

**Opinion of the Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes'**

(2002/C 94/02)

On 25 January 2002 the Council decided to consult the Economic and Social Committee, under Article 95 of the EC Treaty, on the above-mentioned proposal.

The Section for Agriculture, Rural Development and the Environment, which was responsible for the Committee's work on the subject, adopted its opinion on 29 January 2002. The rapporteur was Mr Jaschick.

At its 388th Plenary Session of 20 and 21 February 2002 (meeting of 20 February), the Economic and Social Committee adopted the following opinion by 116 votes with one abstention.

## 1. Introduction

1.1. In 1998 the EU became a party to Council of Europe Convention ETS 123 for the protection of vertebrate animals used for experimental and other scientific purposes.

1.2. Council Directive 86/609/EEC<sup>(1)</sup>, together with its annexes, is the implementing tool for Convention ETS 123. The annexes to the Directive need to be adapted on an ongoing basis to bring them into line with the latest scientific knowledge and state-of-the-art technology.

1.3. With a view to securing improvements as rapidly as possible in the physiological and ethological situation of animals, the Council of Europe has put forward a 'Protocol of Amendment' (ETS 170) to Convention ETS 123, setting out a simplified procedure for adapting the appendices to the Convention more quickly. The Commission thinks that the EU will scarcely be able to comply with its obligations under the Convention unless use is made of the 'Regulatory Committee Procedure' as it is proposing.

## 2. General comments

2.1. The ESC endorses the Commission's proposal, subject to the comments set out below. By providing for a simplified procedure, the Commission's proposal is conducive to securing improved protection for animals within a relatively short period (Phase 1 of the European Commission's strategic plan regarding this topic).

2.2. The proposed Regulatory Committee Procedure fully conforms with the EU's Treaty obligation to take full account of the need to protect animals.

2.3. The ESC, nonetheless, calls for in-depth revision of Council Directive 86/609/EEC (Phase 2 of the European Commission's strategic plan).

2.3.1. This exercise should also introduce a reference to certain basic welfare elements: the three Rs<sup>(2)</sup> and the five freedoms<sup>(3)</sup>, as provided by the ETS 87 on the Protection of animals kept for farming purposes.

2.3.2. The ESC notes that three Member States (Belgium, France and the Netherlands) have still not transposed this Directive into their national legislation even 15 years after its adoption. The ESC is aware that currently three cases are pending before the European Court of Justice involving Belgium, France and the Netherlands. In an earlier opinion<sup>(4)</sup> the ESC stipulated clearly that 'the method of enforcement of this Directive will be essential to achieving its aims'.

2.3.2.1. The Committee deplores this situation, especially since the inadequate implementation in some Member States runs counter to the goal of protecting animals.

2.3.2.2. The Committee would encourage the Commission to continue to take all appropriate steps to bring about full implementation of the Directive at long last.

2.3.2.3. The ESC draws attention to the fact that, at the present time, only seven signatories (out of 43) have ratified this Protocol though without putting it into force; five of those seven are EU Member States (Finland, France, the Netherlands, Sweden and the UK). In general, this Protocol is still not in force at the Council of Europe. In addition, the basic text, i.e. ETS 123, has not yet been ratified by five EU Member States (Austria, Ireland, Italy, Luxembourg and Portugal).

2.3.2.4. The ESC urges the Commission to get more EU Member States to ratify Convention ETS 123 and the Protocol of Amendment.

<sup>(2)</sup> Replacement, reducing and refinement.

<sup>(3)</sup> Freedom from hunger, thirst, stress, pain, injury and illness and freedom to express physiological behaviour, in order to prevent the occurrence of phenomena such as cannibalism.

<sup>(4)</sup> OJ C 207, 18.8.1986, p. 3.

<sup>(1)</sup> OJ C 207, 18.8.1986, p. 3.

### 3. Specific comments

3.1. The ESC approves the Commission's proposal (see point 2.1 above), even though the Regulatory Committee Procedure for amending the Annexes to the Directive in question would result in the ESC's exclusion from the consultation procedure (the EP would still be consulted under the 'right of inspection'). In the past the ESC already stipulated that 'the Annexes to the proposed Directive are of great significance. It must be clear as to whether any additional consultation procedure is envisaged. Small changes in the Annexes could be of major significance to science and industry' <sup>(1)</sup> <sup>(2)</sup>.

3.2. The ESC's endorsement is therefore conditional upon the European Commission taking account of the following points when revising the Directive (Phase 2):

- the need to involve in its preparatory work all stakeholders <sup>(3)</sup> and in particular NGOs and animal welfare associations;
- the need to review Directive 86/609/EEC forthwith;
- the need to involve the competent Scientific Committee of the European Commission (the Scientific Committee on Animal Health and Animal Welfare — SCAHAW).

3.2.1. The ESC expresses such willingness, taking into account that the European Community, being party to the ETS 123, would be obliged to fulfil certain commitments; still, it recalls that international conventions such as the one in question (type of 'mixed' agreements) do not necessarily involve legally binding provisions.

3.3. Furthermore, Directive 86/609/EC has now been in existence for 15 years and no longer reflects the latest scientific knowledge, a view which is also shared by the Commission; inter alia, the definitions must be revised.

<sup>(1)</sup> OJ C 207, 18.8.1986, p. 3.

<sup>(2)</sup> Endeavours should be made to find possible ways of enabling the ESC to be involved, in a particularly appropriate form, in the channel of information.

<sup>(3)</sup> Including the ESC.

3.4. The scope of Convention ETS 123 has also been extended and it now also covers animals used for education and training purposes.

3.5. And finally, the Commission should improve the checking and welfare of particular species, such as non-human primates <sup>(4)</sup>.

3.6. The European Community should withdraw its reservation contained in the instrument of approval deposited on 30 April 1998 regarding its refusal to be bound by the obligations to communicate statistical data, as laid down in Article 28 of the ETS 123. This reservation is the reason for the lack of appropriate and homogeneous results, as shown by the Second report from the Commission to the Council and the European Parliament on the statistics on the number of animals used for experimental and other scientific purposes in the Member States and in the European Union. The European Community should invite France, Germany and Portugal to follow in doing the same.

3.6.1. In parallel, the European Commission should urge Member States to comply fully and more effectively with the provisions of Articles 13 and 26 of Directive 86/609/EEC by, for example, pressing them to draw up annual reports.

3.7. The Committee acknowledges the high reputation, both throughout Europe and worldwide, of the European Centre for the Validation of Alternative Methods (ECVAM); its contribution to this matter in validating alternative testing procedures, in particular in vitro procedures, is of major importance.

### 4. Field of application

4.1. The Committee expressly welcomes the inclusion of the EEA in the field of application of the Directive and thinks that Switzerland should also be included, as soon as the opportunity presents itself.

4.2. The Committee assumes that the Commission will encourage the candidate states to create the requisite conditions to enable them to adopt these provisions as rapidly as possible.

<sup>(4)</sup> In this context one should also examine the situation in their countries of origin of species used for experimental purposes, particularly in the case of non-human primates and endangered species.

Brussels, 20 February 2002.

*The President*  
*of the Economic and Social Committee*  
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