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Council Directive on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes

Dear Chancellor Merkel,

The current status of the deliberations between the European Parliament, European Council and European Commission on the above Directive fills our member societies and us with great trepidation.

Although the initial proposal, presented by the Commission on 5th November 2008, contained numerous meaningful improvements for experimental animals (e.g. comprehensive ban of all severe procedures on animals; positive ethical project evaluation by the competent authority under inclusion of specific and independent ethical expertise as an indispensable requirement for each process; preference of alternative methods as soon as the status of development and validation allows attaining the sought result in a scientifically satisfactory manner without the use of animals or with fewer animals or by reducing the harm done to the animals).

Since then, many of these improvements have fallen victim to the pressure that scientific organisations and pharmaceutical companies exert on the governments of the Member States and on the European Parliament.

It appears that the German government has now also abandoned the publicly proclaimed goal of implementing the standard of protection that is anchored in the German Animal Protection Law into the new EU Directive. This is a great disappointment to the German citizens who care about the protection of experimental animals and who are, among others, represented by our association, especially as the declaration of animal protection as a state aim, which was anchored in the German Basic Law in 2002, confers the obligation of championing the realisation of an effective animal protection at European level to the German government.

Although a constitutional review of the current proposal for the Directive, which has resulted from the trilogue of Council, Parliament and Commission, was recently announced by the

Federal Minister for Research, this is not sufficient to dispel our fears. On the contrary: If this review lays a one-sided focus on the basic rights of freedom of science and research and does not or not sufficiently consider the equally important state aim of animal protection, it will not resolve (or may even worsen) the unsatisfactory situation as viewed from the animal protection perspective.

We thus ask you to advocate an appropriate emphasis on animal protection in the further debate on the Directive and, in line with the Article on animal protection in the new EU Constitution (Part B, Title II, Art. 6 b), to propagate that the most important improvements in the sense of animal protection, which the Commission envisaged in its initial proposal for the Directive for “animals as sentient beings”, be taken up into the new Directive in full.

We have listed these improvements in the attached document for your information.

As the processes are complex and preclude explanation in just a few lines, we would appreciate the opportunity of defining the position of our association and member societies in a personal interview.

Yours sincerely,

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President

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Appendix to the letter to Chancellor Angela Merkel

The most important improvements of animal protection, which were part of the proposal for the Directive of the European Commission presented on 5th November 2008, but which, according to the current status of the deliberations, are obviously no longer wanted:

1
Ethical evaluation I

In the proposal for the Directive of 5th November 2008, point 37 of the justification stressed that "comprehensive ethical evaluation of projects using animals […] forms the core of the project authorisation". It should be "essential to ensure both on moral and scientific grounds that each use of animals is carefully evaluated on the scientific validity, usefulness and relevance of the expected result of that use. […] Therefore, an independent ethical evaluation should be carried out as part of the authorisation process (point 38) […]. Effective implementation of an ethical evaluation should also allow for an appropriate assessment of the use of any new scientific experimental techniques as they emerge." To ensure this and "to ensure an approach to ethical evaluation and ethical review strategies at national level", Member States should establish "national animal welfare and ethics committees" (point 46). Moreover "the competent authority carrying out the ethical evaluation shall consider experts", in particular in the area of "applied ethics"(Article 37(3)(f)). In addition, there is an explicit demand that "Ethical evaluation shall be performed in a transparent manner, by integrating the opinion of independent parties" (Article 37(4)).

We welcomed that in the report of 3rd April 2009 (Draft European Parliament Legislative Resolution) in Article 37(1)(a) it was added that a project has not only to be scientifically justified, but it *also has to be* indispensable and *ethically defensible*. The official justification for this was, "In order to ensure that animal experiments are conducted only if they are indispensable, ethically defensible and represent the only alternative, there must be an ethical evaluation prior to a project being authorised." This corresponds with the demands of the German Animal Protection Law, Article 7(3): Beside the indispensability and the lack of alternatives, the ethical defensibility is a fundamental condition for the authorisation of an animal experiment.

Furthermore, it was added to Article 37(2)(d) of the same report that the harm-benefit analysis of the project, of which the ethical evaluation is a part, must assess whether the harm to the animals in terms of suffering, pain and distress, and to the environment where appropriate, is "*ethically defensible*" in light of the expected advancement of science that may ultimately benefit human beings, animals or the environment. The official justification ran, "It is impossible to carry out a harm-benefit analysis on the basis of objective, scientifically recognised criteria, and such a requirement disregards the nature of science. […] The ethical assessment should therefore examine whether the project is ethically defensible." Article 37, thus embellished with two demands for ethical defensibility, was published on 5th May 2009 (European Parliament legislative resolution of 5th May 2009, first reading).

1.1

To our dismay, the term "ethical" has simply been deleted from all relevant passages of the proposal in the compromise text of 10th December 2009.

In Article 35(2) of the initial proposal a "favourable ethical evaluation by the competent authority" was a requirement for granting authorisation. The current passage stipulates only a "favourable outcome of the project evaluation", a considerably lesser demand. This would mean in practice that the demand would be lesser than the "ethical defensibility" stipulated in Art. 7(3) of the German Animal Protection Law.

1.2

The title of Article 37 is now no longer "Ethical evaluation", but only "Project evaluation". The requirement that a project be "ethically defensible" was stricken from Article 37(1)(a). It had previously been required that "the project is scientifically justified, indispensable and ethically defensible".

It was furthermore deleted from Art. 37(2)(d) that the required weighing of interests must be "ethically defensible". Only one clause mentioning ethics has been inserted in Article 37(2)(d). It requires that harm-benefit-analysis should take into account ethical considerations. This is a much weaker requirement than before, as there is a clear difference between whether a project involving animal experimentation needs to be "ethically defensible" or whether ethical considerations must merely be taken into account in an evaluation that only considers scientific and educational aspects (new draft of (1)(a)). This also contradicts the justification for the adoption of the demand for "ethical defensibility".

The explicit evaluation of the animal experiment, which was one of the central goals of the revision of the Directive, has thus vanished from the draft.

1.3
On the side of the disadvantages of the harm-benefit-analysis also possible negative effects of the procedure on the environment should be covered as foreseen under Article 37(2) of the Commission's proposal.

1.4
The expertise required of the approval committee for the project evaluation now also no longer mentions the in our view absolutely imperative ethical expertise. This is baffling, as a deficit of ethical expertise was not only criticised by the users, but also by the authorities, whose responsibility it is to perform the ethical evaluation as the "core of the project authorisation".

1.5
The goal of introducing the Standard of the German Animal Protection Law into the new Directive also requires retaining the obligatory integration of the opinion of independent parties (instead of making this only an option as done in the current draft) proposed in the draft of 5th November 2008 in Art. 37(4) by the Commission.

It is essential that an independent advisory committee is available to each competent authority, as is realised in Germany with the advisory committees stipulated by Article 15 of the German Animal Protection Law. This is especially important because the "Permanent ethical review bodies", which should be present at each establishment – and which have now been renamed "Animal welfare bodies"– no longer have the task of giving "ethical advice" on their agenda. It should be ensured that these independent national advisory committees include equally represented nominated members of recognised animal protection organisations and that ethical expertise is also compulsory.

1.6
The scope of the national "Animal welfare and ethics committees", which were demanded in November 2008, has now been vastly reduced by deletion of the terms "animal welfare" and "ethics". We are disappointed that it is now no longer required that these committees "shall exchange information on the operation of permanent ethical review bodies and ethical evaluation", because the "ethical evaluation" initially required in Article 37 has been downgraded to "project evaluation". However, an ethical evaluation should be compulsory in view of the circumstance that the Member States have differing standards in terms of the treatment of animals, and an exchange on ethical aspects would benefit the animal-human relationship and thus animal protection in the European community. Harmonisation within the EU and "at the same time strengthening the protection of animals still used in scientific procedures in line with the EC Treaty's Protocol on Animal Welfare" were both named in November 2008 as „Grounds for and objectives of the proposal".

In view of the initially ambitious aims set for the proposal for the Directive in November 2008, whose purpose it was to improve the protection of animals still used in scientific procedures, and in which an ethical review of applications for animal experiments is ranked first of the major aims, "The main points of the proposal are as follows: the new directive will make it compulsory to carry out *ethical reviews* and require that experiments where animals are used be subject to authorisation" (see summary of the proposal for a directive: OD/2008/0211: 05/11/2008 – Commission/Council: initial legislative document), the deletion of the ethical evaluation, especially when considering animal protection to be a state aim, cannot be accepted. Furthermore, the proposal still lacks the tools for balancing and ethical evaluation, which should be provided as an annex in form of a set of criteria.

2
Application of Methods not entailing the use of an animal
According to Art. 13(1), second sentence, of the Commission's proposal, methods not entailing the use of an animal should be used preferentially, even before recognition by Community legislation, if a scientifically satisfactory method or testing strategy for obtaining the result sought is reasonably and practicably available. This sentence has also been deleted from the current draft. An example that it is not justified to postpone the application of validated alternative methods until their formal recognition of Community legislation is the pyrogenicity test, for which live rabbits are still being used today, although a validated and more sensitive in vitro pyrogen test (IPT) using human whole blood has been available for years. The IPT will only be adopted into the European Pharmacopoeia this year. Years and sometimes even decades pass between validation and formal legal recognition. It is neither compatible with Art. 20a of the German Basic Law nor with Part B, Title II, Art. 6 b of the EU Constitution (Article on Animal Protection) that animals be subjected to pain, distress, anxiety and harm during this time.

3
Authorisation procedure
The softening up of the requirement proposed by the Commission that all experiments on vertebrates, cephalopods and decapods undergo an authorisation procedure by the new Art. 41 A also represents a grave regress that is incompatible with the aim of effective animal protection. The primary danger is that the assessment of the ethical defensibility demanded above is not performed with the necessary care in the now simplified administrative procedure. Further, the Member States are authorised by the currently proposed Art. 36(2) to waive the anonymous non-technical project summaries by the applicant in this simplified administrative procedure (with the consequence that these are also no longer published as was originally proposed in Art. 40(4)).

4
Severe procedures
The proposed ban on "severe" procedures, i.e. procedures in which the pain, suffering or distress is likely to be prolonged, suggested in the Commission's draft of 5th November 2008 in

Art. 15(2), is to be weakened and limited by the planned Art. 50(1 A). This is incompatible both with the Article on animal protection of the EU Constitution and with the German state aim of animal protection. There is no scientific benefit that can be so great that it could outweigh severe and prolonged pain, suffering or distress. Furthermore, even scientists who themselves perform animal experiments recognise that animal experiments causing the animal severe distress do not produce reliable results owing to the high stress levels. Thus the lacking validity of such experiments should already suffice to forbid them on scientific grounds.

5
Genetically modified animals

According to the current draft (Art. 17(1)), the production of genetically modified animals shall already no longer fall under the restrictions of the Directive as soon as the scientists end their observation of the progeny, even if further pain, suffering and distress or long-term harm is to be expected. Such an extensive limitation of the applicability of the new Directive reduces the protection of these animals in insupportable measure.

6
Qualification of experimentators

Art. 20 of the Commission's draft of 5th November 2008 rightly requires an obligatory authorisation procedure for all persons who participate in procedures on animals to ensure their expertise and reliability. This authorisation is limited to five years, after which a further proof of qualification must be submitted with the application for an extension. In contrast, the current Art. 23 A (1) leaves it up to the Member States to ensure and check the competence of these persons. This increases the danger of subjecting animals to unnecessary pain, suffering and distress by personnel with insufficient expertise considerably. Further, a renewal of a person's authorisation is now bound to criteria that are difficult to verify and it is only called for when these apply (Art. 21(3)), which opens the door to arbitrariness.

7
Obligation to follow the care and accommodation standards

According to Art. 32(3) of the current draft, the Member States can allow deviance from the care and accommodation standards stipulated in Annex IV at the expense of the animals not only on grounds of animal protection, as envisaged in the Commission's draft of 5th November 2008, but also for other reasons. This is incomprehensible, as the guidelines of the European Treaty on experimental animals (No. 123, Annex A), on which this annex is based, are already based on an extensive weighing of the animals' needs against the possibly contrary scientific interests. The Member States and the European Community itself are legally obliged, according to Art. 5 (1), sentence 3, to adhere to the guidelines set down in this annex. The provision named here contravenes this obligation (as does the transitional period ending in 2017 for the implementation of the standards laid out in Annex IV). Furthermore, the demand for monitoring of health and wellbeing of experimental animals by an expert demanded in Art. 32(1) of the November 2008 draft has been deleted.

8
Inspections of the facilities

Art. 33 of the Commission's draft of 5th November 2008 stipulated relatively frequent inspections of the breeding, supplying and user establishments: These should be inspected at least twice per year; at least one of these visits must be unannounced. The current draft reduces these controls to about one sixth, as it demands that only one third of all establishments be inspected in one year (so that each establishment is inspected only once every three years); a defined minimum of unannounced inspections is also no longer stipulated. This represents an especially depressing result of the lobby work of scientific organisations and the pharmaceutical industry, as it demonstrates how much the persons participating in animal experiments must fear such inspections.

9
National reference laboratories

It is also deeply disappointing that the suggestion of the Commission in Art. 46 to install national reference laboratories for the validation of alternative methods replacing, reducing and refining animal experiments in all Member States has also fallen victim to lobby or cost pressures. This does not contribute to achieving the goal stated as reason no. 8 to fully support the Directive, i.e "this Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so. To meet that end, it seeks to facilitate and promote the advancement of alternative approaches."

10
National standard of animal protection

All improvements suggested by the Commission in the draft of 5th November 2008 were specifications of the precepts "indispensability" and "ethical defensibility" stipulated in § 7(2) and (3) of the German Animal Protection Law of 1987.

Therefore – but also because of Germany's explicitly proclaimed goal of implementing this standard on European level – the German government must champion the inclusion of these improvements (and thus the avoidance of the regresses described above) into the new Directive.