Opinion of the European Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes'

COM(2008) 543 final — 2008/0211 COD

(2009/C 277/10)

Rapporteur: **Richard ADAMS**

On 12 January 2009 the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the:

Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes

(COM(2008) 543 final – 2008/0211 COD).

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 17 April 2009. The rapporteur was Richard ADAMS.

At its 453rd plenary session, held on 13 and 14 May 2009 (meeting of 13 May), the European Economic and Social Committee adopted the following opinion by 173 votes to 14, with five abstentions.

1. **Conclusions and recommendations**

1.1. The EESC welcomes this long overdue Directive which will standardise and regularise the selection, use and treatment of animals for scientific purposes but has reservations about the degree to which the Directive will, in practice, replace, reduce and refine the use of animals in research. The Committee therefore highlights the following recommendations in addition to those others contained in the main text.

1.2. The Commission should monitor more closely the numbers of animals used in scientific purposes. This may require new, sector-specific approaches to data collection and monitoring, some of which will lie outside the scope of the present Directive.

1.3. The Directive should require harmonisation on research reviews across Member States and develop and determine that competent authorities in each Member State hold and effectively apply a database of existing animal experimentation when granting project and procedure approvals.

1.4. The role of ECVAM should be developed from that of a supporting research function to a central coordinating role. An EU Centre of Excellence should be established to promote and prioritise development of 3Rs methods across all current animal uses including basic medical research. The '3 Rs' (replace, reduce and refine) is a general approach first defined in 1958.

1.5. 'Severe' experiments should receive special attention in the efforts to identify humane alternatives. Procedures likely to cause intense pain, suffering or fear should only be performed if no alternative and effective research methods exist making it possible to research certain diseases that seriously affect human health. 'Intense' is defined as a level of suffering or fear above that of 'severe' in the classes of severity set out in the directive.

1.6. The Directive should require that, as soon as practically possible, non-human primates are only used in animal testing if they are the offspring of non-human primates which have been bred in captivity.

1.7. The Directive shall clearly state that it does not restrict the right of the Member States to apply or adopt stricter measures for care and housing of laboratory animals.

1.8. The EESC urges the scientific community to recognise that its research programmes can be made fully compatible with the aims of the 3Rs in practice as well as in principle and commit to this as a dynamic approach.

2. **Introduction**

2.1. The welfare and protection of animals, whether domestic or farmed, is dealt with in a large number of EU directives, decisions and regulations. Protocol 33 on Animal Welfare [1], appended to the Treaty of Amsterdam, established a view: 'Desiring to ensure improved protection and respect for the welfare of animals as sentient beings'. In this way the EU recognised that animals have an inherent status above that of property or objects and

[1] OJ C 340, 10 November 1997.

our dealings with them should be governed both by ethical considerations and through regulation. The higher animals have this status because, like us, they experience pain and pleasure, are aware of their own existence and prefer to experience pleasurable and continuing lives. Some species of these animals, having comparable neurological systems to humans, are used widely in laboratory experimentation for various purposes. The results of such tests can provide varying degrees of benefits to humans, animals themselves and the environment but also, in some instances, cause distress, suffering and death for the animals concerned.

2.2. This directive, revising legislation dating from 1986 ([2]), can be seen as one of a series reflecting changing views on the use of animals. There have been recent revisions on directives dealing with animal slaughter and transport and the introduction of a Community Action Plan on the Protection and Welfare of Animals, all of which have been dealt with recently in this Committee ([3]). A near-total ban on the sale of animal-tested cosmetics throughout the EU and a ban on all cosmetics-related animal testing has come into effect this year ([4]).

2.3. The proposed directive on the protection of animals used for scientific purposes will become part of this body of legislation. It fully accepts the general objective, endorsed in principle by the wider scientific community, to replace, reduce and refine the use of animals in research (known as the 3Rs). The Committee Opinion therefore considers whether the proposal will further this objective and the degree to which a balance has been struck between animal welfare, human benefit and scientific advancement.

3. **Summary of the proposed directive**

3.1. *Scope and permitted purposes*

3.1.1. The directive will apply where animals (mostly vertebrates) are bred for or used for scientific purposes. It excludes agricultural, animal husbandry and veterinary practices. Purposes allowed are basic research for the advancement of knowledge in the biological or behavioural sciences; research aimed at the avoidance, prevention diagnosis or treatment of illness or the assessment, detection, regulation or modification of physiological conditions; the development, manufacture or testing of drugs, foodstuff or other products with the aims of the above; the protection of the environment in the interests of human welfare; research aimed at the preservation of the species; higher education or training and forensic inquiries.

3.2. *Types of animal*

3.2.1. Primates must be purpose-bred for research and may only be used in procedures that are 'undertaken with a view to the avoidance, diagnosis, prevention or treatment of life-threatening or debilitating clinical conditions in human beings.' The use of great apes is banned, although there is a 'safeguard' procedure to allow Member States, with the European Commission's agreement, to authorise their use for research that is considered essential for the preservation of the species or in relation to an unexpected outbreak of a life-threatening disease. Endangered species can only be used for translational/applied research and testing, but not for basic research and stray and feral domestic animals cannot be used, nor can animals taken from the wild unless a specific scientific justification is provided. In addition the usual 'laboratory' species (mice, rats, guinea pigs, hamsters, gerbils, rabbits, frogs, dogs, cats) must be purpose-bred.

3.3. *The severity of procedures*

3.3.1. Four classes of severity are defined. Mild, moderate, severe and non-recovery (i.e. killed while still under general anaesthesia). The Commission will establish criteria for the classification of procedures to be adopted by a regulatory committee. These criteria are relevant to the care and welfare measures that need to be taken and the 're-use' of an animal in testing and some restrictions apply.

3.4. *Authorisation*

3.4.1. Individuals require authorisations to supervise or carry out procedures, humane killing and the supervision of animal care staff. Institutions require authorisation for breeding, supplying or using animals in procedures. Named staff must be responsible for projects and to deal with non-compliance. Each institution must have a permanent ethical review body. Project authorisations of up to 4 years can be given by competent authority as assigned by Member State based on a transparent ethical evaluation which includes the scientific or legal justification of the project; the application of the 3 Rs in project design; the severity of the procedures involved and a harm-benefit analysis (is the animal use and suffering justified by the expected advancement of science that ultimately benefits human beings, animals or the environment.)

([2]) OJ L 358, 18.12.1986.

([3]) OJ C 28, 3.2.2006, p. 25; OJ C 151, 17.6.2008, p. 13; OJ C 161, 13.7.2007, p. 54; OJ C 324, 30.12.2006, p. 18 and the EESC additional opinion CESE 879/2009 (NAT/431) adopted on 13 May 2009.

([4]) OJ L 262, 27.9.1976, OJ L 66, 11.3.2003.

3.4.2. Non-technical project summaries are required to be published in applications for all authorised projects. Member States can decide to use a reduced project application system (which does include such summaries) for any non-primate projects which only use procedures classified as 'mild'.

3.5. *Care and Inspection*

3.5.1. The guidelines on the accommodation and care of laboratory animals set out in the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (Council of Europe, European Treaty Series – Nr. 123), will be in most parts mandatory requirements. All Member States will be required to have an appropriate infrastructure with sufficient numbers of trained inspectors; each establishment will have at least 2 inspections a year by the national authority, at least one of which will be unannounced, with larger establishments having more frequent inspections. There is provision for the Commission to undertake controls of the infrastructure and operation of national inspections. Detailed records on the provenance, use, re-homing or disposal of the animal will be required, with extra provisions for dogs, cats and non-human primates.

3.6. *Alternatives to the use of animals*

3.6.1. Data on testing methods legally required in one Member State will be accepted by all to avoid duplication. Each Member State will contribute to the development of alternative, non-animal, approaches and must designate a national reference laboratory for the validation of alternative methods. The Commission will set the work priorities for these national reference laboratories in consultation with the Member States and coordinate them. If a method of testing not involving the use of animals exists and may be used in place of a procedure, Member States are specifically required to ensure that the alternative method is used. Member States must also ensure that the number of animals used in projects is reduced to the minimum without compromising the objectives of the project.

4. **General comments**

4.1. Although data on animal experimentation continues to accumulate the number of animals used in laboratory testing has recently begun to rise and is now estimated at a minimum of 12 million within Europe. It should also be noted that 'surplus' animals – those bred but not used and subsequently destroyed, and animals bred, killed and whose tissue is subsequently used for testing - are not included in the figures. Details of the numbers of animals used, supplied under a voluntary process, have been published by the Commission: Fifth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes, 5 November 2007. Rodents and rabbits, for example, represent 77,5 %, birds 5,4 % and non-human primates 0,1 % of all animals used. Some of this is due to the trend for researchers to use genetically modified animals in experiments and for new legal testing requirements - for example the REACH legislation ([5]). Animal welfare organisations are concerned about the overall impact of REACH on animal testing, which will result in an increase in numbers used. Others, WWF for example (http://www.wwf.org.uk/filelibrary/pdf/aniamltesting03.pdf) (only available in English), point out that in the long term the environmental benefits to fauna carry significant advantages.

4.2. Biomedical research bodies have raised a number of issues of clarification concerning the proposed directive. In general the main concern seems to be an increase in administration and bureaucracy, a possible weakening of the right to protect confidential research and the opportunity provided for greater access to information and procedures by campaigning groups. Users of animals in experiments often express frustration that the public and campaign groups fail to recognise that animal testing is largely a last resort because of its expense and ethical ambivalence. The Committee believes that the research industry can, to some extent, make a case for all the above points but that these issues have already been taken fully into account in the framing of the Directive.

4.3. It should be noted that replacement of animals used in testing will ultimately be of commercial benefit to companies. Given that animal testing is expensive and time-consuming alternatives will provide future commercial opportunities.

4.4. The EESC finds that the proposed Directive does not fully take the opportunity to reflect progress on non-animal testing alternatives. Given that there is no legal basis for the Commission to require harmonisation on research reviews across Member States the EESC has doubts about the possibility of competent authorities in each Member State holding and effectively applying a database of existing animal experimentation when granting project and procedure approvals. The Commission should do all in its powers to ensure that the national bodies responsible for authorisation, and likewise the national centres for the validation of alternative methods, are fully aware of the activities of their respective counterparts and are able to develop joint approaches in order to discourage distortion of the internal market.

([5]) OJ L 396, 30.12.2006.

4.5. There is considerable public interest in, and sensitivity to, the issue of animal testing in some member states. The EESC believes it is accurately reflecting mainstream attitudes by wishing to see animal suffering minimised, whilst at the same time accepting that animal testing is sometimes necessary for the greater good.

5. **Specific comments**

5.1. The Committee recognises that the proposed Directive could be influential in reducing the numbers of animals in testing, and in improving the welfare of animals involved in tests. Whilst the long-term objective should be the significant reduction of numbers of animals involved in tests, setting targets could be counterproductive, driving regulated use overseas. However, the Commission should try to find ways of monitoring the numbers of animals being tested, and review its approach if need be. This may require new, sector-specific approaches to data collection and monitoring, some of which will lie outside the scope of the present Directive.

5.2. Current EU activity on developing alternatives concentrates on regulatory toxicology which covers less than 10 % of animal testing at present. An EU wide approach to the development of alternatives across all research sectors using animals (articles 44-47) is highly desirable, recognising that the oversight of coordination will be a major task. Significantly increasing the uptake of alternatives will require considerable effort from multidisciplinary scientific groups and from legislators, and will require increased support for the European Centre for the Validation of Alternative Methods (ECVAM), created by the EU in 1991, and other European and national centres. The role of ECVAM should be developed from that of a supporting research function to a central coordinating role in pushing alternatives into the mainstream. In addition, the Committee recommends that an EU Centre of Excellence is established to promote and prioritise development of 3Rs methods across all current animal uses including basic medical research. This remit would be considerably greater than that held by ECVAM.

5.3. REACH represents a significant challenge to both industry and regulatory authorities, if the timetable is to be adhered to. It also represents an opportunity to develop progressive testing strategies which will lead not only to the development of alternatives and the reduction in animal suffering, but also to improved data, and reduced costs for industry resulting from more efficient methods. Tiered testing approaches, building on the work of ECVAM, have been outlined by a number of authors and should be considered. Such approaches are already in use, especially in North America.

5.4. The Committee accepts majority scientific opinion that animal testing has made a valuable contribution to scientific research and that it will continue to do so in the future. However there is also a need for the wider scientific community involved in animal testing to be able to accept the limitations of current approaches and the need to consider all methods when reviewing the rational behind specific experimentation. Those research programmes where animal testing is considered to be of doubtful value should be a priority for the development of alternatives. The Committee welcomes the forthcoming retrospective assessment of the benefit of animal procedures and believes that it has the potential, if applied to all procedures to avoid redundant animal use and meet the concern of some stakeholders as to the value of some animal procedures.

5.5. The Committee welcomes the forthcoming classification as to degree of suffering in experiments. The 'severe' experiments should receive special attention in the efforts to identify humane alternatives. Procedures likely to cause intense pain, suffering or fear should only be performed if no alternative and effective research methods exist making it possible to research certain diseases that seriously affect human health.

5.6. In the Directive it is required that each Member State will support the development and use of procedures and approaches that promote the 3 Rs, aiming to reduce animal use and suffering. This can be achieved partly through improved experimental design, through the avoidance of duplication, and by not undertaking unnecessarily broad exploratory studies. Methods capable of reducing, refining and ultimately replacing animal testing as part of integrated testing strategies, such as *in vitro* tests, quantitative structure-activity relationships (QSAR), expert systems, computer modelling, and statistical methods, must be supported. Member states should also be required to nominate a reporting body on such initiatives to ensure that alternatives are being developed and applied.

5.7. The Committee welcomes the position taken in the Directive concerning the near total ban on the use of Great Apes.

5.8. The Committee recognises that non-human primates will continue to be used in specific research contexts but believes the elimination of all primate use in tests should be a long term aim, once sufficient alternative exists. In the meantime the Directive should require that non-human primates may only be used in animal testing if they are the offspring of non-human primates which have been bred in captivity; competent authorities may grant exemptions on the basis of a scientific justification (article 10).

Considering the uncertainty the EESC proposes that the Commission shall carry out an animal welfare assessment and a feasibility evaluation of the implementation of these requirements after 5 years of entry into force of the Directive.

5.9. At present the Directive requires that Member States shall apply the minimum standards for care and accommodation set out in Annex IV and the Commission can adapt the standards to technical and scientific progress in accordance with the proposed committee procedure and also make them binding (article 32). Article 95 of the Treaty as legal basis for the proposed Directive gives only very strict procedures for Member States to defend higher standards. In order to eliminate uncertainty the EESC wishes to see the inclusion of a clear statement in article 32 confirming that the Directive shall not restrict the right of the Member States to apply or adopt stricter measures for care and housing of laboratory animals.

5.10. At present the Directive requires that the decision to authorise a project is taken and communicated to the establishment at the latest within 30 days from the submission of the application. If the Member State fails to take a decision within that period, the authorisation shall be deemed to have been granted, where the project concerned involves only procedures classified as 'up to mild' and non-human primates are not used (Article 43). The EESC finds that this is not justified and should not apply if the ethical evaluation is an integrated part of the project authorisation process.

Brussels, 13 May 2009.

The President
of the European Economic and Social Committee
Mario SEPI