



COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT

pursuant to the second subparagraph of Article 189 b (2) of the EC-Treaty

**Common position adopted by the Council on 26 February 1998 on
the proposal for a European Parliament and Council Directive on
the legal protection of biotechnological inventions**

Communication from the Commission to the European Parliament
pursuant to the second subparagraph of Article 189b(2) of the Treaty

Subject: Common position adopted by the Council on 26 February 1998 on the proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions

1. Background

- On 25 January 1996 the Commission submitted a proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions.¹
- The Economic and Social Committee delivered its opinion on 11 July 1996.²
- Parliament delivered its opinion at first reading on 16 July 1997.³
- The Commission presented an amended proposal on 29 August 1997.⁴

2. Content of the Commission proposal

The aim of the proposal for a Directive is to establish clear provisions under which biotechnological inventions will enjoy the same level of protection by patent in all Member States. To this end, it elucidates the application of existing patent law. It incorporates a number of definitions and rules of interpretation which seek to clarify what can and what cannot be patented and to resolve the differentiation issues raised by plant production rights. It also lays down provisions designed to ensure that patent offices follow uniform practices in issuing patents and to achieve uniform national case-law, particularly as regards inventions whose commercial exploitation would be contrary to public policy or morality. Finally, the proposal determines the scope of the protection provided by a patent on a biotechnological invention.

Following Parliament's rejection of the joint text, approved by the Conciliation Committee, for a European Parliament and Council Directive on the legal protection of biotechnological inventions,⁵ Parliament and the Council determined that the legal protection of biotechnological inventions required clarification.

¹ OJ No C 296, 8.10.1996, p. 4.

² OJ No C 295, 7.10.1996, p. 11.

³ OJ No C 286, 22.9.1997, p. 87.

⁴ OJ No C 311, 11.10.1997, p. 12.

⁵ OJ No C 68, 20.3.1995, p. 26.

The situation which led to the first proposal in 1988⁶ applies equally today, as regards both the expanding market for biotechnological products and lack of certainty about the application of existing patent law. This uncertainty is liable to hamper the workings of the single market and investment in product research or research into new biotechnological techniques.

3. Remarks on the common position

3.1 General observations

Acting by qualified majority, the Council endorsed the approach taken in the Commission's amended proposal incorporating Parliament's amendments at first reading. It thereby acknowledged that the two issues of most importance to Parliament - the patentability of individual parts of the human body and the ethical aspect of biotechnological inventions - had to be dealt with directly under patent law.

3.2 Amendments adopted by Parliament at first reading

The amendments accepted by the Commission and incorporated into its amended proposal have also been incorporated into the common position. They are as follows:

Amendment 1	Recital 19
Amendment 2	Recital 3
Amendment 3	Recital 4
Amendment 5	Recital 9
Amendment 6	Recital 10
Amendment 7	Recital 11
Amendment 8	Recital 12
Amendment 9	Recital 14
Amendment 11	Recital 16
Amendment 12	Recital 17
Amendment 13	Recital 18
Amendment 14	Recital 20
Amendment 15	Recital 21
Amendments 16, 99, 17 and 79	Recitals 22-28
Amendment 18	Recital 29
Amendment 19	Recital 30
Amendment 20	Recital 31
Amendment 21	Recital 32
Amendment 22	Recital 33
Amendment 23	Recital 34
Amendment 24	Recital 35
Amendment 26	Recital 36
Amendment 27	Recital 37

⁶ OJ No C 10, 13.1.1989, p.3.

Amendment 28	Recital 21 of the original proposal deleted
Amendment 80	Recital 38
Amendment 30	Recital 39
Amendment 31	Recital 40
Amendments 10 and 33	Recital 43
Amendment 34	Recital 45
Amendment 35	Recital 50
Amendment 36	Recital 53
Amendment 37	Recital 54
Amendment 38	Article 16(b)
Amendment 39	Article 16(c)
Amendments 40, 67 and 68	Article 1(2)
Amendments 41, 42, 77 and 43	Recital 55
Amendment 44	Recital 56
Amendment 48	Articles 2 and 3
Amendment 47	Article 4
Amendments 100 and 49	Article 5
Amendment 50	Article 4 of the original proposal deleted
Amendment 51	Article 5 of the original proposal deleted
Amendment 52	Article 6 of the original proposal deleted
Amendment 53	Article 7 of the original proposal deleted
Amendment 54	Article 8 of the original proposal deleted
Amendment 76/rev.	Recitals 26 and 27
Amendment 55	Article 6
Amendment 78	Article 7
Amendment 57	Article 8(2)
Amendment 58	Article 9
Amendment 59	Article 11(2)
Amendment 60	Article 12(3)(b)
Amendment 61	Article 12(4)
Amendment 62	Article 17 of the original proposal deleted
Amendment 63	Article 15(1), first subparagraph
Amendment 64	Article 16(a)

3.3 Amendments tabled during the Council discussion

Recital 22

The Council thought it appropriate to incorporate into Recital 22 the content of Recitals 16c and 16e, proposed by Parliament's Amendment 16. The technical content of these recitals is similar and may be incorporated into a single statement.

Recitals 24 and 25

The Council thought it preferable to divide Recital 16d, proposed by Parliament's Amendment 16, into two separate recitals. The first part of Recital 16d relates to the conditions governing patentability, particularly the need to respect the criterion of industrial application. The second part refers to the scope of the protection provided by a patent. In order to avoid confusion of any sort, the Council therefore decided that the technical content of this recital would be clearer if it were divided into two separate recitals.

Recital 26

This recital incorporates Recital 16g, proposed by Parliament's Amendment 17. The Council has altered the wording slightly in order to emphasise that the verification of consent is necessarily subject to the principle of subsidiarity.

Recital 27

This recital is new. It incorporates to some extent the idea behind paragraph 1 of Amendment 76/rev, which the Commission was unable to accept as part of its amended proposal. The Council took the view that the most appropriate approach was for the inventor voluntarily to provide information on the geographical origin of the biological material used for the invention.

Recital 33

Parliament's Amendment 22 defined with some technical precision the concept of an essentially biological procedure for the breeding of plants and animals. To avoid any problems of interference between Article 2(2) of the draft Directive, which defines this idea, and Recital 33, the Council thought it preferable that the technical aspects of the concept should be incorporated into Article 2(2). As a result, Recital 33 now reads like a statement of the issue.

Recital 19c of the amended proposal

Recital 19c of the amended proposal corresponded to Recital 19d as proposed by Parliament's Amendment 26. However, the Commission took the view that the final part of the recital should not be included, as it could lead to confusion between compliance with the conditions governing patentability and the need to respect the procedures relating to authorisation of commercial exploitation. The Council noted that what remained of Recital 19c was still open to misinterpretation. It therefore decided not to incorporate it into its common position.

Recital 39

The wording of Recital 39, incorporating Parliament's Amendment 30, has been amended to some extent. The Council thought it more appropriate to take the view that it is the ethical and moral principles which correspond to public order and morality in the Member States. This is closer to the context of Article 6.

Recital 41

The Council deemed it necessary to amend the wording used by the Commission in its amended proposal so as to make it more precise. As regards the definition of processes for the cloning of human beings, it became apparent that the technique of embryo splitting needed to be taken into consideration, in the same way as the technique based on replacement of the nucleus.

Recital 42

The Council thought it important to incorporate this new recital, which includes the details necessary for a full understanding of the scope of the exclusion from patentability of the uses of embryos referred to in Article 6(2)(c).

Recital 43

The Council took the view that, as regards references to the protection of human rights, it was not appropriate for a directive harmonising national laws to refer to a convention which has not yet entered into force and which has not been signed by all Member States. This is why Recital 43 no longer refers to the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of 19 November 1996. As regards the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950, the Council took the view that it was more appropriate to refer to Article F(2) of the Treaty on European Union.

Recital 44

This new recital refers to the European Group on Ethics in Science and New Technologies, which replaces the Group of advisers on ethics and biotechnology. The remit of this new group has been broadened to include sciences and new technologies, including biotechnology. Recital 44 defines the precise context in which the European Group on Ethics will operate.

Recital 45

The Council considered it necessary to extend the criteria for substantial medical benefit by referring to research and prevention, in addition to diagnosis and therapy.

Recital 35 of the amended proposal

The Council took the view that it was more appropriate to transfer the content of this recital to the main body of the text. Article 16 of the amended proposal called on the Commission to draw up a report for Parliament and the Council. There would thus have been little point in a recital's laying down the same requirement. The Council decided it made more sense to place this stipulation in a single article. As a result, Recital 35 of the amended proposal has been deleted and an addition made to Article 16.

Recital 36 of the amended proposal

See the remarks on Recital 35.

Article 1

The Council took the view that it was not appropriate to mention in Article 1(2) Member States' rights in relation to international agreements which are not liable to be affected by the Directive. Only the Member States' obligations must be mentioned here.

Article 2

The Council thought it more appropriate that Article 2(2) should incorporate all the technical aspects of the definition of an essentially biological process for the production of plants or animals (see remarks on Recital 33).

Article 6

The Council considered it more accurate to replace the expression 'procedures for human reproductive cloning' by the expression 'processes for cloning human beings' in paragraph 2(a). Recital 41 defines such procedures.

In Article 6(2)(c), the Council decided to replace the expression 'methods in which human embryos are used' by 'uses of human embryos for industrial or commercial purposes'. Recital 42 clarifies the nature of such uses.

Article 7

The Council thought it more advisable to say that the European Group on Ethics in Science and New Technologies 'evaluates' all ethical aspects of biotechnology, rather than that it 'shall assess' such aspects. Recital 44 describes the scope of such evaluation.

Article 11

The Council deemed it necessary to harmonise the wording used in paragraphs 1 and 2, so as to avoid difficulties of interpretation.

Article 12

As regards paragraph 4, the Council decided that it was important to refer to Article 29 of Regulation (EC) No 2100/94 in cases where a licence for a plant variety can be granted only by the Community Plant Variety Office.

Article 15

As regards paragraph 1, the Council thought it more advisable for the deadline for the entry into force of the Directive in the Member States to be set for a particular date after the date of the Directive's publication in the Official Journal of the European Communities.

Article 16

As noted in the remarks on Recitals 35 and 36 of the amended proposal, the Council considered it more advisable for the reports which the Commission is to draw up for Parliament and the Council to be referred to in an article.

As regards (c), it should be noted that the Council decided that the Commission's annual report on the development of patent law in the field of biotechnology and genetic engineering should also consider the implications of such development.

3.4 Commission position on the amendments tabled by the Council

The Commission accepted the amendments arising from the Council's discussions.

4. Conclusions

The Commission believes that the common position incorporates and completes as appropriate the amendments accepted at first reading. Moreover, the Council has made a number of changes which constitute technical improvements to the amended proposal.