COUNCIL OF THE EUROPEAN UNION

Brussels, 17 June 2009

11001/09

Interinstitutional File: 2008/0211 (COD)

LIMITE

AGRILEG 106
CODEC 848
VETER 17
ENV 437
RECH 204

NOTE

from :	Presidency
to :	Council
No. Cion prop. :	15546/08 + ADD1 + ADD2 – COM(2008) 543 final
Subject :	Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes - Progress report

I. INTRODUCTION

On 5 November 2008, the Commission adopted the above Proposal concerning the protection of animals used for scientific purposes based on Article 95 of the Treaty (establishment and functioning of the internal market). It is intended to replace the existing legislation in this domain (Council Directive 86/609/EEC).

The objective of the proposed Directive is to ensure a level playing field throughout the EU for industry and the research community and to strengthen the protection of animals still used in scientific procedures in line with the European Union's Protocol on Animal Welfare. It aims at re-establishing the objectives of the internal market by rectifying a variety of weaknesses in the current Directive which have lead into considerable differences in its national implementation by the Member States. While recognising that the use of animals in scientific procedures today still remains essential for an unforeseeable future for ensuring a level of safety for human beings, animals and the environment, the proposal introduces a number of measures to promote alternative approaches, including their development, validation, acceptance and implementation, also at international level. Generally the proposal requires that the commonly accepted principles of the "Three Rs" - Replacement, Reduction and Refinement of animals in experiments - are fully taken into account when developing Community measures in this domain.

II. STATE OF PLAY

The European Parliament appointed Neil Parish (European People's Party and European Democrats) as rapporteur. The lead Committee responsible for the file is the Committee on Agriculture and Rural Development[1]. Due to the approaching end of its legislative term, the European Parliament decided to finalise its first reading before the elections and its opinion was therefore already adopted on 5 May 2009[2]. Faced with this strict time schedule of the European Parliament and taking into account the multi-disciplinary nature of the proposal, no attempt at negotiations for a first reading agreement was made. Instead, the Presidency considered it necessary to allow enough time for its technical examination by the expert Working Party and for the internal coordination of the positions by the Member States.

The Economic and Social Committee[3] has been consulted.

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1 Two other Committees involved are the Committee on Industry, Research and Energy (in enhanced cooperation) and the Committee on Environment, Public Health and Food Safety.

2 Doc. 9312/09.

3 The EESC delivered its opinion (NAT/422 - CESE 874/2009) on 13 May 2009.

The Working Party of Veterinary Experts (Animal Welfare) examined the proposal on 25 March, 17 April, 29 May, 11 and 12 June 2009[1].

In their preliminary general remarks, delegations broadly welcomed the Commission's initiative, stressing in particular the aim of harmonisation and the re-enforcement of the "Three Rs" principles. It was considered important that the proposal could also contribute to facilitating the exchange of best practices within the Scientific Community. However, concerns were expressed about the possibility that too much additional administrative burden could lead to the dislocation of research activities to countries outside the EU.

The Working Party undertook a detailed examination of both the Proposal and the outcome of the European Parliament's first reading. Following delegations remarks made during meetings or in written comments, the Commission representative explained the Commission's position and provided answers to questions raised or agreed to examine further.

A number of **key issues** requiring further discussion were identified, including in particular those briefly set out in paragraphs A - G below[2].

A. Scope

Several delegations requested clarifications to the scope of the proposed Directive. In particular, some delegations questioned the scientific justification of the inclusion into the scope of specific invertebrate species and/or developmental forms of vertebrate animals. Other requests for clarification were made, among other, concerning purposes that are not strictly scientific, such as the use of animals in education, breeding of animals for organs and tissues or agricultural or clinical veterinary trials.

[1] Following its presentation to the Working Party of Research and Joint Research /Atomic Questions on 15 December 2008 and to the Chief Veterinary Officers on 11 February 2009.

[2] Several delegations have indicated that they are still reflecting certain aspects of the proposal.

A large number of delegations urged for the establishment of the severity classification of the procedures without delay, considering it indispensable for a clear definition of the scope of the proposed measures. Due to the linkage of such classification to several parts of the proposal, the request was repeated in the context of various articles, on which many delegations entered scrutiny reserves pending the establishment of the classification.

B. Evaluation and authorisation of projects

Delegations made suggestions and requests for clarifications with regard to the different stages required for the authorisation of projects, especially concerning their proposed mandatory ethical evaluation, retrospective assessment and the required non-technical project summaries. A number of delegations considered that the roles and tasks of the permanent ethical review body and of the competent authority/authorities responsible for the ethical evaluation and for the authorisation of the projects should be made clearer and more easily distinguishable, without making the provisions too rigid for the Member States.

C. Use of non human primates

Delegations generally agreed that special attention should be given to non-human primates and that their use in procedures should be limited to certain essential purposes which could not be achieved by the use of other species. Some delegations considered it, however, necessary to somewhat expand these purposes and some questioned the justification and effect of the proposed requirement for all non-human primates to be offspring of animals bred in captivity. Clarifications were requested as regards the relation of the proposed requirements to animals imported from third countries.

D. Authorisation of persons

Delegations generally welcomed the proposed common approach for the requirements on the professional competence of persons dealing with animals, including the mandatory authorisation of those persons. Several delegations contested the proposed time limit of five years for that authorisation, preferring a requirement on continuous training and maintaining of professional skills. It was agreed to further discuss the issue also in the light of the European Parliament's amendment concerning the mutual recognition.

E. National reference laboratories for alternative methods

The Commission's objective to strengthen the infrastructures necessary for the validation of alternative methods was generally considered very welcome. However, delegations raised several questions and concerns with regard to various aspects related to the proposed national reference laboratories, concerning among other their funding, the workload involved and the wide scope of competencies required, the coordination of work between different laboratories and between Member States and the Commission, and the role of the European Centre for the Validation of Alternative Methods (ECVAM).[1]

F. Re-use

While delegations agreed that the same animals should not be exposed to pain repeatedly, some pointed out that responsible re-use of animals helped to reduce the overall number of animals used in procedures. A few delegations suggested that the approach should be made more flexible and based on a case by case assessment e.g. in the context of the project authorisation. Requests were also made for a clearer distinction between re-use and continued use of animals in procedures.

G. Technical requirements

Other open issues requiring further examination on the technical level include the requirements for methods of killing animals and the specific requirements for their care and accommodation. In this context, also the transitional periods for the entry into force of these provisions will need to be examined closer.

[1] A responsibility of the Directorate General Joint Research Centre of the European Commission.

III. PROCEDURE

Thanking the Czech Presidency for the important body of work undertaken, the incoming Swedish Presidency announced its commitment to continue the work with the view to establishing a concrete mandate that would enable it to represent the Council in the coming negotiations with the European Parliament.