



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.11.2001
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2001/0277 (COD)

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. BACKGROUND

In 1986 the Council adopted Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. The Directive seeks to improve the controls on the use of laboratory animals, to set minimum standards for housing and care as well as to the training of personnel handling these animals and supervising the experiments. It also aims at reducing the numbers of animals used for experiments by encouraging the development and the validation of alternative methods to replace animal methods.

The Directive contains two Annexes; Annex 1 listing the species of animals covered by Article 21 of the Directive and Annex 2 containing the guidelines for the housing and care of laboratory animals. These Annexes are of a technical nature, and 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 guidelines need periodic adaptation to the latest scientific and technical developments and results in the research within the fields covered.

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.

2. DEVELOPMENTS AT THE COUNCIL OF EUROPE

In 1998 the Community became a Party to the 31 March 1986 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 transformed into Annex 2 of the Directive. Appendix B of the Convention contains statistical tables. However, at the time of concluding the Convention, the Community made a reservation in respect of Article 28(1) of the Convention on the requirement to provide statistical. Therefore the Community is not bound by Appendix B.

The Council of Europe has opened for signature and ratification a "Protocol of Amendment" to the Convention. This Protocol of Amendment will allow the Appendices of the Convention to be amended by a simplified procedure, instead of via a fully-fledged amendment to the Convention, necessitating ratification by all of its Parties. The Commission is proposing a Council Decision on the conclusion, on behalf of the European Community of the Protocol of Amendment to that effect.

Under the auspices of the Council of Europe, a Working Party is currently reviewing Appendix A of the Convention, which contains the guidelines on housing and care. This revision is scheduled to be finalised and ready for adoption in 2002. The Council of Europe intends to use the simplified procedure contained in the Protocol of Amendment for the first time to adopt these amendments to Appendix A.

3. COMMUNITY PARTICIPATION IN THE COUNCIL OF EUROPE

The Community has to ensure full and timely implementation of the Convention and the Protocol. Currently any changes to the Annexes can only be adopted by the co-decision procedure. The co-decision procedure will in most cases not meet the twelve-month period for entering into force of amendments of the Appendices as provided for in Article 2(3) of the Protocol. 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 beforehand 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 Regulatory Committee Procedure would provide for a simplified procedure, to ensure that the Annexes of the Directive are kept up-to-date with the latest available scientific knowledge and research on the welfare of laboratory animals, including amendments to the Appendix A of the Council of Europe Convention.

If the Protocol of Amendment is ratified by the Community, and should the Directive not provide for a simplified procedure as regards adaptation to technical progress by, in this case, a Regulatory Committee Procedure, the Community will risk to run into a situation whereby its implementing legislation (the Annexes to the Directive) would not be in line with the obligations resulting from the Protocol.

4. FURTHER REVISION OF THE DIRECTIVE

The Commission acknowledges the fact that Directive 86/609/EEC requires a full revision. Since the scientific basis of the Directive dates back at least 15 years, some provisions are out of date. Furthermore, the scope of the Council of Europe Convention goes beyond that of Directive 86/609/EEC and also covers animals used for the purposes of education and training. The Directive would need to be aligned accordingly. At the same time the Commission could fulfil its commitments to improve the controls and welfare of certain species such as non-human primates, and to provide an opportunity to revisit some of the definitions and existing provisions.

5. TWO STEPS FOR THE NECESSARY AMENDMENTS

To safeguard progress in the field of welfare of laboratory animals through the Council of Europe Convention, with a view to meet the international animal welfare standards without unnecessary delay, as well as to allow for an in-depth discussion of the further revision of the Directive, the amendments will be carried out in two phases.

The first amendment of the Directive will introduce the Regulatory Committee Procedure. Since this does not require scientific-technical discussions it can be adopted quite swiftly and will therefore not jeopardise the conclusion of the Protocol of Amendment.

The second amendment should provide stakeholders an opportunity for in-depth scientific-technical discussions thus contributing to a fully-fledged revision of the Directive.

6. CONCLUSION

- Since the nature of the Annexes to the Directive requires their regular revision in order to strive for the highest possible animal welfare standards in the Community;
- Since the welfare of laboratory animals is increasingly becoming a politically sensitive issue in the Community, especially in the light of the increase in the Commission's responsibilities towards animal protection imposed by the recent amendment of the Treaty on European Union, which includes a Protocol requiring the European Union and Member States to pay full regard to the welfare of animals when drawing up agriculture, transport, single market and research policies, and the recently adopted White Paper on the Strategy for a future Chemicals Policy in the EU;
- Since an implementing tool should exist in the Community legislation to allow the Community to adhere to the Protocol of Amendment

it is appropriate for the Council and the European Parliament to adopt the Proposal for a Directive presented here in order to amend Directive 86/609/EEC to include a Regulatory Committee Procedure for the purposes of updating the Annexes of the said Directive.

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) On 23 March 1998 the Council adopted Decision 1999/575/EC³ concerning the conclusion by the Community of the European Convention of 18 March 1986 for the protection of vertebrate animals used for experimental and other scientific purposes (hereinafter referred to as "the Convention").
- (2) Council Directive 86/609/EEC⁴ is the implementing tool of the Convention incorporating the same objectives as the Convention.
- (3) Appendix A of the Convention is transformed into Annex 2 of Directive 86/609/EEC containing guidelines for accommodation and care. The provisions contained in Appendix A to the Convention and the Annexes to the said Directive are of a technical nature.
- (4) It is necessary to ensure the consistency of the Annexes to Directive 86/609/EEC with the latest scientific and technical developments and results in the research within the fields covered. Currently, changes to the Annexes can only be adopted by the long lasting co-decision procedure with the consequence that their content is lagging behind the latest developments in the field.

¹ OJ C ...

² OJ C ...

³ OJ L 222, 24.8.1999, p. 29.

⁴ OJ L 358, 18.12.1986., p. 1.

- (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 Commission⁵, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.
- (6) Therefore Directive 86/609/EEC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

“Article 24a

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.”

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ... at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

⁵ OJ L 184, 17.7.1999, p. 23.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Environment

Activit(y/ies): Implementation of Environmental Policies

TITLE OF ACTION: 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.

1. BUDGET LINE(S) + HEADING(S): A-7031

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): 0 € million for commitment

2.2. Period of application: Starts in 2002 and is open ended

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

not applicable

(b) Technical and administrative assistance and support expenditure *(see point 6.1.2)*

not applicable

(c) Overall financial impact of human resources and other administrative expenditure *(see points 7.2 and 7.3)*

€ million *(to three decimal places)*

	Year [n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Commitments/ payments	0,027	0,027	0,027	0,027	0,027	0,027	0,160

TOTAL a+b+c							
Commitments	0,027	0,027	0,027	0,027	0,027	0,027	0,160
Payments	0,027	0,027	0,027	0,027	0,027	0,027	0,160

2.4. Compatibility with financial programming and financial perspective

Proposal is compatible with existing financial programming.

2.5. Financial impact on revenue:

Proposal has no financial implications (involves technical aspects regarding implementation of a measure)

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Non-comp	Non-diff	YES	NO	NO	No [5]

4. LEGAL BASIS

Article 95 of the Treaty establishing the European Community

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention⁶

5.1.1. Objectives pursued

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. This simplified procedure would be a Regulatory Committee Procedure. Without a Regulatory Committee Procedure the Community will risk to run into a situation whereby its implementing legislation (namely the Annexes to the

⁶ For further information, see separate explanatory note.

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 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.

5.1.2. Measures taken in connection with ex ante evaluation

not applicable

5.2. Action envisaged and budget intervention arrangements

Organisation of one meeting a year to adapt the Annexes to the latest scientific and technical progress.

5.3. Methods of implementation

Implementation as provided in Article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

not applicable

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)

not applicable

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A		-		Organisation of the meetings including preparation of the working documents
	B	0.1		0.1	
	C	0.05		0.05	
Other human resources					
Total		0.15		0.15	

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials	16.200	108.000 / year / post x 0.15
Temporary staff		
Other human resources (specify budget line)		
Total	16.200	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line (number and heading)	Amount €	Method of calculation
Overall allocation (Title A7)		
A0701 – Missions		
A07030 – Meetings		
A07031 – Compulsory committees ¹	10.500	1 meeting of € 10.500 / year
Regulatory Committee		
A07032 – Non-compulsory committees ¹		
A07040 – Conferences		
A0705 – Studies and consultations		
Other expenditure (specify)		
Information systems (A-5001/A-4300)		
Other expenditure - Part A (specify)	10.500	
Total	10.500	

The amounts are total expenditure for twelve months.

¹ Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	€ 26.700
II.	Duration of action	open ended
III.	Total cost of action (I x II)	€ 26.700

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

Not applicable.

8.2. Arrangements and schedule for the planned evaluation

Not applicable.

9. ANTI-FRAUD MEASURES

Not applicable.