Protection of animals used for scientific purposes

2008/0211(COD) - 22/09/2010 - Final act

PURPOSE: to strengthen the protection of animals used for scientific purposes and contribute to the reduction of animal use and ensure that the animals used in experiments receive appropriate care and humane treatment.

LEGISLATIVE ACT: Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

CONTENT: the Council adopted a draft directive for the protection of animals used for scientific purposes, aimed at strengthening the protection of animals whilst allowing research to continue playing a key role in the fight against diseases.

To recall, Council Directive 86/609/EEC was adopted in order to eliminate disparities between laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Since the adoption of that Directive, further disparities between Member States have emerged.

This new Directive provides for more detailed rules in order to reduce such disparities by approximating the rules applicable in that area and to ensure a proper functioning of the internal market.

Subject matter and scope: this Directive establishes measures for the protection of animals used for scientific or educational purposes. To that end, it lays down rules on the following:

(a) the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures;

(b) the origin, breeding, marking, care and accommodation and killing of animals;

(c) the operations of breeders, suppliers and users;

(d) the evaluation and authorisation of projects involving the use of animals in procedures.

This Directive shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes. This Directive shall apply until the animals have been killed, rehomed or returned to a suitable habitat or husbandry system.

The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods shall not exclude the use of an animal in procedures from the scope of this Directive.

This Directive shall apply to the following animals: (a) live non-human vertebrate animals, including: (i) independently feeding larval forms; and (ii) foetal forms of mammals as from the last third of their normal development (as there is scientific evidence showing that such forms in the last third of the period of their development are at an increased risk of experiencing pain, suffering and distress, which may also affect negatively their subsequent development); (b) live cephalopods (as there is scientific evidence of their ability to experience pain, suffering, distress and lasting harm).

Methods of killing: the methods selected should avoid, as far as possible, death as an end-point due to the severe suffering experienced during the period before death. Where possible, it should be substituted by

more humane end-points using clinical signs that determine the impending death, thereby allowing the animal to be killed without any further suffering.

Principle of the three Rs (replacement, reduction and refinement): Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project. They shall also ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.

Project evaluation: comprehensive project evaluation, taking into account **ethical considerations** in the use of animals, forms the core of project authorisation and should ensure the implementation of principles of replacement, reduction and refinement in those projects.

Non-human primates: the keeping and use of non-human primates for scientific purposes will be subject to **tight restrictions**. Experiments with great apes such as chimpanzees, gorillas and orangutans will be prohibited; a Member State may however allow exceptionally the use of great apes if it has justifiable reasons for believing that it is essential for the survival of the species itself or because of an unexpected outbreak of a life-threatening or debilitating disease in human beings. As a general rule, animals taken from the wild will not be allowed to be used in experiments, with some exceptions. The directive will also progressively require that non-human primates may only be used if they are the offspring of animals which have been bred in captivity or if they are sourced from self-sustaining colonies.

Inspections by the Member States: Member States shall ensure that the competent authorities carry out regular inspections of all breeders, suppliers and users, including their establishments, to verify compliance with the requirements of this Directive.

Alternative approaches: the Commission and the Member States shall contribute to the development and validation of alternative approaches which could **provide the same or higher levels of information** as those obtained in procedures using animals, but which do not involve the use of animals or use fewer animals or which entail less painful procedures, and they shall take such other steps as they consider appropriate to encourage research in this field. The Commission shall take appropriate action with a view to obtaining **international acceptance** of alternative approaches validated in the Union.

Union Reference Laboratory: it shall be responsible, inter alia, for: (i) coordinating and promoting the development and use of alternatives to procedures including in the areas of basic and applied research and regulatory testing; (ii) promoting dialogue between legislators, regulators, and all relevant stakeholders. The Union Reference Laboratory may collect charges for the services it provides that do not directly contribute to the further advancement of replacement, reduction and refinement (three Rs).

Safeguard clauses: two safeguard clauses are included in the Directive to take into account of possible future situations where, for scientifically justifiable grounds, Member States deem it is necessary to authorise the use of nonhuman primates in areas not linked with debilitating and life-threatening conditions in humans or to surpass the upper limit for severity of procedures. This authorisation could only be provisional and would be subject to a Union control procedure.

Classification of the severity of procedures: Member States shall ensure that all procedures are classified as ‘non-recovery’, ‘mild’, ‘moderate’, or ‘severe’ on a case- by-case basis using the assignment criteria set out in Annex VIII. The severity of a procedure shall be determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure. Subject to the use of the safeguard clause, Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

Reporting: Member States shall by 10 November 2018, and every 5 years thereafter, send the information on the implementation of this Directive to the Commission. They shall collect and make **publicly available**, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures. The Commission shall by 10 May 2012 establish a common format for submitting the information.

Commission report: by 10 November 2019 and every 5 years thereafter, the Commission shall report on the implementation of this Directive. By 10 November 2019 and every 3 years thereafter, it shall present a summary report on that information.

Review: the Commission shall review this Directive by 10 November 2017, taking into account advancements in the development of alternative methods not entailing the use of animals, in particular of non-human primates, and shall propose amendments, where appropriate. The Commission shall, where appropriate, and in consultation with the Member States and stakeholders, conduct periodic thematic reviews of the replacement, reduction and refinement of the use of animals in procedures, paying specific attention to non-human primates, technological developments, and new scientific and animal-welfare knowledge.

Transitional provisions: Member States shall not apply laws, regulations and administrative provisions adopted in accordance with Articles 36 to 45 (Requirements for projects) to projects which have been approved before 1 January 2013 and the duration of which does not extend beyond 1 January 2018. Projects which have been approved before 1 January 2013 and the duration of which extends beyond 1 January 2018 shall obtain project authorisation by 1 January 2018.

ENTRY INTO FORCE: 10/11/2010.

TRANSPOSITION: 10/11/2012.