Protection of animals used for scientific purposes

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The Committee on Agriculture and Rural Development adopted the report drawn up by Neil PARISH (EPP-ED, UK) 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 were as follows:

Purpose: according to MEPs, this Directive shall apply to the accommodation and husbandry of animals used or intended to be used in procedures or where they are bred specifically so that their organs or tissues may be 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 should apply to live non-human vertebrate animals, including independently feeding larval forms and embryonic or foetal forms of species of mammals as from the last third of their normal development.

Alternative methods: pursuant to this Directive, testing methods which involve the use of human embryonic and foetal cells shall not be regarded as alternatives.

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 thatwhen 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.

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 should therefore be conducted ahead of any mandated move towards establishing a policy of only sourcing from F2 self sustaining colonies.

Severity classifications: the Commission identifies a number of severity clauses, "up to mild"

"moderate" and "severe" 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 distressis likely to be prolonged. Such procedures

must be exceptional and shall be subject to particular harm/benefit analysis and scrutiny by the competent authority.

Reuse: MEPs support the principle of re-use however they believe that current restriction will result in dramatic increase in numbers of animals used for experimental purposes. They 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’. 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.

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.

Breeding strategy of non-human primates: EU establishments acquiring non-human primates shall supply proof to the competent authority, on request, that the establishment from which animals have been acquired have a breeding strategy in place. The Commission and the Member States should also take the necessary measures to support appropriate transport conditions for nonhuman primates on the territory of the European Union.

Project authorisation: the Commission may undertake controls of the infrastructure and operation of national inspections in Member States and to ensure that severity classifications are applied correctly and uniformly within the territory of the EU. Member States shall ensure that projects classified as “severe” or any projects involving non-human primates are not 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.

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.