



## **Response to the European Commission's proposal to revise Directive 86/609 on the protection of animals used for scientific purposes [COM(2008)543/5]**

The Dr Hadwen Trust for Humane Research (DHT), Four Paws and the Humane Society International welcome the fact that the European Commission has proposed a revision of the Directive with measures to enhance animal welfare and further the replacement of animal experiments. However, it is vital that the new legislation represents real and meaningful improvements for animals, ultimately by eliminating their use and replacing them with more advanced and humane research methods.

The revision presents Europe with a valuable opportunity to lead the world in animal protection and non-animal replacement. To realise that ambition, there are aspects of the Commission's proposal that must be strongly defended against attempts to dilute them, and new measures that must be introduced to strengthen Europe's ability to combine progressive animal welfare with cutting-edge science.

Through the revision of Directive 86/609 we wish to see:

- improved protection of animals with regular reviews of animal welfare provisions;
- transparency and accountability relating to animal use;
- creation of structures at EU and member state level to develop and promote the replacement of animal procedures with modern, scientifically robust alternatives.

**Replacing animal experiments is the ultimate goal:** The ultimate goal of the replacement of animal experiments must be at the heart of the new Directive as a guiding principle, facilitated not least through creation of EU facilities to develop and validate non-animal methods to replace all areas of animal use. The proposal already recognises that the EU and Member States have a responsibility to contribute to the development of alternative methods (Article 45), but explicit and practical steps to achieve progress in this area are needed. It is essential that the replacement goal is more than simply aspirational. Specific mechanisms must be introduced to ensure targeted progress. The Directive must create incentives, and replacement evaluation and implementation must be part of the authorisation process.

The European Commission acknowledges that implementation of the 3Rs (reduction, refinement and replacement) is a priority but falls short of proposing a strategy to accelerate the replacement of animals, and fails to provide incentives for the research community and industry to pursue the replacement goal with vigour.

**Extending the scope:** The new proposals would see the scope of the Directive extended to include sentient foetal animals and invertebrate species (Article 2) which have previously been excluded from protection under EU legislation. The list of invertebrates and foetal animals to be protected under the Commission's proposal has been compiled following expert input from the EFSA Animal Health and Animal Welfare Panel. This will not lead to 'needless counting' as is sometimes claimed. Larval forms that are currently protected have never been included in statistical reports, so there is no reason to expect that protecting such animals in future will create an unnecessary burden for industry. The proposal will also regulate fundamental research for the first time at EU level, along with the use of animals for educational purposes and those animals who are bred (and killed) for their organs and tissues. This is a major gain for animal welfare particularly as basic research accounts for a large portion of EU animal use. This measure will also harmonise different standards applied currently in the Member States.

**Non-human primates:** The Commission has proposed an end to the use of great apes and a phase-out of the use of 'F1' primates (ie: the first generation born in captivity to wild-caught parents) (Article 10). These proposals must be maintained but also strengthened to remove exemptions and ban the use of wild-caught primates. The ban on F1 primates will reduce pressure on wild populations and prevent the cruelty associated with the trade in wild primates. The Commission proposes a 'phase out', which allows sufficient time to stabilise captive breeding stock and prevent production of 'surplus' males. The so-called 'safeguard clause' relating to exemptions in the great ape ban, should be deleted because the use of great apes in procedures should be absolutely prohibited, without exception.

In 2007 a majority of Members of the European Parliament signed Written Declaration 40 calling for an end to the use of great apes and wild-caught primates and a timetable for the replacement of primates in experiments.

**European and national facilities for alternatives/replacements:** EU and Member State level structures should be established to promote the development of new 3Rs methods with a view to replacing all animal procedures. Functions performed should include relevant research and commissioning of research, overseeing scientific validation of new methods where applicable, and formulating strategies to replace animal procedures in defined scientific or research fields. Current proposals relating to National Research Laboratories do not go far enough as they ignore the need for increased effort to replace animals used in basic and applied biomedical and veterinary research.

**Procedures causing severe (substantial) suffering:** The absence of criteria for classification of procedures is of concern because many measures contained in the proposal depend on severity classifications. Either more detail should be provided now, or temporary definitions should be introduced to inform decision making. In any case, an upper limit of severity (permissible pain and suffering) should define a level of suffering beyond which procedures will not be authorised. The requirement for Member States to ensure that procedures classified as 'severe' are not performed if the pain and distress is likely to be prolonged, should be protected against attempts to introduce more 'flexible' rules, and preferably strengthened (Article 15).

**Harmonisation of care and welfare:** The new Directive should introduce standards of housing and care that will be consistently applied throughout Europe. The derogations on killing methods, purpose-breeding, use of endangered species etc., must be deleted.

**Duplication and data sharing:** A clear framework (such as that achieved under REACH) is needed to guarantee data sharing at the point of authorisation. A separate mechanism will be needed for academic/fundamental research. The principle should be established that authorisation is refused if data is already available (against payment where relevant).

**Transparency/accountability:** Publication of non-technical summaries (Article 40) will increase transparency and is a major step forward. It is essential that the new Directive increases the level of publicly available information to ensure greater accountability. The Commission's measures take account of the need to safeguard confidential information, and reflect current practice in some Member States, and should be supported or preferably strengthened. A public comment period prior to authorisation would also be beneficial in order to allow for improved scientific scrutiny of research proposals. Evaluations and authorisation applications, infringements, retrospective assessments and comprehensive statistics must also be made public.

**Ethical and scientific review committees:** The Directive should create a genuinely independent framework for ethical and scientific evaluation, project authorisation and the functioning of the cost / benefit assessment. For example, this could be modelled on current human research ethics committees which would include lay members, members who are independent of the institution and the research field in question, and those with expertise in non-animal replacements.

**Prohibitions of areas of animal use:** The use of animals for experiments in higher education, forensic studies, household product testing and psychology experiments should no longer be allowed. Other areas would be added under the periodic reviews [see final point].

**Methods used in experiments:** Death as an endpoint should not be permitted under any circumstances. Toxicological and other studies requiring

death as an endpoint should be refined (as has already happened to some extent) to prevent animals suffering beyond the time at which death is inevitable. So-called 'humane endpoints' should be compulsorily applied.

**Humane killing:** The proposal rightly suggests employing the most welfare-friendly methods of killing as described in Annex V – claims that these may not be the 'most up to date' can be addressed by improved 3Rs requirements, and regular welfare reviews, not by undermining the requirement to apply Annex V.

**Re-use of animals:** The requirement that animals should not be used in a second experiment if the first experiment is classified as 'moderate' or 'severe' should be supported (Article 16).

**National and EU inspections:** An EU inspectorate should be established to perform unannounced inspections of establishments and to ensure that severity classifications are applied uniformly and correctly in the Member States. Reports of national and EU inspections should be published. At least one unannounced inspection per year is essential and should be supported and supplemented by EU inspections. (Articles 33 and 34).

**Biannual Review:** The Commission has proposed a review of the Directive ten years after entry into force, but this should be amended to implement regular thematic reviews of animal protection measures, including: the list of species falling within the scope of the Directive; the use of specific species for specific purposes; use of primates; the use of retrospective and systematic reviews; statistics; data sharing; implementation of replacement techniques and developments in ethical and scientific evaluation, and advances in knowledge on animal welfare and sentience.

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