1994AG0409(04)

COMMON POSITION (EC) No 4/94 adopted by the Council on 7 February 1994 with a view to adopting European Parliament and Council Directive 94/. . ./EC of . . . on the legal protection of biotechnological inventions

Official Journal C 101 , 09/04/1994 P. 0065

COMMON POSITION (EC) No 4/94 adopted by the Council on 7 February 1994 with a view to adopting European Parliament and Council Directive 94/. . ./EC of . . . on the legal protection of biotechnological inventions (94/C 101/04)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 189b of the Treaty establishing the European Community;

(1) Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the Member States and such differences could create barriers to trade and to the creation and proper functioning of the internal market;

(2) Whereas such differences in legal protection could well become greater as Member States adopt new and different legislation and administrative practices or as national case law interpreting such legislation develops differently;

(3) Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will definitely be of fundamental importance for the Community's industrial development;

(4) Whereas the legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law;

(5) Whereas the rules of national patent law remain the essential basis as far as the legal protection of biotechnological inventions is concerned; whereas, however, they must be adapted or supplemented in certain specific respects in order to take fully into account technological developments involving biological material but which also fulfil the requirements for patentability;

(6) Whereas no prohibition or exclusion exists in national or international patent laws which precludes the patentability of living matter as such;

(7) Whereas in implementing the Directive regard should be had to existing national patent laws, as amended by the Directive; whereas those laws contain provisions on the criteria for patentability or exclusion from patentability, including provisions to the effect that a patent may not be granted in respect of inventions the publication or exploitation of which would be contrary to public policy or morality;

(8) Whereas it is advisable to include in the body of the Directive such a reference to public policy and morality in order to highlight the fact that some applications of biotechnological inventions, by dint of some of their consequences or effects, are capable of offending against them;

(9) Whereas the body of the Directive should also mention a list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to public policy or morality;

(10) Whereas, in the light of the general principle that the ownership of human beings is excluded, the human body or parts of the human body as such, for example a gene, protein or cell in the natural state in the human body, including germ cells and products resulting directly from conception, must be excluded from

patentability, but isolated parts of the human body should not be unpatentable merely because of their human origin, it being understood that the parts of the human body from which such isolated parts are derived are excluded from patentability;

(11) Whereas, however, isolated human nucleic acids having no described application other than the expected properties attributable to any such nucleic acid, for example their ability to be used as a probe or as a primer for synthesis of further copies of nucleic acid, should be unpatentable;

(12) Whereas processes for modifying the genetic identity of the human body which are contrary to the dignity of man must be excluded from patentability;

(13) Whereas, even if it were possible to obtain a patent for a process for modifying genetic identity, for example a process which would enable a modification of the human genetic code to be controlled in connection with in vitro fertilization intended to correct certain genetic deficiencies, such a process should be compatible with the dignity of man. This assessment must take account of the therapeutic aims which the process would enable to be achieved. Even if this condition were fulfilled, that would in no way imply automatic recognition of the patentability and legitimacy of what is known as germ gene therapy since, if such a patent were to be granted, the national or Community authorization procedures applying to this type of therapy would of necessity have to be observed before any use of this therapy;

(14) Whereas the principle currently recognized by the laws of the Member States and by the Convention on the Grant of European Patents that methods of treatment of human or animal bodies by surgery or therapy or of diagnosis practised on human or animal bodies are not capable of industrial application remains applicable, having regard to the practice which has developed in this respect, to processes for modifying the genetic identity of human beings which are consonant with human dignity;

(15) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal and the products of such processes must likewise be excluded from patentability in so far as the suffering or physical handicaps inflicted on the animals concerned are out of proportion to the objective pursued;

(16) Whereas national patent systems have in the past adapted to technical developments and scientific breakthroughs in according patent protection to such developments;

(17) Whereas the investments required in research and development, particularly for genetic engineering, are especially high and especially risky and the possibility of recouping that investment can only effectively be guaranteed through adequate legal protection;

(18) Whereas without effective and harmonized protection throughout the Member States of the Community such investments might well never be made;

(19) Whereas some inventions developed through biotechnology and genetic engineering are at present not clearly protected in all Member States by existing legislation, administrative practice or case law, and such protection, where it exists, is not the same or has different attributes;

(20) Whereas the uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could result in the creation of new disincentives to trade to the detriment of further industrial development in such inventions and of the smooth operation of the internal market;

(21) Whereas existing differences having such effects need to be removed and new ones having a negative impact on the functioning of the common market and the development of trade in biotechnological goods and services prevented from arising;

(22) Whereas international developments in the field of legal protection of the results of biotechnology and genetic engineering demonstrate the advantages to be gained from approximation of national legislation;

(23) Whereas scientific and technological progress is often the result of international collaboration on research and, in consequence, it is desirable to ensure that biotechnological inventions may benefit from cpmparable protection on an international level;

(24) Whereas although international instruments exist or are under consideration to harmonize various aspects of the legal protection of biotechnological inventions, they are not entirely sufficient for the needs of Community science and industry and a Community market;

(25) Whereas the patent laws applicable at present in the Member States contain disparities which hinder the development of trade in biotechnological goods and services, distort competition within the common market and therefore directly affect the establishment and functioning of that market; whereas it is particularly important to remove these disparities because there is an urgent need to ensure that undertakings will be offered the possibility of obtaining effective and equivalent legal protection in all Member States for the results

of their research activities;

(26) Whereas harmonization of the laws of the Member States is also necessary to clarify certain concepts in national laws originating in certain international patent and plant variety conventions which have led to some vagueness as to the possibility of protecting biotechnological inventions concerning plant matter and microbiological inventions, concepts such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals;

(27) Whereas it is necessary to encourage potential innovation in the full range of human endeavours by recognizing that human intervention and its impact on the result achieved must be taken into account in determining whether the exclusion from patentability of essentially biological processes applies, it being understood that a process which, taken as a whole, does not exist in nature and is more than a mere traditional breeding process is patentable;

(28) Whereas the legislation of the Member States should be harmonized in such a way so as not to conflict with the existing international conventions on which several Member States' patent and plant variety laws are based;

(29) Whereas the Community's legal framework for the protection of biotechnological inventions can be limited to laying down certain principles as they appoly to the patentability of biological material as such, to the ability to us a deposit mechanism in supplementing written descriptions to satisfy the disclosure requirements for patent application procedures, to a reversal of the burden of proof and to the right to a non-exclusive compulsory licence for plant varieties;

(30) Whereas, in view of the fact that the function of a patent is to reward the inventor with an exclusive but time-bound right for his creative efforts and thereby encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducible material in situations analogous to those where it would be permitted to prohibit such use of patented, non-self-reproducible products, namely in respect of the production of the patented product itself;

(31) Whereas it is necessary to provide for a derogation from the rights of the holder of the patent when the propagating material incorporating the protected invention is sold to a farmer by the holder of the patent or with his consent;

(32) Whereas that derogation must authorize the farmer to use the product of his harvest for further multiplication or propagation on his own farm;

(33) Whereas the extent and the conditions of that derogation must be limited in accordance with the corresponding extent and conditions of Community plant variety rights;

(34) Whereas only the fee envisaged under Community plant variety rights as a condition of application of the derogation from Community plant variety rights can be required of the farmer;

(35) Whereas, however, the holder of the patent may defend his rights against a farmer abusing the derogation or against the breeder who developed the plant variety incorporating the protected invention if the latter fails to adhere to his commitments;

(36) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access against a fee must be granted in a Member State in the form of a compulsory licence where, in relation to the genus or species concerned, public interest demands the exploitation of the plant variety for which the licence is requested and the plant variety represents significant technical progress;

(37) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access against a fee must be granted in the form of a compulsory licence where public interest demands the exploitation of the invention for which the licence is requested and where the invention represents significant technical progress;

(38) Whereas this Directive should be without prejudice to national and Community laws on the monitoring of the applications of research and of the use or commercialization of its results, notably from the point of view of the requirements of public health, safety, the protection of the environment, the protection of animals, the preservation of genetic diversity and compliance with certain ethical standards.

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I Patentability

Article 1

Member States shall protect biotechnological inventions under national patent law. Member States shall if necessary adjust their national patent law to take account of the provisions of this Directive.

Article 2

1. The subject-matter of an invention shall not be considered unpatentable merely on the grounds that it is composed of, uses or is applied to biological material.

2. 'Biological material' within the meaning of this Directive means any material containing genetic information and capable of self-reproducing or capable of being reproduced in a biological system.

3. Inventions shall be considered unpatentable where publication or exploitation would be contrary to public policy or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Member States.

On this basis, the following inter alia shall be unpatentable:

(a) the human body or parts of the human body as such;

(b) processes for modifying the genetic identity of the human body contrary to the dignity of man;

(c) processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and animals resulting from such processes.

Article 3

Biological material, including plants and animals, as well as parts of plants and animals, except plant and animal varieties as such, shall be patentable.

Article 4

Uses of plant or animal varieties and processes for their production, other than essentially biological processes for the production of plants or animals, shall be patentable.

Article 5

1. Microbiological processes shall be patentable. For the purposes of this Directive 'microbiological process' means a process involving or performed upon or resulting in microbiological material.

2. A process consisting of a succession of steps shall be treated as a microbiological process if at least one essential step of the process is microbiological.

Article 6

Essentially biological processes for the production of plants or animals shall not be considered patentable. In determining this exclusion, human intervention and its effects on the result obtained shall be taken into account. A process which, taken as a whole, does not exist in nature and is more than a traditional breeding process shall be considered patentable.

Article 7

An invention concerning a biological material shall not be considered a discovery or lacking in novelty merely on the grounds that it formed part of an existing material.

Article 8

A process comprising a succession of steps shall not be excluded from patentability merely on the grounds that one or more of the steps involve a method of treatment of the animal body by surgery or therapy or a diagnostic method practised on the animal body. This treatment or diagnostic method shall not, however, be protected as such.

CHAPTER II Scope of protection

Article 9

1. The protection conferred by a patent on a biological material possessing, as a result of the invention, specific characteristics shall extend to any biological material derived from that biological material through multiplication or propagation in an identical or different form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables the production of a biological material possessing, as a result of the invention, specific characteristics shall extend to biological material directly obtained using that process and to any other biological material derived from the biological material directly obtained through multiplication or propagation in an identical or different form and possessing those same characteristics. The protection thus conferred on the product obtained using the process shall not affect the exclusion from patentability of plant and animal varieties as such provided for in Article 3 of this Directive.

Article 10

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material in which the product is incorporated and in which the genetic information is contained and expressed.

Article 11

The protection referred to in Articles 9 and 10 shall not extend to biological material obtained from the multiplication or propagation of biological material marketed in the territory of a Member State by the holder of the patent or with his consent, if the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the obtained material is not subsequently used for other multiplication or propagation.

Article 12

By way of derogation from Articles 9 and 10, the sale of propagating material to a farmer by the holder of the patent or with his consent implies authorization for the farmer to use the product of his harvest for further reproduction or propagation by him on his own farm, the scope of and procedure for this derogation being limited to those relating to the corresponding exception under Community law on plant variety rights.

CHAPTER III Compulsory cross-licensing

Article 13

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States may provide that where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

2. Where the holder of a patent on a biotechnological invention cannot exploit it without infringing a prior plant right on a variety, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right inasmuch as the licence is necessary for the exploitation of his invention, subject to payment of an appropriate royalty. Member States may provide that where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

(a) they applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;

(b) exploitation of the plant variety or the invention for which the licence is requested is dictated by the public interest and the plant variety or the invention constitutes significant technical progress.

4. Each Member State shall designate the authority or authorities responsible for granting the licence.

CHAPTER IV Deposit, access and re-deposit of a biological material

Article 14

1. Where an invention involves the use of or concerns a biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the description shall be considered inadequate for the purposes of patent law unless:

(a) the biological material has been deposited, no later than the date on which the patent application was filed with a recognized depositary institution. At least the international depositary authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the international recognition of the deposit of micro-organisms for the purposes of patent procedure, hereinafter referred to as the Budapest Treaty, shall be recognized;

(b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited;

(c) the patent application states the name of the depositary institution and the accession number.

2. Access to the deposited biological material shall be provided through the supply of a sample:

(a) up to the first publication of the patent application, only to those persons who are authorized under national patent law;

(b) between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

(c) after the patent has been granted, and notwithstanding subsequent revocation or cancellation of the patent, to anyone requesting it.

3. The sample will be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

(a) not to make it or any matter derived therefrom available to third parties and

(b) not to use it or any matter derived therefrom except for experimental purposes,

unless the patent holder or applicant, as applicable, expressly waives such an undertaking.

4. At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed. In the abovementioned case, paragraph 3 shall apply.

5. The applicant's requests referred to in paragraphs 2 (b) and 4 may only be made up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.

Article 15

1. If the biological material deposited in accordance with Article 14 ceases to be available from the recognized depositary institution, a new deposit of the material shall be permitted on the same terms as those laid down in the Budapest Treaty.

2. Any new deposit shall be accompanied by a statement signed by the applicant certifying that the newly deposited biological material is the same as that originally deposited.

CHAPTER V Burden of proof

Article 16

1. If the subject matter of a patent is a process for obtaining a new product, the same product when produced by any other party shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process.

2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

CHAPTER VI Transitional and final provisions

Article 17

Pending the entry into force of the Council Regulation on Community plant variety rights, a farmer's entitlement to use the product of his own farm's harvest for further multiplication or propagation on his own farm shall be governed by national laws, rules or practice.

Article 18

This Directive shall not affect national and Community laws on the monitoring of the applications of research and of the use or commercialization of its results.

Article 19

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 1997.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 20

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

Article 21

This Directive is addressed to the Member States.

Done at . . ., . . .

For the European Parliament

The President

For the Council

The President

(1) OJ No C 10, 13. 1. 1989, p. 3.

(2) OJ No C 159, 26. 6. 1989, p. 10.

THE COUNCIL'S REASONS

I. Introduction

On 20 October 1988 the Commission forwarded to the Council a proposal for a Directive on the legal protection of biotechnological inventions (1).

The European Parliament gave its opinion on first reading on 29 October 1992, suggesting a number of amendments to the Commission proposal (2).

The Economic and Social Committee had delivered its opinion on 26 April 1989 (3).

In response to the opiniion of the European Parliament, the Commission submitted an amended proposal for a Directive (4) to the Council on 16 December 1992, in accordance with Article 149 (3) of the EC Treaty.

The Council made a number of amendments to the amended Commission proposal which are explained below. The Commission was able to agree to all these amendments.

On 7 February 1994 the Council adopted a common position on the Directive by a qualified majority, with the Danish, Spanish and Luxembourg delegations voting against. The legal basis adopted by the Council is Article 100a of the EC Treaty.

II. Aim of the Commission proposal

The purpose of this proposal for a Directive is to lay down clear provisions to provide an equal level of patent protection for biotechnological inventions in all the Member States. To this effect, it contains a series of definitions and rules of interpretation which are designed to specify clearly what is or is not patentable and to settle demarcation difficulties which arise in connection with plant variety rights. The proposal further contains provisions designed to make the patent offices of the Member States follow a uniform procedure for granting patents, and also result in a uniform national judicial practice. Lastly, it lays down the extent of protection given by a patent on a biotechnological invention.

This need to supplement patent law is vital in view of the growth in de market for biotechnoilogical products and the uncertainty surrounding the application of existing patent law, an uncertainty which may hamper free circulation of biotechnological products and investment in research into new biotechnological products or processes.

III. Outcome of the amendments suggested by the European Parliament and adopted by the Commission

1. Subject to the remarks in paragraph 2 the Council accepted the substance of the following of Parliament's amendments adopted by the Commission, in the same or similar wording.

>TABLE>

2. The Council made the following amendments or clarifications to the amended Commission proposal (5), although the content of the proposed provisions is not thereby changed; nor, consequently, is the import of the amendments suggested by the Parliament. All these amendments or clarifications were agreed to by the Commission:

2.1. With regard to Article 2 (3), on the ethical aspects of the patentability of biotechnological inventions, the Council

2.1.1. - stated in recital 10 and in new recital 11 (6) what in its view should be the scope of the exclusion from patentability of parts of the human body required by point (a) of the second subparagraph in paragraph 3

2.1.2. - removed from point (b) of the aforementioned provision the reference to the non-therapeutic purpose of (unpatentable) processes intended to modify the genetic identity of the human body, since the concept of

the dignity of man should be paramount in this context; the Council also inserted a new recital 13 on this subject which in its view, by referring to processes for modifying genetic identity in general and germ gene therapy in particular, might provide guidance on the scope which it wanted to accord to the unpatentability of those processes, in so far as they are contrary to the dignity of man;

2.1.3. - extended the scope of point (c) of the aforementioned second subparagraph, stating that animals resulting from such processes are also unpatentable.

2.2. Since Article 2 (4) has no direct connection with the patentability of biotechnological inventions, the Council placed it at the end of the Directive as a new Article 18.

2.3. The wording of Article 6, which augments Article 4, was aligned with that of Article 4 by insertion of the words '(processes) for the production of plants or animals'.

This improvement is also more in line with amendment No 23 suggested by the Parliament (7).

2.4. Article 11

2.4.1. The Council wanted to restrict the exemption resulting from the reference to Article 9 to cases where the biological material marketed by the holder of the patent (or with his consent) is actually used for the multiplication or propagation intended. It therefore added the words 'provided that the obtained material is not subsequently used for other multiplication or propagation'.

2.4.2. The Council also introduced a further derogation by adding to the reference to Article 9 a reference to Article 10.

2.5.1. With regard to the substance of Article 12 on farmer's privilege, the Council adopted only the first part of the Commission proposal, concering plant varieties (8).

On this point, the Council was careful to ensure that the derogation provided for farmers exactly matched that to be adopted for their benefit as part of the future Community legislation on plant variety rights, so that the rights resulting from implementation of this Directive would not be in conflict with those resulting from Community legislation on plant variety rights. A reference to the 'scope and procedure' relating to 'the corresponding exception under Community law on plant variety rights' was therefore inserted in Article 12.

In addition, among the new recitals relating to Article 12, recitals 32 to 35 are intended to define the scope of farmer's privilege.

2.5.2. To cover the theoretical possibility, considered unlikely by the Council, that the Community Regulation on new plant varieties is not yet in force by the deadline set for transposition of this Directive (1 January 1997), Article 17 provides for the maintenance of the status quo until the entry into force of that Regulation.

2.6. With regard to Article 13 on compulsory licences, the amended Commission proposal was adopted by the Council more or less in its entirety, although in a considerably different form. In this context, the following details are worthy of note:

2.6.1. The present paragraph 1 corresponds to the proposed paragraph 1; the present paragraph 2 corresponds to the proposed paragraph 3.

The present paragraph 3 groups together the material and formal conditions for granting a licence.

The present paragraph 4 corresponds to the proposed paragraph 2.

The proposed paragraph 4 was deleted, as the Council considered Member States' general legislative principles on the matter to be sufficient.

2.6.2. At the request of several members of the Council the concept of the public interest as a material condition for granting a licence (paragraph 3 (b)) was augmented by the requirement that the plant variety or the invention for the exploitation of which the licence is requested must constitute significant technical progress.

2.6.3. The Council introduced into the Commission proposal the option for Member States to provide for the granting of cross-licences, i.e. licences to persons who have themselves been required to grant licences (last sentences of paragraphs 1 and 2). This option thus broadly corresponds to paragraphs 2 and 4 of amendment No 34, which were not adopted by the Commission in its amended proposal. The Commission agreed to the inclusion of this option.

2.7. With regard to Article 14 on the deposit, access to and re-deposit of a biological material, the Council

2.7.1. - deleted from paragraph 3 (b), 'in any country' as this terms created difficulties for certain members of the Council,

2.7.2. - deleted from paragraph 4 the reference to revocation and cancellation of the patent, as it considered that in accordance with a practice now widely recognized, the deposited sample of the microbiological organism must be accessible after issue of the patent to anyone requesting it, and remain accessible even if the patent is subsequently cancelled; the Council also amended paragraph 2 (c) accordingly;

2.7.3. - added a useful rule of procedure with a new paragraph 5.

2.8. With regard to Article 15, the Council felt it appropriate to reintroduce, as paragraph 2, a provision aimed at facilitating control of the identity of the sample by the depositary institution. The Commission had included such a provision in its original proposal but deleted it in its amended proposal. The Commission agreed to its reinsertion by the Council.

2.9. In Article 19, the Council considered it realistic to set 1 January 1997 as the deadline for transposition of the Directive.

3. However, the Council did not accept the following European Parliament amendments adopted in the same or similar wording by the Commission in its amended proposal. The Commission endorsed the Council's amendments.

3.1. Amendment No 20, first and third paragraphs

The Commission made these two paragraphs into Article 8 of its amended proposal, stipulating that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not patentable, but that products for use in such methods are.

Although it was in agreement with the content of the proposed Article 8, which in fact reproduced word for word Article 52 (4) of the European Patent Convention, the Council preferred not to adopt this provision as an article, in view of the risk of differing interpretations of the phrase 'for a non-therapeutic purpose' occurring in point (b) of the second subparagraph of Article 2 (3) of the amended proposal (9). The Council did however include the content of Article 8 in a new recital (No 14).

3.2. Amendment No 32, paragraph 2

The Council could not at this stage accept a farmer's privilege for breeding cattle as proposed by the Commission in its amended proposal.

Any such privilege would be in conflict with the fundamental principle of patent law according to which the holder of a patent may prohibit any third party from using the protected invention. The Council does not see any valid reason for departing from this principle to the benefit of one category of individuals (farmers), which in any case would be difficult to define.

For the Council the decisive difference as compared with the situation in the field of plant variety rights (where it acknowledged farmer's privilege in principle) is that, in the latter case, a derogation from the rights of holders of patents on plant varieties in favour of farmers will be provided for in a Community regulation which is about to be finalized. It is precisely within the limits of that derogation that the Council acknowledged farmer's privilege in order to avoid possible contradictions with regard to farmer's rights (10).

The situation could of course change in the future, should there be Community rules on the subject of animal variety rights including a derogation in favour of livestock farmers. However, no such rules are contemplated at present.

IV. Outcome of the amendments suggested by the European Parliament but not adopted in the amended Commission proposal

1. The amendments concerned are numbers 1 to 8, 10 to 12, 21, 26 to 28, 33 and 47.

The Council considers the Commission's decision not to adopt these amendments to be justified, and is in broad agreement with the reasons adduced by the Commission (11).

2. With regard to amendment No 17, the basic idea of which the Commission claims to have incorporated in its proposal for point (c) of the second subparagraph of Article 2 (3) (12), the Council believes that the Commission was right not to accept the amendment more explicitly, since the amendment's rather vague wording would be unlikely to lend itself to precise implementation by the Member States and their competent authorities.

3. With regard to amendment No 23 which the Commission says it did not accept (13), the Council considers that this amendment was adequately covered

- in Article 4, which states that processes by which plant or animal varieties are obtained are in principle patentable, and

- in Article 6, which states that essentially biological processes for obtaining plant or animal varieties are not patentable.

(1) OJ No C 10, 13. 1. 1989, p. 3.

(2) OJ No C 305, 23. 11. 1992, p. 173.

(3) OJ No C 159, 26. 6. 1989, p. 10.

(4) OJ No C 44, 16. 2. 1993, p. 36.

(5) The numbering of Articles is that in the common position.

(6) The first and third paragraphs were not retained; see point 3.1.

(7) The Council considers that the substance of amendment No 23 is contained in Articles 4 and 6. See IV.3.

(8) Paragraph 2 was not retained; see point 3.2.

(9) Only amendments or amplifications of some degree of substantive importance are mentioned.

(10) Numbering of recitals follows that in the common position.

(11) See also IV.3.

(12) Article 13 (1) of the Commission proposal. On farmer's privilege with regard to cattle for breeding (Article 13 (2)), see point 3.2.

(13) This phrase was deleted at a late stage of discussions.

(14) Contradictions of this kind could result e.g. where a farmer is authorized under the future regulation on new plant varieties to use a particular variety, but is prohibited from such use under patent law. See also 2.5.1.

(15) See COM(92) 589 final of 16 December 1992, containing the amended proposal.

(16) Last paragraph on page 11 of COM 589.

(17) Commentary on Article 4 (page 13 of COM 589). See also point III.2.3.