

Protection of animals used for scientific purposes

2008/0211(COD) - 05/05/2009 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 540 votes to 66, with 34 abstentions, a legislative resolution amending, under the first reading of the codecision procedure, the proposal for a directive of the European Parliament and of the Council on the protection of animals used for scientific purposes.

The main amendments are as follows:

Purpose: according to MEPs, this Directive shall apply to the accommodation and husbandry of animals used for scientific purposes, and shall cover all uses of animals in procedures that are likely to cause them pain, suffering, distress or lasting harm.

Scope: the Directive shall apply to live non-human vertebrate animals, including embryonic or foetal forms of species of mammals as from the last third of their normal development. However, independently feeding larval forms shall be excluded from the scope.

Alternative methods: where a method of testing or experimentation exists which, from a scientific point of view, is a satisfactory method or testing strategy for obtaining the result sought, Member States shall ensure that the alternative method is used, provided it is not prohibited in the Member State concerned.

Pursuant to this Directive, testing methods which involve the use of human embryonic and foetal cells shall not be regarded as alternatives, in other words the Member States may take their own ethical decisions concerning the use of these methods of testing.

MEPs request that Member States should ensure that funding is provided for training and research on, and development and implementation of, scientifically satisfactory methods or testing strategies that do not entail the use of animals.

Humane method of killing: a new measure has been introduced stipulating that, when more humane methods of killing are developed, this will allow them to be used immediately instead of waiting several years for Annex V to be updated.

National measures: this Directive shall not prevent Member States from applying or adopting stricter national measures seeking to improve the well-being and protection of animals used for scientific purposes.

Non-human primates (NHP): the proposal bans the use of NHPs except in certain circumstances. There is no scientific justification for the special status granted to NHPs, so that basic research should be allowed, without being restricted to experiments designed to achieve specific medical research objectives. A new paragraph is inserted to introduce a review of the use of non-human primates in procedures which is to be conducted by the Commission every two years.

Use of cadavers, tissue and organs of animals for training purposes: MEPs consider that, for higher education and training purposes, the cadavers, tissue and organs of animals may be used only if they come from animals slaughtered in accordance with the provisions of Council Regulation (EC) No .../2009 [on the protection of animals at the time of killing].

Animals bred for use in procedures: MEPs consider that the recommendation made in the proposal only to source non-human primates from self sustaining colonies of F2 primates (the second generation bred in

captivity) is a noble aim and one which in the long term will ensure that fewer animals are taken from the wild. However, the proposal is not practical within the timescale that the Commission has envisioned. Moreover, five years after the entry into force of this Directive, the Commission shall carry out a feasibility study ahead of any mandated move towards establishing a policy of only sourcing from F2 self sustaining colonies.

Anaesthesia: Member States shall ensure that, where appropriate, all procedures are carried out under general or local anaesthesia or using other methods that may alleviate pain or minimise suffering.

Severity classifications: in its proposal, the Commission identifies a number of severity clauses - "up to mild", "moderate" and "severe" or "non-recovery" - governing how experiments can be undertaken. However it does not define what the classifications are. MEPs wish to clarify this situation by including a new Annex VIIa called "General Definitions of Degrees of Severity".

MEPs note that the ban on "prolonged" "severe" procedures appears to preclude any "severe" category procedures, and could be highly restrictive. This is why they propose that Member States should ensure that the procedures classified as "severe" are scientifically justified, and ethically monitored if the pain, suffering or distress is likely to be more than transient. Such procedures must be exceptional and shall be subject to particular harm/benefit analysis and scrutiny by the competent authority.

Reuse: the Parliament supports the principle of re-use but believes that current restriction will result in dramatic increase in numbers of animals used for experimental purposes. MEPs propose that an animal already used in the procedure may be re-used where the previous procedure performed on the animal is classified as 'up to moderate' as opposed to 'up to mild'.

In any event, an animal that has undergone a "severe" procedure should not be re-used. In contrast, those previously subjected to a "moderate" procedure should be permitted to undergo a further "moderate" procedure. The repeated re-use of the animal is supported by veterinary examination.

Authorised persons: Member States shall ensure the mutual recognition of education and training qualifications and authorisation to conduct designated procedures. Where an establishment no longer complies with requirements set out in the Directive, the competent authority shall have the power to suspend or withdraw its authorisation, or take appropriate remedial action or require such action to be taken. There shall be appropriate procedures for the license-holders to appeal against any such decision.

Each breeding, supplying and user establishment shall ensure that there is at least one trained person available at all times to look after the animals' welfare.

Tasks of the permanent ethical review body: MEPs consider it judicious to provide a yearly review of all projects classified as "severe" or those on non-human primates, and every 3 years for all other projects. Member States shall pay particular attention to the collection, collation and publication of records relating to projects classified as "severe" or those on non-human primates.

Breeding strategy of non-human primates: the obligations shall only concern EU breeding and supplying establishments of non-human primates. Where the use of non-human primates is authorised, the Commission and the Member States shall take all necessary measures to ensure appropriate transport conditions.

Monitoring inspections: the Commission shall undertake controls of the infrastructure and operation of national inspections as well as of the correct application of severity classifications in Member States. To that end, the Commission shall set up a system to monitor each Member State's inspections and enforcement of this Directive on average once every three years, ensuring harmonised practices for the use and the care of animals used or intended to be used in scientific procedures.

Project authorisation: MEPs consider that projects classified as "moderate" or "severe" or any projects involving non-human primates should not be carried out without a prior authorisation by the competent authority. All other projects shall be notified in advance to the competent authority following ethical review by the institution's permanent ethical review body.

Retrospective evaluation: it should be up to an ethical committee to decide whether a retrospective ethical evaluation is required, depending on objective criteria, whatever species is involved.

Granting project authorisations: project authorisations shall be granted for a period not exceeding five years (instead of three years).

Sharing of data: Member States shall ensure the sharing of data generated by procedures, including those which have taken place in the European Union prior to the coming into force of this Directive. Anyone seeking to rely on data owned by another shall, where appropriate, contribute towards the cost of producing such data.

European Centre for the Validation of Alternative Methods: MEPs suggest that the remit of the European Centre for the Validation of Alternative Methods shall be extended so that it includes the co-ordination and promotion of the development and use of alternatives to animal procedures including applied and basic biomedical research and veterinary research and regulatory testing by, for instance, coordinating research undertaken to facilitate the development of alternatives to animal procedures by the National Centres or providing databases to facilitate the exchange of relevant information.

Each Member State shall nominate **a centre** responsible for supporting the development, validation and promotion of alternatives to animal tests used for regulatory purposes, and facilities to develop and promote the use of alternatives to animal procedures undertaken for other purposes, such as basic and applied biomedical and veterinary research.

Thematic review: the Commission shall conduct a thematic review of the use of animals in procedures every two years commencing two years after the entry into force of this Directive. The review shall examine the impact of developments in technological, scientific and animal welfare knowledge, and set targets for the implementation of validated replacement methods.

In the periodic reviews, the Commission shall give priority to the reduction and elimination of procedures causing the greatest permissible pain, suffering, distress or lasting harm and those which are not designed to alleviate life-threatening or debilitating clinical conditions in human beings, with a view to the elimination of all procedures.

The Commission shall take into account evolving public opinion about the use of animals in procedures in the periodic reviews.