is important to make the most of every opportunity to gain information which can guarantee their continued existence. Placing restrictions on using endangered species in basic research would be equivalent to avoiding possibly important insights into maintaining the species. Furthermore, regulations on species protection already stipulate that only animals bred specifically for the purpose may be used for research purposes. This regulation means that using animals from protected species in experiments has no effect on population sizes in the wild – this applies equally to applied and basic research. Thus, a ban on certain kinds of research work, especially on basic research, does not serve a useful purpose for species protection.

→ Steps must be taken to ensure that animals from endangered species which are bred for use in procedures are excluded from the restrictive regulations of Articles 7 and 8 (1A).

re 6. Legal uncertainties, imprecise definitions and lengthy procedures: To achieve targeted, efficient research, legal uncertainties, imprecise definitions and lengthy procedures must be avoided in regulating animal experimentation. However, the limit on applied research using non-human primates to research related to "debilitating clinical conditions" is highly uncertain due to the lack of a clear definition. The exception clauses intended by the safeguard clauses in Article 50 are not suitable for relaxing the blanket bans. In practice, the safeguard clauses lead to legal uncertainties, as member states are only allowed to grant permission on a provisional basis, and their decisions can be overturned by the European Commission. Moreover, in the procedure as planned, this overturning is not based on a scientific evaluation of the facts. All in all, it is highly questionable whether funding will be granted under these circumstances.

→ In the interests of targeted, efficient research, care must be taken to avoid legal uncertainties, imprecise definitions and lengthy procedures when the Directive is transposed into national law.

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