

EUROPEAN PARLIAMENT

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19 June 2002

REPORT

on the proposal for a Council decision concerning the conclusion of the Protocol of Amendment to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (COM(2001) 704 – C5-0037/2002 – 2001/0278(CNS))

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 25 January 2002, the Council consulted Parliament, pursuant to Article 95 and Article 300 (2) and (3), first sub-paragraph of the EC Treaty on the proposal for a Council decision concerning the conclusion of the Protocol of Amendment to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (COM (2001) 704 - 2001/0278 (CNS)).

At the sitting of 4 February 2002 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Legal Affairs and the Internal Market for its opinion (C5-0037/2002).

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

At its meeting of 26 February 2002, the Committee on the Environment, Public Health and Consumer Policy decided to request the opinion of the Committee on Legal Affairs and the Internal Market on the proposal's legal basis under Rule 63(2).

The committee considered the Commission proposal and draft report at its meetings 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 on the legal basis of the Committee on Legal Affairs and the Internal Market is attached. On 24 January 2002, the Committee on Legal Affairs and the Internal Market decided not to deliver an opinion on the contents of the proposal.

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.

LEGISLATIVE PROPOSAL

Proposal for a Council decision concerning the conclusion of the Protocol of Amendment to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (COM (2001) 704 – C5-0037/2002 – 2001/0278(CNS))

The proposal is approved.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a Council decision concerning the conclusion of the Protocol of Amendment to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (COM(2001) 704 – C5-0037/2002 – 2001/0278(CNS))

(Consultation procedure)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2001) 704¹),
 - having been consulted by the Council pursuant to Articles 95 and 300 (2) and (3), first sub-paragraph of the EC Treaty (C5-0037/2002),
 - having regard to the opinion of the Committee on Legal Affairs and the Internal Market on the proposed legal basis,
 - 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 (A5-0238/2002),
1. Approves the Commission proposal;
 2. Calls on the Council to notify Parliament should it intend to depart from the text approved by Parliament;
 3. Asks to be consulted again should the Council intend to amend the Commission proposal substantially;
 4. Instructs its President to forward its position to the Council and Commission.

¹ OJ C 25, 29.1.2002, p. 538.

EXPLANATORY STATEMENT

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 in 1998. 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 - in particular Appendix A which covers guidelines for the housing and care of laboratory animals.

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 (Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission). The Commission is proposing a Directive to amend Directive 86/609/EEC to include the Regulatory Committee procedures concerning the exercise of implementing powers conferred on the Commission.

It is finally recommended that the Council should only allow the signature to take place once those Member States who are also Parties to the Convention have ratified the Protocol of Amendment themselves.

Your rapporteur proposes that the European Parliament approves the Council decision unamended.

EUROPEAN PARLIAMENT

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Committee on Legal Affairs and the Internal Market
The Chairman

Mrs Caroline F. Jackson
Chairman on the Committee
on the Environment, Public Health and Consumer Policy
BRUSSELS

Subject: Legal basis of the proposal for a Council decision concerning the conclusion of the Protocol of Amendment to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes

Dear Madam President,

By letter of 25 March 2002 you requested the Committee on Legal Affairs and the Internal Market, under Rule 63(2), to consider the issue of the appropriate legal basis for the above proposal. You did so because, while the Commission had based its proposal on Article 300(2) and the first sub-paragraph of Article 300(3) EC, you took the view that the second subparagraph of Article 300(3) should be used as the legal basis.

The Committee on Legal Affairs and the Internal Market considered the above question at its meeting(s) of 23 April 2002.

1. European convention for the protection of vertebrate animals

This Convention of the Council of Europe applies to any animal used or intended for use in any experimental or other scientific procedure where that procedure may cause pain, suffering, distress or lasting harm.¹ The Convention is designed primarily to reduce both the number of experiments and the number of animals used for such purposes. It encourages Parties not to experiment on animals except where there is no alternative method. Animals to be experimented on should be selected on the basis of clearly established quantitative criteria and must be well cared for and spared avoidable suffering whenever possible.

¹ Article 1 of the said Convention.

To this end, the Convention lays down a number of principles that are designed to help the signatory States to harmonise the introduction of national schemes to guarantee that animals are treated properly and humanely and that where procedures which may possibly cause pain, suffering, distress or lasting harm to an animal are unavoidable, they are kept to a minimum.¹

In particular, Article 5 of the Convention sets out the duty to do everything possible to ensure animals' well-being under the conditions in which they have to be kept. In the implementation of this provision, the Parties should paid regard to the detailed guidelines for the accommodation and care of animals set out in Appendix A.

Article 28 of the Convention provides that each Party is to communicate to the Secretary-General of the Council of Europe statistical information in respect of:

- a) The numbers and kinds of animals used in procedures;
- b) The numbers of animals in selected categories used in procedures directly concerned with medicine and in education and training;
- c) The numbers of animals in selected categories used in procedures for the protection of man and the environment;
- d) The numbers of animals in selected categories used in procedures required by law.²

Such statistical information is presented in the form set out in Appendix B to the Convention and is to be published by the Secretary-General of the Council of Europe.

Article 30 provides for the possibility of the parties being convened at regular intervals to hold multilateral consultations within the existing structures of the Council of Europe. The Parties recognised that the aims of the Convention would be more easily achieved if the representatives of the Parties had the possibility of meeting regularly, either to monitor the implementation of the provisions, to adapt the Convention to changing circumstances and new scientific evidence, or to develop common and co-ordinated programmes in the field covered by the Convention.³

Articles 31 to 37 of the Convention concern *inter alia* signature, ratification, acceptance or approval of the Convention by the Parties, entry into force, accession, reservations. Finally, Appendixes A and B are attached to the Convention.⁴ The Convention entered into force on 1.1.1991.⁵

This Convention was concluded by the European Community by means of a Council decision⁶ and entered into force on 1.11.1998 in the territory of the Community. The Council decision is based in Article 95 EC (ex Article 100a) in conjunction with Article 300(2) and (3), first subparagraph EC [ex Article 228(2) and (3), first subparagraph]. Upon conclusion of the Convention, the European Community made a reservation, whereby it does not consider itself bound by the requirements to communicate statistical data laid down in Article 28(1) of

¹ Explanatory Report to the Convention.

² Articles 27(2) and 28 of the Convention.

³ Explanatory Report to the Convention.

⁴ See <http://conventions.coe.int>.

⁵ Pursuant to Article 32 of the Convention.

⁶ Council decision 1999/575/EC of 23.3.1998 concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, OJ L 222 of 24.8.1999, p. 29.

the convention.¹

Prior to the conclusion by the European Community of the Convention, its content had been already incorporated in 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.²

It is to be noted that international agreements concluded by the Community are to be published in the Official Journal. This is provided in the Council rules of procedure³, not in the EC Treaty. It is further to be noted that, whereas the Convention was published in the Official Journal, Appendixes A and B have not.

While it may be considered that non-publication of Appendix B is a result of the reservation made by the European Community as concerns communication of statistical data, that is not the case for Appendix A, which contains guidelines for accommodation and care of animals, pursuant to Article 5 of the Convention. The latter is contained in Annex 2 of Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

2. The Protocol of Amendment to the Convention

The Council of Europe drew up a Protocol of Amendment to the Convention, which is the result of the work made, in accordance with Article 30 of the Convention, by the Parties in multilateral consultations to examine the application of the Convention, and the advisability of revising it or extending any of its provisions.

Considering the evolution of scientific knowledge and changing circumstances, the Parties have agreed that the Appendices - of a mere technical nature - might need to be adapted more frequently than the other provisions of the Convention.

A simplified procedure for amendments of the technical Appendices was considered by the Parties as facilitating such adaptation. Accordingly, the new Article 30 empowers Parties themselves, without formal adoption by the Committee of Ministers, to amend the Appendices of a technical nature which might require more frequent adaptation in the light of new scientific evidence and experience acquired, and the modification of which is unlikely to have direct political consequences for the Council of Europe.

Under this simplified procedure, amendments to Appendices A and B, proposed by a Party or by the Committee of Ministers of the Council of Europe are examined at a multilateral consultation where it may be adopted by a two-thirds majority of the Parties. Twelve months after its adoption at a multilateral consultation, any amendment enters into force unless one third of the Parties have notified objections.

3. Article 300 EC

Article 300 EC sets out the procedure which the Community has to follow where the Treaty provides for the conclusion of agreements between the Community and one or more states or international organisations. That Treaty provision does not itself confer any power on the Community to act internationally, but applies whenever the Community wishes to conclude

¹ Annex B to the Council decision 1999/575/EC.

² OJ L 358, 18.12.1986, p. 1.

³ Article 17(1)(g) of Council Rules of Procedure adopted by Council decision 2000/396/EC, ECSC, Euratom of 5.6.2000, OJ L 149 of 23.6.2000, p. 21. Previously Article 15(1)(g) of Council Rules of Procedure adopted by Council decision 1999/385 of 31.5.1999, OJ L 147, 12.6.1999, p. 13.

an agreement pursuant to a power contained expressly or impliedly in the Treaty.¹

The procedural requirements apply to amendments of agreements and to additional or implementing protocols concluded together with or on the basis of the agreement itself. The denunciation of an agreement also falls under the scope of Article 300 EC.

In conferring certain powers on the Community institutions, Article 300 EC seeks to establish a balance between the institutions.² The general rule laid down in the EC Treaty is that, except in the case of tariff and trade agreements³, the Council concludes agreements after consulting the European Parliament, even where the agreement covers a field for which the co-decision procedure or the cooperation procedure is required for the adoption of internal rules [Article 300(3), first subparagraph, first sentence EC]. The European Parliament also has to be consulted where no involvement at all of the European Parliament is prescribed for the adoption of internal rules.

In the case of four categories of agreement, the EC Treaty makes their conclusion dependent upon the prior assent of the European Parliament [Article 300(3), second subparagraph EC]. The assent procedure applies to association agreements within the meaning of Article 310 EC; other agreements establishing a specific institutional framework by organising cooperation procedures; agreements having important budgetary implications for the Community; and agreements entailing amendment of an act adopted under the procedure laid down in Article 251 EC. Accordingly, the Council may not, by means of an international agreement, detract from internal legislation which the European Parliament and the Council adopted under the codecision procedure. However, so long as no internal act has been adopted, the Council is entitled to conclude international agreements in the field in question after merely consulting the European Parliament.

4. Assessment

It is to be reminded that, pursuant to Rule 63(2), the opinion of the Committee on Legal Affairs and Internal Market concerns the legal basis of the Commission's proposal only. The Convention was concluded under Article 95 EC (ex Article 100a), in conjunction with Article 300(2) and (3), first subparagraph EC [ex Article 228(2) and (3), first subparagraph].

The Protocol of Amendment refers to a Convention concluded under Article 95 EC. By applying the general principle of law of *accessorium sequitur principale*, and in light of the above considerations under 3., the appropriate legal basis for the conclusion of the Protocol of Amendment to the Convention is Article 95 and Article 300(2) and (3), first subparagraph EC.

However, for the sake of clarity, the attention of the Committee on the Environment, Public Health and Consumer Policy is drawn to the fact that Directive 86/609 set up a permanent consultative committee to assist the Commission in organising the exchange of appropriate information, and in the other questions raised by the application of that Directive.⁴ In contrast, in the explanatory memorandum of the proposal for a Council decision concerning the conclusion of the Protocol of Amendment, it is mentioned that "before the Community

¹ See Article 133(3), third subparagraph; Article 170, second paragraph; Article 174(4), first subparagraph; Article 181, first paragraph EC.

² Case C-327/91 *France v Commission* [1994] E.C.R. I-3641, para. 28.

³ Agreements mentioned in Article 133(3) EC.

⁴ Article 22 of Directive 86/609.

concludes the Protocol of Amendment (...) Directive 86/609/EEC should be amended to include the regulatory committee procedure". It is announced that the Commission is proposing a Directive to amend Directive 86/609 to that sole effect. In other words, the creation of a regulatory committee to be included in Directive 86/609 may result in removing from the codecision procedure any future modifications (via the simplified procedure of the Protocol) to Appendices A and B to the Convention.

Furthermore, from a strictly legal viewpoint, the introduction of a simplified procedure to update the terms of the Convention and its Appendices results in Community law being amended as a result of informal consultations between the parties to an international Convention, thus modifying the distribution of law-making power as between the Community institutions and between the Community and the Member States.

At its meeting of 23 April 2002, the Committee on Legal Affairs and the Internal Market thus decided unanimously¹ that Article 95 and Article 300(2) and (3), first subparagraph of the EC Treaty is the appropriate legal basis.

Yours sincerely,

(s) Giuseppe Gargani

¹ At its meeting of 23 April 2002, the following were present for the vote:

Willi Rothley (acting-chairman), Ioannis Koukiadis, Bill Miller (vice-chairmen), Paolo Bartolozzi, Ward Beysen, Marie-Françoise Garaud, Evelyne Gebhardt, Fiorella Ghilardotti, Malcolm Harbour, Kurt Lechner, Klaus-Heiner Lehne, Neil McCormick, Arlene McCarthy, Manuel Medina Ortega, Rijk van Dam, Rainer Wieland, Joachim Wuermeling and Stefano Zappalà.