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REPORT

on the proposal for a European Parliament and Council directive 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 (COM(2001) 703 – C5-0605/2001 – 2001/0277(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Caroline F. Jackson

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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PROCEDURAL PAGE

By letter of 28 November 2001 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 95 of the EC Treaty, the proposal for a European Parliament and Council directive 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 (COM(2001) 703 - 2001/0277 (COD)).

At the sitting of 10 December 2001 the President of Parliament announced that he had referred the proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Budgets and the Committee on Legal Affairs and the Internal Market for their opinions (C5-0605/2001).

The Committee on the Environment, Public Health and Consumer Policy appointed Caroline F. Jackson rapporteur at its meeting of 22 January 2002.

The committee considered the Commission proposal and draft report at its meeting of 16 April 2002 and 18 June 2002.

At the latter meeting it adopted the draft legislative resolution by 38 votes to 0, with 1 abstention.

The following were present for the vote: Caroline F. Jackson, chairman and rapporteur; Mauro Nobilia, Alexander de Roo and Anneli Hulthén, vice-chairmen; and Per-Arne Arvidsson, María del Pilar Ayuso González, Hans Blokland, David Robert Bowe, John Bowis, Hiltrud Breyer, Dorette Corbey, Chris Davies, Marialiese Flemming, Karl-Heinz Florenz, Cristina García-Orcoyen Tormo, Laura González Álvarez, Robert Goodwill, Françoise Grossetête, Jutta D. Haug (for Anne Ferreira), Piia-Noora Kauppi (for Raffaele Costa, pursuant to Rule 153(2)), Christa Kieß, Eija-Riitta Anneli Korhola, Peter Liese, Rolf Linkohr (for Rosemarie Müller), Giorgio Lisi (for Martin Callanan), Torben Lund, Minerva Melpomeni Malliori, Patricia McKenna, Jorge Moreira da Silva, Emilia Franziska Müller, Giuseppe Nisticò, Guido Sacconi, Karin Scheele, Horst Schnellhardt, Inger Schörling, María Sornosa Martínez, Catherine Stihler, Antonios Trakatellis and Phillip Whitehead.

The opinion of the Committee on Budgets is attached. On 24 January 2002, the Committee on Legal Affairs and the Internal Market decided not to deliver an opinion.

The report was tabled on 19 June 2002.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a European Parliament and Council directive 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 (COM(2001) 703 – C5-0605/2001 – 2001/0277(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COMCOM(2001) 703¹),
 - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0605/2001),
 - having regard to Rule 67 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinion of the Committee on Budgets (A5-0239/2002),
1. Approves the Commission proposal as amended;
 2. Asks to be consulted again should the Commission intend to amend the proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

Amendments by Parliament

Amendment 1 Recital 5

(5) ***Since*** the measures necessary for the implementation of this ***Directive are measures of general scope within the meaning of Article 2 of*** Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers

(5) ***The*** measures necessary for the implementation of this ***instrument shall be adopted in accordance with*** Council Decision 199/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

¹ OJ C 25, 29.1.2002, p. 536.

conferred on the Commission¹, ***they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.***

the Commission.

Justification

Standard text for reference to the comitology procedure as agreed between EP and Council (SN 4814/99).

Amendment 2 ARTICLE 1

Article 24a (new) (Dir. 86/609/EEC)

The ***amendments*** necessary for ***adapting the Annexes of this Directive*** shall be adopted in accordance with the procedure ***referred to*** in Article 24b.

The ***measures*** necessary for the ***implementation of this instrument relating to the subject matters referred to below*** shall be adopted in accordance with the ***regulatory*** procedure ***set out*** in Article 24b ***(2)***

- Annexes of Directive 86/609/EEC

Justification

See amendment 1.

Amendment 3 ARTICLE 1

Article 24b (new) (Dir. 86/609/EEC)

1. The Commission shall be assisted by a committee ***composed of the representatives of the Member States and chaired by the representative of the Commission.***

2. Where reference is made to this

1. The Commission shall be assisted by a committee ***(hereinafter referred to as "the Committee").***

2. Where reference is made to this

¹ OJ L 184, 17.7.1999. p. 23.

paragraph, ***the regulatory procedure laid down in*** Article 5 of Decision 1999/468/EC shall apply, ***in compliance with Article 7 and*** Article 8 thereof.

paragraph, Articles 5 ***and*** 7 of Decision 1999/468/EC shall apply, ***having regard to the provisions of*** Article 8 thereof.

3. ***The period provided for in Article 5 (6) of Decision 1999/468/EC shall be three months.”***

3 ***The Committee shall adopt its rules of procedure***

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at [three] months

Justification

See amendment 1.

Amendment 4 ARTICLE 3 A (new)

The Commission shall have carried out the necessary revision of the directive and have forwarded the outcome thereof to the European Parliament no later than 1 January 2003.

Justification

A deadline must be set to ensure that the necessary revision of the existing directive is carried out effectively.

EXPLANATORY STATEMENT

In 1998, the Community became a Party to the 1986 Council of Europe Convention for the protection of vertebrate animals used for experimental and other scientific purposes. The implementing tool for the Convention is Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

The Council of Europe has opened for signature a "Protocol of Amendment", which will allow the Appendices of the Convention to be amended via a simplified procedure, instead of via a fully-fledged amendment to the Convention which would necessitate ratification by all of the Parties to the Convention. The aim of the Protocol of Amendment is to allow for speedy changes to the Appendices as and when technological developments necessitate this - in particular Appendix A which covers guidelines for the housing and care of laboratory animals. Appendix A of the Convention is equivalent to Annex 2 of the Directive.

According to the Commission, before the Community concludes the Protocol of Amendment, a corresponding implementing tool should exist at Community level. Consequently, Directive 86/609/EEC should be amended to include the Regulatory Committee Procedure (as foreseen in Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission) and provide for a simplified procedure as regards adaptation of annex 2 of the Directive to technical progress without which the Community's implementing legislation will be out of line with the Convention. The existing Regulatory Committees do not cover the area of the protection of animals used in experiments. Therefore it is necessary to establish a Regulatory Committee that has the appropriate competence.

The proposal also includes annex 1 of the Directive, which contains the "list of experimental animals covered by the provisions of art. 21 of the Convention" to be modified through the Regulatory Committee Procedure.

22 May 2002

OPINION OF THE COMMITTEE ON BUDGETS

for the Committee on the Environment, Public Health and Consumer Policy

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
(COM(2001) 703 – C5-0605/2001 – 2001/0277(COD))

Draftsman: Kathalijne Maria Buitenweg

PROCEDURE

The Committee on Budgets appointed Kathalijne Maria Buitenweg draftsman at its meeting of 22 January 2002.

It considered the draft opinion at its meeting of 21 May 2002.

At the latter meeting it adopted the following amendments unanimously.

The following were present for the vote: Terence Wynn, chairman; Francesco Turchi, vice-chairman; Kathalijne Maria Buitenweg, draftsman; Joan Colom i Naval, Den Dover, Göran Färm, Salvador Garriga Polledo, Catherine Guy-Quint, María Esther Herranz García, Ian Stewart Hudghton, Wilfried Kuckelkorn, Juan Andrés Naranjo Escobar, Joaquim Piscarreta, Per Stenmarck, Kyösti Tapio Virrankoski and Ralf Walter.

SHORT JUSTIFICATION

1. Background

The Community is a Party to the Council of Europe Convention ETS 123 for the protection of vertebrate animals used for experimental and other scientific purposes. The implementing tool for the Convention is Directive 86/609/EEC. Appendix A of the Convention contains guidelines for the housing and care of laboratory animals. Appendix A of the Convention is equivalent to Annex 2 of the Directive.

The Appendices to the Convention are of a technical nature. They rely on scientific knowledge on the physiological and ethological needs of the animals, as well as on the

influence of the environment on their well-being. The Appendices need periodic adaptation to the latest scientific and technical developments and results in the research within the fields covered. Since the Community has to ensure full and timely implementation of the Convention including its Appendices, also the Annexes to the Directive require periodic adaptation.

To simplify the amendments of the Appendices, the Council of Europe has opened for signature and ratification a "Protocol of Amendment" to the Convention. Consequently, also Directive 86/609/EEC should provide for a simplified procedure as regards the adaptation of its Annexes to technical progress. The Commission proposes that this simplified procedure would be a Regulatory Committee Procedure and claims that, without this procedure, the Community would risk to run into a situation whereby its implementing legislation (namely the Annexes to the Directive) would not be in line with the Appendices to the Convention. The Community would then be in breach of its international obligations in this area.

The existing Committees do not cover the area of the protection of animals used in experiments. Therefore it would be necessary to establish a Committee that has the appropriate competence.

The Commission further acknowledges that, at a second stage, a full revision of the Directive is needed since it dates back 15 years and the scope of the Council of Europe Convention goes beyond that of the Directive. The Commission states that it would also be an opportunity to fulfil its commitments to improve the controls and welfare of certain species such as non-human primates.

2. Financial and legislative remarks

2.1. Budgetary impact

The proposal has virtually no budgetary impact. It simply provides for the organisation of one (technical) committee meeting a year to adapt the Annexes to the latest scientific and technical progress, covered by budget line A-7031 (Expenditure on meetings of committees) of the Commission budget. The annual cost of this additional committee meeting is estimated at € 0.027 million. Part B of the budget (operational expenditure) will not be affected at all.

2.2. Commitology

With regard to commitology your draftsman follows the traditional approach of the Committee on Budgets. She therefore tables two amendments which aim at replacing the proposed Regulatory Committee Procedure by the Advisory Committee Procedure.

2.3. Future full revision of Directive 86/609/EEC

Your rapporteur would like to seize this opportunity to state that the future full revision of the Directive should indeed be used to improve the controls and welfare of certain species such as non-human primates. She believes that the external costs of rehousing and care taking of animals that have been used for experiments must be incorporated in research expenditure and be eligible for support from the European budget.

AMENDMENTS

The Committee on Budgets calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission¹

Amendments by Parliament

Amendment 1 Recital 5

(5) Since the measures necessary for the implementation of this Directive are measures *of general scope* within the meaning of **Article 2** of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission², they should be adopted by use of the *regulatory* procedure provided for in **Article 5** of that Decision.

(5) Since the measures necessary for the implementation of this Directive are measures *(deletion)* within the meaning of **Article 2(c)** of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission³, they should be adopted by use of the *advisory* procedure provided for in **Article 3** of that Decision.

Justification

The draftsman considers that the legislative proposal should comply with the traditional approach of the Committee on Budgets as regards commitology.

Amendment 2 Article 1

Article 1

In Directive 86/609/EEC the following Articles 24a and 24b are inserted:

“Article 24a

Article 1

In Directive 86/609/EEC the following Articles 24a and 24b are inserted:

“Article 24a

¹ OJ C 25 E, 29.01.2002, p. 536.

² OJ L 184, 17.7.1999, p. 23.

³ OJ L 184, 17.7.1999, p. 23.

The amendments necessary for adapting the Annexes of this Directive shall be adopted in accordance with the procedure referred to in Article 24b.

Article 24b

1. The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.
2. Where reference is made to this paragraph, the **regulatory** procedure laid down in **Article 5** of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.
3. ***The period provided for in Article 5 (6) of Decision 1999/468/EC shall be three months.***

The amendments necessary for adapting the Annexes of this Directive shall be adopted in accordance with the procedure referred to in Article 24b.

Article 24b

1. The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.
 2. Where reference is made to this paragraph, the **advisory** procedure laid down in **Article 3** of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.”
- Deleted.***

Justification

The draftsman considers that the legislative proposal should comply with the traditional approach of the Committee on Budgets as regards commitology. Paragraph 3 is deleted because it does not apply to the advisory procedure.