Revision of EU Animal Experimentation Legislation (COM(2008)543)

November 2009

As deliberations continue between the Parliament, Council and Commission, we call on you to seriously consider the concerns of ADI, Eurogroup, our Members and the EU citizens whom we represent. This is a remarkable opportunity to shape the use and treatment of laboratory for years to come and we urge that every effort be made to consider the following areas priorities.

Concerns include:

- The extension of the **scope** of the directive
- The use of **non-human primates**
- Stray and feral animals
- **Authorisation** of animal use, including need for **ethical review** and **retrospective assessment**
- The development and use of **alternative methods** to replace, reduce and refine animal experiments
- The **severity** of procedures, and **re-use** of animals
- Proper enforcement of the directive through **inspections**
- **Reviews** of animal experimentation including specific reviews applying to primate use

Scope – Article 2

All sentient animals and research in the EU should be covered including basic research and tests in which invertebrates; and embryos & fetal forms of vertebrates are used as recommended by EFSA. It is important that scientific evidence of the capacity for animals to suffer is reflected in the Directive.

Furthermore, it is of utmost importance to ensure that Member States may go beyond the provisions of the Directive in all aspects and not only in respect to accommodation and care. It would not be acceptable that established strong authorisation procedures in Member States are weakened.

Non-human Primates (Articles 8 and 10)

The use of primates in experiments is a matter of extreme concern to animal welfare organizations and the public. Any use of non-human primates must be strictly controlled. Their use must be scientifically and ethically justified. Allowing the use of primates for basic research would effectively remove any restrictions on primate use, which is unacceptable.

Whilst we agree that the term "debilitating" needs definition, the recommended one is too broad. We believe that the use of the word debilitating was to allow for research into diseases such as Alzheimer's, Parkinson's, or Multiple Sclerosis and NOT used to allow hangovers and obesity to be studied in primates – the Directive must ensure this. Debilitating should mean a "*permanent and substantial reduction in a person's normal physical and psychological ability to function*." The use of the term "substantial" would reflect the terminology considered in Recital 16. The EP amendment is the weakest proposal; it affords no special consideration at all to primates.

We strongly support EP amendment 59 for primate experimentation should be reviewed every two years with a view to setting targets for the implementation of alternative methods. A cautious approach that was strongly supported in the European Parliament which addresses concerns about the need for primate experiments, and how these might be replaced.

For a long time the suffering and damaging environmental impacts of taking animals from the wild have been acknowledged – macaque monkeys are now in rapid and widespread decline throughout their Asian range. It is vital that the Directive ensures that steps are taken to end the practice of restocking breeding farms from the wild in order to supply European laboratories. As breeding monkeys are replaced this must be done with captive bred animals.

We strongly supported the Commission proposals and believe available data supports the timetables that were proposed. EP amendments 61 & 62 seriously undermine the commitment to ending the wild capture of primates for research by delaying it indefinitely. We are concerned that dealers, who currently trap wild monkeys for breeding farms, will see this text as an indication that the EU is not serious about ending the use of wild caught monkeys to supplement breeding stock. If they do not see a clearly emerging market for F2 animals they will have no incentive to change current practices.

We believe a timetable is the only way of influencing the current operating practices of the dealers based outside Europe, even if this is reviewed on a regular basis with an option to extend or reduce the deadline – we urge that the Council proposals for a "feasibility study" be a review of the progress of the phase out.

Stray and feral animals (Article 11)

We strongly support the Commission Text. The use of stray and ex-pet cats and dogs in experiments has steadily been eradicated throughout Europe. This has happened because of ethical grounds, great public concern and also, importantly on scientific grounds. These animals have unknown backgrounds including age and disease history. To allow the use of stray and feral animals is a retrograde step without any credible scientific justification.

Severity (Article 15)

We welcome formulation of draft severity classifications ahead of the expected schedule, and the attempt to set an upper limit of severity in Article 15.2. However, we believe that the current wording of this article should be amended to ensure that procedures causing severe suffering that is more than transient should be prohibited. We strongly oppose the proposed exemption to the restriction described in Article 15.2 because this strips animals of the most basic level of protection, by allowing the most extreme suffering.

Re-Use (Article 16)

With regard to re-use, we support the Council in calling for assessment of the cumulative welfare impacts of re-use on individual animals, but strongly disagree with the proposal to allow re-use of animals that have undergone severe procedures.

Ethical review body / Animal welfare Body(Articles 25 and 26)

A central pillar of the Commission Proposal is the system of ethical review and authorisation of all projects and ensuring improved implementation of the 3Rs.

There are concerns over the call to reduce the membership of the permanent ethical review body (PERB). With a large number of competencies required to advise on all the tasks of the PERB outlined in Article 26 a broader membership of capable persons is necessary. While we do not entirely oppose the expansion of the role of review body to cover more welfare and husbandry matters, we are concerned that the proportion concerning replacing animal experiments has been diminished.

The role of the PERB should encompass matters relating to ethics as well as to animal welfare. It should help develop the local 'culture of care' and ensure that all animal use carried out at the establishment is fully justified, the 3Rs are fully implemented, that animal husbandry and care is of a high standard, and that local perspectives are taken into account. This requires provision of ethical advice as well as advice on animal welfare. The removal of the word 'ethical' in any circumstance should not be supported.
We strongly support the second part of the EP amendment 87. This ensures that establishments are

committed to having people involved who have expertise in techniques which replace animals. Without the involvement of these experts, there will not be significant progress in replacement. We support re-insertion of Commission Article 26(d) requiring annual assessment of ongoing long-term projects classified as 'severe' and those using non-human primates.

Authorisation (Article 36 and 43)

We support full ethical and scientific review and authorisation applied to **ALL** projects. We consider the draft position of the Council to be partially acceptable and urge you to ensure that applications classified as 'moderate' are **NOT** included for tacit approval.

Alternative Methods

The European Parliament adopted amendments that would require the European Commission and the Member States to contribute to the development, validation (performance assessment) and promotion of alternatives to all animal procedures. We aim to ensure that all the functions supported by the European Parliament are allocated appropriately, so that EU level activities and those undertaken by the Member States are carefully coordinated, and are informed by high-level scientific discussion and strategy setting. New structures and processes at both EU and national levels are needed, and the Parliament has proposed that the European Commission should be tasked with coordinating the formulation and implementation of strategies to replace animal procedures and otherwise avoid animal use. We believe mechanisms such as thematic review (see articles 8 and 53) and effective authorisation (see articles 37 and 45) are essential for ensuring that alternatives methods are actually implemented in place of animals.

National Reference Laboratories and Community Reference Laboratory (Articles 45 and 46)

We welcome the European Parliament's first reading amendments on the development of alternatives to animal procedures at both national and EU level, and appreciate the inclusion of some of the measures supported by Parliament in the Presidency draft text.

However, we would like to see two broad areas of improvement. At national level, the Parliament's call for creation of centres for alternative methods needs to be better reflected through addition of points specifically requiring activity at national level to replace animal procedures carried out for the purpose of applied and basic research.

At EU level, we strongly support the creation of a Community Reference Laboratory, as well as the functions outlined in Annex VIII. However we feel that an additional function is needed so that the Community Reference Laboratory is also required to coordinate formulation of strategies to replace particular areas of animal use.

Inspections (Article 33 and 34)

The Commission put forward the notion that national inspections are to be carried out at least twice a year (1 unannounced). We urge the Parliament and Council to support this proposal and to strongly support the requirement that the Commission is tasked with ensuring that national inspections are properly applied through implementing a system of EU level controls.

Thematic Review (Article 53a)

We strongly **support** the European Parliament in calling for a thematic review of the use of animals in procedures every two years, so that in consultation with relevant stakeholders the impacts of developments in technological, scientific and animal welfare knowledge can be assessed and targets can be set for the implementation of replacement methods. Regular review will enable a scientific, co-ordinated and manageable approach to implementation of available alternatives across Europe.