

Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2001/0277(COD) Procedure completed
Protection of animals used for experimental and other scientific purposes See also 2008/0211(COD)	
Subject 4.20.02.06 Clinical practice and experiments	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy		22/01/2002
		PPE-DE JACKSON Caroline	
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy		22/01/2002
		PPE-DE JACKSON Caroline	
	Former committee for opinion		
	BUDG Budgets		22/01/2002
		V/ALE BUITENWEG Kathalijne Maria	
	JURI Legal Affairs and Internal Market	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2494	17/03/2003
European Commission	Commission DG Environment	Commissioner	

Key events			
28/11/2001	Legislative proposal published	COM(2001)0703	Summary
10/12/2001	Committee referral announced in Parliament, 1st reading		
18/06/2002	Vote in committee, 1st reading		Summary
18/06/2002	Committee report tabled for plenary, 1st reading	A5-0239/2002	
02/07/2002	Decision by Parliament, 1st reading	T5-0339/2002	Summary
17/03/2003	Council position published	05240/1/2003	Summary

27/03/2003	Committee referral announced in Parliament, 2nd reading		
22/05/2003	Vote in committee, 2nd reading		Summary
22/05/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0185/2003	
19/06/2003	Decision by Parliament, 2nd reading	T5-0278/2003	Summary
22/07/2003	Final act signed		
22/07/2003	End of procedure in Parliament		
16/09/2003	Final act published in Official Journal		

Technical information

Procedure reference	2001/0277(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	See also 2008/0211(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16436

Documentation gateway

Legislative proposal	COM(2001)0703 , OJ C 025 29.01.2002, p. 0536 E	28/11/2001	EC	Summary
Economic and Social Committee: opinion, report	CES0186/2002 OJ C 094 18.04.2002, p. 0005	20/02/2002	ESC	
Committee report tabled for plenary, 1st reading/single reading	A5-0239/2002	18/06/2002	EP	
Text adopted by Parliament, 1st reading/single reading	T5-0339/2002 OJ C 271 12.11.2003, p. 0028-0151 E	02/07/2002	EP	Summary
Document attached to the procedure	COM(2003)0019	22/01/2003	EC	Summary
Council statement on its position	06532/2003	04/03/2003	CSL	
Council position	05240/1/2003 OJ C 113 13.05.2003, p. 0059-0060 E	17/03/2003	CSL	Summary
Commission communication on Council's position	SEC(2003)0367	25/03/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading	A5-0185/2003	22/05/2003	EP	
Text adopted by Parliament, 2nd reading	T5-0278/2003	19/06/2003	EP	Summary
Follow-up document	COM(2005)0007	20/01/2005	EC	Summary
Follow-up document	COM(2007)0675	05/11/2007	EC	Summary

Follow-up document		SEC(2007)1455	05/11/2007	EC	
Follow-up document		COM(2010)0511	30/09/2010	EC	Summary
Follow-up document		SEC(2010)1107	30/09/2010	EC	

Additional information

European Commission

[EUR-Lex](#)

Final act

[Directive 2003/65](#)

[OJ L 230 16.09.2003, p. 0032-0033](#) Summary

Protection of animals used for experimental and other scientific purposes

PURPOSE : to amend Council Directive 86/609/EEC on the protection of animals used for experiments, to bring it into line with the Council of Europe Convention. **CONTENT** : The Community is a Party to the Council of Europe Convention ETS 123 ("the 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. 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, and rely on scientific knowledge. They need periodic adaptation to the latest scientific and technical developments. Therefore, the Annexes to the Directive also require periodic adaptation. To simplify the amendments of the Appendices, the Council of Europe has opened for signature a "Protocol of Amendment" to the Convention. The Directive should also provide for a simplified procedure as regards adaptation of the Appendices to technical progress. This simplified procedure is a Regulatory Committee Procedure, 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.?

Protection of animals used for experimental and other scientific purposes

The committee adopted the report by Caroline JACKSON (EPP-ED, UK) broadly approving the proposal under the codecision procedure (1st reading), subject to some minor drafting amendments. It also felt that a deadline should be set for the revision of the directive and proposed that this should be 1 January 2003.?

Protection of animals used for experimental and other scientific purposes

The European Parliament, using its procedure without debate, adopted a resolution drafted by Caroline Jackson (EPP-ED, United Kingdom) and approved the proposal without amendment.?

Protection of animals used for experimental and other scientific purposes

The objective of this report is to present to the Council and the European Parliament, in accordance with Article 26 of Directive 86/609/EEC, the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU. For this third Report, 14 Member States (all except Germany) submitted the data from 1999, as far as possible, in the format of eight harmonised statistical tables. The aim of this report is to provide a comprehensive overview on the numbers of animals used in various experimental purposes in the Community in 1999. Because previous reports have been compiled on the basis on non-harmonised data it was only possible to make very limited comparisons with previous results. The main difference with the previous reports is that the data submitted by the Member States now covers a much wider range of procedures and purposes, due to the introduction of harmonised tables. The purposes of experiments are described in more detail including aspects such as regulatory requirements and types of tests versus products. This allows for a much more precise and comprehensive picture to be drawn at the EU level for the first time. The estimated total number of animals used for experimental and other scientific purposes in 1999 is 9,8 millions. The total number of animals reported in 1996 was 11,6 millions. It is evident that in 1999 the total number has passed below 10 million mark, which indicates a significant reduction. By far the biggest group of animals was rodents and rabbits. Since this is a new procedure, the report issues a warning about the consistency of data submitted by Member States. The report is divided into two parts: - a global compilation and overview for the European Union of the statistical data submitted by the Member States for 1999. - the data submitted by the Member States with a summary of the comments provided by the Member States. The information may be summarised as follows: - mice and rats are by far the most used species. Rodents together with rabbits represent the majority of animals with some 86,9%. There is a significant reduction in the use of cold-blooded animals compared to the previous report (12,9%); however, it still amounts to 6,6% of all the species used. The group containing horses, donkeys and cross-breeds, pigs, goats, sheep and cattle represents only 1,25% of the total number of animals used. Carnivores represent 0,36 % of the total number of animals and primates represent less than 0,1% of the animals used in 1999. - more than 60 % of animals have been used in research and development for human medicine, veterinary medicine, dentistry and in biological studies. Production and quality control of products and devices in human medicine, veterinary medicine and dentistry required the use of 21 % of the total number of animals reported in 1999. Toxicological and other safety evaluation represents

the third important group of experimental purposes with 10% of animals used. On the question of the latter, it is emphasised that animals used for toxicological and other safety evaluation represent only 10% of the total number of animals used for experimental purposes. The number of animals used for toxicological evaluation of products/substances for animal feed, for additives for human food consumption, for cosmetics and for household is very small (4%) when compared to the other products or endpoints. Products or devices used for human medicine, veterinary medicine and dentistry occupy 54% of the chart surface. The group of products/substances falling under the scrutiny of authorities concerned with safety of health and of the environment by chemical products, such as industrial chemicals and pesticides, is responsible for the use of 19% of animals. It is important to note that 16% form "other" toxicological evaluations.?

Protection of animals used for experimental and other scientific purposes

The Council welcomes and supports the Commission proposal as useful and appropriate. As the European Parliament adopted the Commission proposal unchanged, there are no amendments to be taken into account. However, in contrast to the European Parliament, the Council is not able to accept the Commission proposal unchanged, as it insists on the standard wording for the reference to the comitology procedure and it has specified a time limit for compliance with the Directive by setting it to 1 year following the publication of the Directive in the Official Journal of the European Union.?

Protection of animals used for experimental and other scientific purposes

The Commission welcomes the amendments proposed by the Council. The Commission considers that the common position does not alter the objectives of the proposal and this supports the common position as it stands.?

Protection of animals used for experimental and other scientific purposes

The committee adopted the report by its chair, Caroline JACKSON (EPP-ED, UK), approving the Council's common position without amendment under the 2nd reading of the codecision procedure. ?

Protection of animals used for experimental and other scientific purposes

The European Parliament adopted a resolution drafted by Caroline JACKSON (EPP-ED, UK) and approved the common position.?

Protection of animals used for experimental and other scientific purposes

PURPOSE : to revise Directive 86/609/EEC concerning the protection of animals used for experimental and other scientific purposes.
LEGISLATIVE ACT : Directive 2003/65/EC 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. **CONTENT :** to recall, on 23 March 1998 the Council adopted Decision 1999/575/EC concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes. Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes is the implementing tool for Council of Europe Convention on the protection of vertebrate animals used for experimental and other scientific purposes, of which the Community is a Party. Annex II to Directive 86/609/EEC containing guidelines for accommodation and care of animals takes over Appendix A to the Convention. The provisions contained in Appendix A to the Convention and the Annexes to the said Directive are of a technical nature. It is the aim of this Directive to ensure the consistency of the Annexes to Directive 86/609/EEC with the latest scientific and technical developments and results of research within the fields covered. Currently, changes to the Annexes can only be adopted by the long-drawn-out co-decision procedure with the consequence that their content is lagging behind the latest developments in the field. The Council of Europe has opened for signature and ratification a "Protocol of Amendment" to the Convention. It provides for amending the Appendices of the Convention by a simplified procedure rather than by the usual procedure that involves ratification by all parties. As stated, this would allow the Convention to keep up-to-date with the latest scientific knowledge and research on the welfare of laboratory animals quicker than today. This Directive shall amend Directive 86/609/EEC and bring it in line with the Protocol of Amendment. A regulatory committee procedure for a quicker introduction of changes to the Annexes of the Directive shall be set up. **ENTRY INTO FORCE :** 16/09/2003. **IMPLEMENTATION :** 16/09/2004.?

Protection of animals used for experimental and other scientific purposes

The objective of this fourth report is to present to the Council and to the European Parliament statistics on the number of laboratory animals used in the EU, in accordance with Article 26 of 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.

This Report is accompanied by a Commission Staff Working Paper - Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union in the year 2002. The Staff Working Paper provides more details and also includes data from the single Member States and their respective comments.

The main difference with the previous Reports is that the data now cover the complete range of procedures and their purposes. This allows, for the first time, for a more precise and comprehensive picture at EU level. Data are far more coherent amongst the different Tables than in previous Reports. Nevertheless, for the next Report coherence still needs to be improved. In this regard, the accession of the ten new Member

States will require additional efforts.

The report highlights that the total number of animals used for experimental and other scientific purposes in 2002 was 10.7 million (with data from France from 2001). This indicates an increase beyond the 9.8 million counted in 1999, but it is still a decrease compared to the 11.6 million of 1996. By far the biggest group of animals used was rodents and rabbits, as in the previous Reports. A significant increase in the use of fish has made the group of cold-blooded animals account for over 15 % of all animals used.

Protection of animals used for experimental and other scientific purposes

The objective of this report is to present to the Council and the European Parliament, in accordance with Article 26 of Directive 86/609/EEC the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU.

The EU 10 are reporting data for the first time, and, therefore, it is not possible to draw conclusions on the evolution of the use of animals for experimental purposes in the EU by comparing data with those of the previous reports. However, some comparisons in trends will be attempted and significant changes in use will be highlighted in the report. Malta informed the Commission that no animal experiments were carried out in their country in 2005.

The total number of animals used for experimental and other scientific purposes in 2005 in the 25 Member States (EU 25) amounts to 12.1 million (with data from France of 2004). The number of animals used in the EU 10 represents 8.6% of the total number of animals used in the EU 25.

As in previous reports rodents together with rabbits represent almost 78% of the total number of animals used in the EU. Mice are by far the most commonly used species covering 53% of the total use, followed by rats with 19%. The second most used group of animals was, as in previous years, cold-blooded animals representing 15%. The third biggest group of animals was birds with a little over 5% of the total use.

As in 2002, no Great Apes were used in experiments in the EU in 2005.

Protection of animals used for experimental and other scientific purposes

The Commission presents its sixth report on the statistics on the number of animals used for experimental and other scientific purposes in the EU, in accordance with Directive 86/609/EEC.

It gives an overview of the number of animals used in Member States for experimental purposes for the year 2008, with the exception of one Member State which provided data from 2007. As the two newest Member States Bulgaria and Romania have submitted data for the first time (representing below 1.0% of the total number of animals used in the EU 27), it is in principle not possible to draw accurate quantitative conclusions on the evolution of the use of animals for experimental purposes in the EU by comparing data with those of the previous reports. However, some comparisons in trends have been attempted, and significant changes in use have been highlighted in the report.

Overview: the total number of animals used for experimental and other purposes in 2008 in the 27 Member States EU is just above 12 million. As in previous reports rodents together with rabbits represent more than 80% of the total number of animals used in the EU. Mice are by far the most commonly used species accounting for 59% of the total use, followed by rats with 17%. The second most used group of animals was, as in previous years, cold-blooded animals which represent almost 10%. The third largest group of animals used was birds with a little over 6% of the total use.

As stated in the previous two statistical reports no Great Apes were used in experiments in the EU in 2008.

Comparison with previous years: the inclusion of the data from Bulgaria and Romania did not lead to an increase in the total number of animals. On the contrary, there is a decrease of more than 116,500 animals.

However, noticeable changes have occurred for the use of some individual species compared to data from the 2005 report.

Significant increases occurred in 2008 for mice, rabbits, pigs and 'other birds' where percentage changes ranged from 5% to 28%. The increase in the number of mice used since 2005 is 691,842 animals which represents 9.71% of the total number of mice used in 2008.

The total number of pigs, goats, prosimians, and reptiles has increased by between 28 - 46%.

On the other hand the total number of rats, guinea-pigs, other rodents, dogs, cattle and other mammals as well as amphibians and fish used has decreased substantially since the last report.

When expressed in percentages these decreases range from more than 70% to around 10%.

The largest percentile change has been noted in the decrease of the use of other carnivores.

However, these species are not used in great numbers (from 8711 to 2853). There is also a large decrease of 75% in the total number of 'other mammals'.

The following animals which are normally used in fewer numbers show an increase in use: ferrets (16%), horses, donkeys and cross-breeds (11%), goats (44%) and reptiles (39%). It is also worth noting the large decrease in the use of new world monkeys of 73% as well as a decrease of 11% of old world monkeys. As in 2002 and 2005, no great apes were used for experimental or other scientific purposes in 2008.