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COMMON POSITION (EC) No 19/98 adopted by the council on 26 February 1998 with a view to adopting Directive 98/.../EC of the European Parliament and of the Council on the legal protection of biotechnological inventions

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COMMON POSITION (EC) No 19/98 adopted by the council on 26 February 1998 with a view to adopting Directive 98/. . ./EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (98/110/02)

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 (3),

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

(2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

(4) Whereas following the European 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 (4), the European Parliament and the Council have determined that the legal protection of biotechnological inventions requires clarification;

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

(6) Whereas such differences could well become greater as Member States adopt new and different legislation and administrative practices, or whereas national case-law interpreting such legislation develops differently;

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

(8) Whereas 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; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;

(9) Whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts in national laws based upon international patent and plant variety conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said uncertainty;

(10) Whereas regard should be had to the potential of the development of biotechnology for the environment

and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground; whereas the patent system should be used to encourage research into, and the application of, such processes;

(11) Whereas the development of biotechnology is important to developing countries, both in the field of health and combating major epidemics and endemic diseases and in that of combating hunger in the world; whereas the patent system should likewise be used to encourage research in these fields; whereas international procedures for the dissemination of such technology in the Third World and to the benefit of the population groups concerned should be promoted;

(12) Whereas the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) (5) signed by the European Community and the Member States, has entered into force and provides that patent protection must be guaranteed for products and processes in all areas of technology;

(13) Whereas the Community's legal framework for the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of biological material as such, such principles being intended in particular to determine the difference between inventions and discoveries with regard to the patentability of certain elements of human origin, to the scope of protection conferred by a patent on a biotechnological invention, to the right to use a deposit mechanism in addition to written descriptions and lastly to the option of obtaining non-exclusive compulsory licences in respect of interdependence between plant varieties and inventions, and conversely;

(14) Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;

(15) Whereas no prohibition or exclusion exists in national or European patent law (Munich Convention) which precludes a priori the patentability of biological matter;

(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;

(17) Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system;

(18) Whereas, since the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or 'orphan` diseases, the Community and the Member States have a duty to respond adequately to this problem;

(19) Whereas account has been taken of Opinion No 8 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission;

(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;

(22) Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial

sequence must be disclosed in the patent application as filed;

(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;

(24) Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;

(25) Whereas, for the purposes of interpreting rights conferred by a patent, when sequences overlap only in parts which are not essential to the invention, each sequence will be considered as an independent sequence in patent law terms;

(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law;

(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;

(28) Whereas this Directive does not in any way affect the basis of current patent law, according to which a patent may be granted for any new application of a patented product;

(29) Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;

(30) Whereas the concept 'plant variety` is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties;

(31) Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants;

(32) Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process;

(33) Whereas it is necessary to define for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological;

(34) Whereas this Directive shall be without prejudice to concepts of invention and discovery, as developed by national, European or international patent law;

(35) Whereas this Directive shall be without prejudice to the provisions of national patent law whereby processes for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability;

(36) Whereas the TRIPs Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law;

(37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against ordre public or morality must also be stressed in this Directive;

(38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to ordre public and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;

(39) Whereas ordre public and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the

invention;

(40) Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against ordre public and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings;

(41) Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being;

(42) Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;

(43) Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law;

(44) Whereas the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law;

(45) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit in terms of research, prevention, diagnosis or therapy to man or animal, and also animals resulting from such processes, must be excluded from patentability;

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

(47) Whereas it is necessary to provide for a first derogation from the rights of the holder of the patent when the propagating material incorporating the protected invention is sold to a farmer for farming purposes by the holder of the patent or with his consent; whereas that initial derogation must authorise the farmer to use the product of his harvest for further multiplication or propagation on his own farm; whereas the extent and the conditions of that derogation must be limited in accordance with the extent and conditions set out in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (6);

(48) Whereas only the fee envisaged under Community law relating to plant variety rights as a condition for applying the derogation from Community plant variety rights can be required of the farmer;

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

(50) Whereas a second derogation from the rights of the holder of the patent must authorise the farmer to use protected livestock for agricultural purposes;

(51) Whereas the extent and the conditions of that second derogation must be determined by national laws, regulations and practices, since there is no Community legislation on animal variety rights;

(52) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;

(53) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest;

(54) Whereas Article 34 of the TRIPs Agreement contains detailed provisions on the burden of proof which are binding on all Member States; whereas, therefore, a provision in this Directive is not necessary;

(55) Whereas following Decision 93/626/EEC (7) the Community is party to the Convention on Biological Diversity of 5 June 1992; whereas, in this regard, Member States must give particular weight to Articles 3 and

8(j), the second sentence of Article 16(2) and Article 16(5) of the Convention when bringing into force the laws, regulations and administrative provisions necessary to comply with this Directive;

(56) Whereas the Third Conference of the Parties to the Biodiversity Convention, which took place in November 1996, noted in Decision III/17 that 'further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPs Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity`,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I Patentability

Article 1

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

2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

Article 2

1. For the purposes of this Directive,

(a) 'biological material` means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

(b) 'microbiological process` means any process involving or performed upon or resulting in microbiological material.

2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

3. The concept of 'plant variety` is defined by Article 5 of Regulation (EC) No 2100/94.

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 4

1. The following shall not be patentable:

(a) plant and animal varieties;

(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequenced or a partial sequence of a gene must be disclosed in the patent

application.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

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

Article 7

The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

CHAPTER II Scope of protection

Article 8

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

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product in incorporated and in which the genetic information is contained and performs its function.

Article 10

The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

Article 11

1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.

CHAPTER III Compulsory cross-licensing

Article 12

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 shall 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 concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall 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 above must demonstrate that:

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

(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

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

Article 13

1. Where an invention involves the use of or concerns 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 reproduced 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 recognised depositary institution. At least those 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 recognised;

(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 depository 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 authorised 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 revocation or cancellation of the patent, to anyone requesting it.

3. The sample shall 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 material derived from it available to third parties, and

(b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, 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 twenty years from the date on which the patent application was filed. In that case, paragraph 3 shall apply.

5. The applicant's requests referred to in point (b) of paragraph 2 and in paragraph 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 14

1. If the biological material deposited in accordance with Article 13 ceases to be available from the recognised 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 depositor certifying that the newly deposited biological material is the same as that originally deposited.

CHAPTER V Final provisions

Article 15

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than . . . (8*). They shall forthwith inform the Commission thereof.

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 text of the provisions of national law which they adopt in the field covered by this Directive.

Article 16

The Commission shall send the European Parliament and the Council:

(a) every five years as from the date specified in Article 15(1) a report on any problems encountered with regard to the relationship between this Directive and international agreements on the protection of human rights to which the Member States have acceded;

(b) within two years of entry into force of this Directive, a report assessing the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable;

(c) annually as from the date specified in Article 15(1), a report on the development and implications of patent law in the field of biotechnology and genetic engineering.

Article 17

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

Article 18

This Directive is addressed to the Member States.

Done at . . .,

For the European Parliament

The President

For the Council

The President

(1) OJ C 296, 8.10.1996, p. 4 and OJ C 311, 11.10.1997, p. 12.

(2) OJ C 295, 7.10.1996, p. 11.

(3) Opinion of the European Parliament of 16 July 1997 (OJ C 286, 22.9.1997, p. 87). Council Common Position of 26 February 1995 and Decision of the European Parliament of ... (not yet published in the Official Journal).

(4) OJ C 68, 20.3.1995, p. 26.

(5) OJ L 336, 23.12.1994, p. 213.

(6) OJ L 227, 1.9.1994, p. 1. Regulation as last amended by Regulation (EC) No 2506/95 (OJ L 258, 28.10.1995, p. 3).

(7) OJ L 309, 31.12.1993, p. 1.

(8*) Two years after the date of its publication in the Official Journal of the European Communities.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 25 January 1996, the Commission submitted a proposal for a Directive of the European Parliament and of the Council on the legal protection of biotechnological inventions (1), based on Article 100a of the EC Treaty.

2. The Parliament delivered its Opinion on first reading on 16 July 1997 (2). Further to that Opinion the Commission sent an amended proposal for a Directive on 29 August 1997 (3). The Economic and Social Committee delivered its Opinion on 11 July 1996 (4).

3. The Council adopted its common position in accordance with Article 189b of the Treaty on 26 February 1998.

II. OBJECTIVE

4. The aim of the proposal is to establish harmonised, clear and improved standards for the protection of biotechnological inventions with a view to furthering the innovative potential and the competitivity of Community science and industry in this important area of modern technology. The provisions of the proposal systematically adapt the rules of patent law in the biotechnological field in order to ensure that patent legislation is more effectively applied in this area.

III. THE COMMON POSITION (5)

Recitals

5. Comments on the recitals are given in the context of the Articles to which they refer.

Articles of the proposal

Article 1

6. Paragraph 1 remains as it was in the original Commission proposal.

7. The European Parliament proposed replacing the reference to national and Community legislation in paragraph 2 with a reference to the rights and obligations of the Member States pursuant to international agreements, and in particular the Convention on Biological Diversity and the agreement on aspects of intellectual property relating to trade (the TRIPs Agreement) (amendment 67).

The Commission incorporated this amendment in its amended proposal while maintaining its belief that the reference to the rights of Member States was not appropriate.

The Council concurred with the Commission on that point.

8. As regards the obligations arising from international conventions, reference should be made to three recitals of the common position. Firstly, the European Parliament proposed two new recitals (amendments 10 and 33) which refer to conventions on the protection of human rights.

In its amended proposal, the Commission grouped them all in a single recital (24b).

The Council thought there should not be any reference to the Convention on the Protection of Human Rights and the Dignity of the Human Person with respect to Applications of Biology and Medicine (Convention on Human Rights and Biomedicine) of 19 November 1996, which had not yet come into force and had not been signed by all the Member States. As regards the way reference was made to the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950, the Council thought in would be more proper from an institutional point of view to do so by referring to Article F(2) of the Treaty on European Union (recital 43 of the common position).

9. In recital 37 of its amended proposal, the Commission summarised several amendments proposed by the European Parliament (amendments 40, 41, 42, 43, 68 and 77) regarding the Convention on Biological Diversity. Instead of citing certain Articles of the Convention in full, it preferred to give references only.

The Council concurred with the Commissions's approach, pointing out that the Community was a party to that Convention (recital 55 of the common position).

10. The European Parliament proposed a new recital which quoted from a decision of the signatories to the Convention on Biological Diversity (amendment 44).

The Commission and the Council accepted this new recital (recital 56 of the common position).

Article 2

11. The Council concurred with the amended Commission proposal which incorporated paragraphs 2 and 3a as in the European Parliament's amendment 48 in paragraph 1 of this Article.

12. The Commission incorporated paragraph 3b of the European Parliament's amendment 48 in paragraph 2 of its amended proposal.

The Council tightened up the definition of the essentially biological notion of procedure in this provision on the basis not only of amendment 48 but also of amendment 22 proposed by the European Parliament with regard to recital 18 of the original proposal.

13. Given the inclusion of a complete definition in Article 2(2), the Council made the corresponding recital declaratory in tone (recital 33 of the common position).

14. The Council concurred with the amended Commission proposal and incorporated paragraph 3c as in the European Parliament's amendment 48 in Article 2(3), while referring to the definition of the notion of plant variety given in Article 5 of Regulation (EC) No 2100/94.

Article 3

15. The Council concurred with the amended Commission proposal and incorporated paragraphs 1 and 3 as in the European Parliament's amendment 48 in a separate Article.

Article 4

16. The European Parliament proposed a new Article 2a (amendment 47).

The Commission incorporated this Article in its amended proposal (Article 4) while amending slightly the wording of paragraph 2.

The Council also adopted this Article and found that the European Parliament's wording of paragraph 2 was more appropriate.

17. In conjunction with that Article, the Parliament proposed amendments to recital 17 (amendment 18) as well as the new recitals 17a to 17c (amendments 19 to 21).

The Commission incorporated these recitals in its amended proposal while making some textual changes to recitals 17 and 17 c.

The Council also accepted these recitals (recitals 29 to 32 of the common position), while clarifying the wording of the latter one.

Article 5 (Article 3 in the original Commission proposal)

18. This Article is one of the key provisions of the proposal for a Directive. It deals with the distinction between a discovery (excluded from patentability) and an invention (patentable).

19. The European Parliament proposed clarifying this Article (amendments 100 and 49).

20. The Commission incorporated in its amended proposal paragraph 1 of this Article as amended by the European Parliament.

The Council followed suit in its common position without any change, on the understanding that the words 'the human body, at the various stages of its formation and development` covered the human embryo.

21. The Commission incorporated the amendment proposed by the European Parliament to paragraph 2 but by analogy with the terminology in paragraphs 1 and 3 replaced 'the structure or partial sequence of a gene` with 'the sequence or partial sequence of a gene`.

The Council accepted the Commission's amended proposal.

22. The Commission incorporated the amendment proposed by the European Parliament to paragraph 3 but put 'the function` instead of 'the industrial application`.

The Council preferred the term 'industrial application` which was more current in patent law.

23. In conjunction with this Article, the European Parliament proposed amendments to recitals 13, 14, 15, 16 and 19 and to the new recitals 14a and 16a to 16g (amendments 11 to 16, 99 and 23).

The Commission incorporated these amendments in its amended proposal while making textual amendments to several of them. In recital 16g of its amended proposal it summarized recitals 16f (amendment 99) and 19b (amendment 79) proposed by the European Parliament.

The Council incorporated recitals 13 to 16, 16b, 16g and 19 as in the Commission's amended proposal

(recitals 16 to 21, 23, 28 and 34 of the common position). It simplified the matter by combining recitals 16a, 16c and 16e of the amended proposal in a single recital (recital 22 of the common position). However, it divided recital 16d of the amended proposal into two separate recitals (recitals 24 and 25 of the common position), with the first dealing with the industrial application criterion and the second with interpreting rights conferred by a patent.

Articles 4 to 8 of the original proposal

24. The European Parliament proposed deleting Articles 4 to 8 of the original Commission proposal (amendments 50 to 54) since the contents thereof were to be found in amendments 48 and 47.

The Commission and the Council agreed to the deletion of these Articles.

Article 8a proposed by the European Parliament

25. The European Parliament proposed a new Article 8a containing requirements concerning an invention which consists of biological material of plant or animal origin or human origin (amendment 76).

The Commission did not accept that amendment in its amended proposal. It said that the first paragraph went beyond the international commitments entered into by the Community and its Member States within the framework of the approval and ratification of the Convention on Biological Diversity of 5 June 1992 (6), and that the second paragraph in particular did not comply with the requirements on the protection of personal data (7).

The Council shared the Commission's misgivings about this amendment and further pointed out that the Patents Offices would not be able to verify that foreign legislation was complied with (paragraph 1) or that the agreement of the person concerned had been given (paragraph 2), and that therefore the requirements contained in the amendment could not be conditions for patentability.

26. However, the Council incorporated some important features of the amendment in recitals 26 and 27 of its common position. These recitals state the principles whereby the person from whose body material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law (recital 26), and an application for a patent for an invention which uses biological material of plant or animal origin should, where appropriate, contain information on the geographical place of origin of such material, if known, (recital 27), although the lack of such agreement or information could not affect the patentability of the invention in question. Recital 26 of the common position is an adaptation of the new recital 16g proposed by the European Parliament (amendment 17) and adopted by the Commission in its amended proposal as recital 16f.

Article 6 (Article 9 of the original Commission proposal)

27. This Article, which covers the exclusion of the patentability of inventions commercial exploitation of which would be contrary to public policy or morality, is the second key provision in the proposal for a Directive.

28. The European Parliament proposed changes to this Article (amendment 55).

29. As regards paragraph 1 of this Article, the Commission did not include in its amended proposal the words 'exploitation or publication` proposed by the Parliament, preferring the words 'commercial exploitation` on the lines of Article 27(2) of the TRIPs Agreement.

The Council concurred with the Commission.

30. In conjunction with Article 6(1), the European Parliament proposed two new recitals 19c and 19d (amendment 26), the amendment to recital 20 (amendment 27) and the deletion of recital 21 (amendment 28).

In its amended proposal the Commission aligned the wording of the first of these two recitals (recital 19b of its amended proposal) on Article 27(2) of the TRIPs Agreement, and the wording of recital 20 on that adopted in Article 6(1) (point 29 above).

The Council concurred with the Commission in this respect (recitals 36 and 37 of its common position).

31. As regards the second new recital proposed by the European Parliament, the Commission incorporated it in its amended proposal (recital 19c), apart from the last part of the sentence, which did not take account of the fact that an invention could be excluded from patentability for reasons which did not affect authorization for the marketing of the product in question.

The Council preferred to delete not only that part of the sentence but the whole recital, which it thought was open to misinterpretation.

32. The Commission and the Council agreed to delete recital 21 of the original proposal.

33. The Commission added the word 'notamment` to the French text of the introductory phrase in paragraph 2 of this Article in its amended proposal to make it clear that the list of exclusions from patentability under paragraph 1 was not exhaustive.

The Council concurred with the Commission.

34. The Commission incorporated in paragraph 2 of its amended proposal the exclusions from patentability listed in paragraph 2 of amendment 55 from the European Parliament, apart from the one under (bb). Since it thought that this last subparagraph defined the concept of human cloning under (a), it preferred to transfer its content to the new recital 24a of its amended proposal in order to avoid repetition in the terms of the Directive.

The Council, in paragraph 2 of its common position, incorporated the same exclusions as the Commission together with the clarifications as set out in points 35 and 37 below. It agreed with the Commission that it was better to put the definition of human cloning in the recitals, and it tried to clarify the wording proposed by the Commission, in particular by the addition of a reference to the techniques for splitting embryos (recital 41 of the common position).

35. Under (a) in paragraph 2 the Council replaced 'procedures for human reproductive cloning` with 'procedure for the cloning of human beings`, since it thought the adjective 'reproductive` could be too restrictive. It was understood that the words 'human beings` referred to the human being from the embryionic state.

36. Subparagraphs (b) and (d) of paragraph 2 in the common position remain as they were in the amended Commission proposal.

37. In subparagraph (c) of paragraph 2, the Council said that the exclusion of patentability for human embryo uses applied when the uses were industrial or commercial. A new recital (recital 42 of the common position) makes it clear that the Council wanted to make a distinction thereby between the uses of human embryos for industrial or commercial purposes, which were excluded from patentability, and inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it, which were not excluded from patentability.

38. In conjunction with Article 6(2), the European Parliament proposed amendments to recitals 22, 23, 24 and 25 (amendments 80, 30, 31 and 34).

The Commission incorporated these amendments in its amended proposal with some textual changes.

The Council preferred to follow the wording proposed by the European Parliament as regards recital 22 (recital 38 of the common position). It clarified the wording of the beginning of recital 23 of the amended proposal (recital 39 of the common position) in order to link it better with Article 6. As regards recital 24 (recital 40 of the common position), it aligned the terminology on that used in Article 6(2). Finally, the Council preferred to include not only diagnosis and therapy but also research and prevention in recital 45 of its common position (recital 25 of the amended proposal) among the areas where it could be determined whether the procedures for changing the genetic identity of animals which caused them suffering were of any major medical value or not.

Article 7

39. The European Parliament proposed a new Article making provision for setting up an Ethics Committee to assess all ethical aspects of biotechnology and its utilisation (amendment 78).

Given that there was a Commission Group of Advisers on the Ethical implications of Biotechnology, and given its terms of reference, the Commission thought it more appropriate to refer to that Group in its amended proposal rather than set up a new committee.

The Council followed the Commission approach while amending slightly the wording proposed by the Commission. It also adjusted the name of the Group to that adopted by the Commission when the Group's term of office was renewed in December 1997 (European Group on Ethics in Science and New Technologies).

40. The Council also thought there should be a new recital (recital 44 of its common position) which states that this Group may be consulted only where biotechnology is to be assessed at the level of basic ethical principles so as to remove all doubt about the possibility of the Group being involved in the procedure for issuing a specific patent.

Article 8 (Article 10 of the original Commission proposal)

41. Paragraph 1 remains as it was in the original Commission proposal.

42. The European Parliament proposed an amendment to paragraph 2 (amendment 57).

The Commission incorporated this amendment in its amended proposal.

The Council also incorporated this amendment in its common position.

Article 9 (Article 11 of the original Commission proposal)

43. The European Parliament proposed an amendment to this Article (amendment 58).

The Commission did not accept the amendment, which involved the addition of a reference to Article 2a(1) (Article 4(1) of the amended proposal); it said that, in view of Articles 11 and 12, the reference would limit the scope of the protection given by a patent in a way which ran counter to current patent law practice.

The council concurred with the Commission. It also thought it was more appropriate to use the words 'in which genetic information is contained and expressed`.

Article 10 (Article 12 of the original Commission proposal)

44. This Article remains as it was in the original Commission proposal.

Article 11 (Article 13 of the original Commission proposal)

45. The European Parliament proposed amendments to paragraph 1 of this Article, firstly, restricting the reference to Article 14 of Regulation (EC) No 2100/94 to paragraphs 1 and 3 thereof and then adding a new sentence (amendment 95).

The Commission did not include these amendments in its amended proposals. It pointed out that Article 14(1) and (3) of Regulation (EC) No 2100/94 could not operate without paragraph 2 since that would invalidate the notion that the derogation laid down in Article 11 was proposed in accordance with what is laid down for new plant varieties. As regards the new sentence proposed by the European Parliament, it noted that it repeated the content of the last sentence of the amendment proposed by the Parliament to paragraph 2; this was not appropriate in its opinion since the net result would be to transpose into the plant domain what was specifically intended for breeding.

The Council concurred with the Commission on both these points. It also aligned the terminology of this paragraph on that of Article 13(2)(d) of Regulation (EC) No 2100/94.

46. The European Parliament proposed amendments to paragraph 2 of this Article (amendment 59).

The Commission incorporated these amendments in its amended proposal together with some textual changes to the last sentence.

The Council sought to clarify the wording of the paragraph on the basis of the changes proposed by the Parliament and the Commission, inter alia by aligning the terminology on that of paragraph 1.

47. Paragraph 3 remains as it was in the original Commission proposal.

48. Among the recitals which relate to Article 11 (recitals 27 to 31 of the original proposal; recitals 47 to 51 of the common position), the European Parliament proposed an amendment to recital 30 (amendment 35).

The Commission incorporated this amendment in its amended proposal together with some textual changes.

The Council concurred with the amended Commission proposal (recital 50 of its common position).

Article 12 (Article 14 of the original Commission proposal)

49. Paragraphs 1, 2 and 3(a) remain as they were in the original Commission proposal.

50. The European Parliament proposed an amendment to paragraph 3(b) (amendment 60).

The Commission incorporated the amendment in its amended proposal, aligning the wording on that of Article 31 (l)(i) of the TRIPs Agreement.

The Council aligned the wording further on the aforementioned provision of the TRIPs Agreement.

51. The European Parliament proposed an amendment to paragraph 4 (amendment 61).

The Commission incorporated the amendment in its amended proposal.

The Council also incorporated the amendment in its common position. Since only the Community Plant Variety Office was intitled to grant a compulsory exploitation right for a plant variety which is protected by a Community plant variety right, the Council added a sentence referring to Article 29 of Regulation (EC) No 2100/94.

However, the Council noted that Article 29 of Regulation (EC) No 2100/94 laid down that the grant of such rights by the Community Plant Variety Office was solely for reasons of public interest, whereas the reasons laid down in Article 12 of the proposal for a Directive for the grant of compulsory exploitation licences between an invention patent and a plant variety right and vice versa were other than that of public interest. Since the proposal for a Directive was not an appropriate instrument for amending Regulation (EC) No 2100/94, and in order to avoid creating an incompatibility between Directive and Regulation, the Council adopted, at the same time as its common position, a Decision pursuant to Article 152 of the Treaty calling on the Commission to examine the implications of Article 12 of the common position on Article 29 of Regulation (EC) No 2100/94, and to submit the results of that examination, together with any appropriate proposals, as soon as possible.

52. Recitals 32 and 33 of the original Commission proposal deal with Article 12. The European Parliament proposed an amendment to recital 33 (amendment 36).

In its amended proposal, the Commission incorporated the amendment proposed by the European Parliament and aligned the wording of the two recitals on that of Article 31(1)(i) of the TRIPs agreement along the lines of the alignment made for Article 12(3)(b) (point 50 above).

The Council adopted the recitals as they stand in the amended Commission proposal (recitals 52 and 53 of the common position).

Articles 13 and 14 (Articles 15 and 16 of the original Commission proposal)

53. These Articles remain as they were in the original Commission proposal.

Article 17 of the original proposal

54. The European Parliament proposed the deletion of Article 17 of the original Commission proposal (amendment 62), since the detailed rules on the burden of proof in Article 34 of the TRIPs Agreement made it superfluous to have a provision on the matter in the proposal for a Directive.

The Commission and the Council agreed to delete the Article.

55. The European Parliament proposed a new recital 33a (amendment 37), which explained why Article 17 was deleted from the original proposal.

The Commission incorporated the new recital in its amended proposal (recital 34).

The Council also adopted this recital (recital 54 of the common position).

56. Given the deletion of Article 17 from the original proposal, the Council deleted from recital 13 of its common position the reference to a reversal of the burden of proof which appeared in recital 10 of the original proposal.

Article 15 (Article 18 of the original Commission proposal)

57. In paragraph 1 of the Article, the European Parliament proposed that the deadline for the implementation of the Directive should be 1 January 1999 instead of 1 January 2000 as proposed by the Commission in its original proposal (amendment 63).

The Commission incorporated the amendment in its amended proposal.

The Council, while sharing the concern that the Directive should be transposed into national law as soon as possible, pointed out that, in the light of the internal procedures in the Member States, a period of two years after the Directive was adopted would be necessary in several Member States for transposing it into national law. The Council therefore amended the provision so that there would be a period of two years for transposing the Directive after it was published in the Official Journal.

58. Paragraph 2 of this Article remains as it was in the original Commission proposal.

Article 16

59. The European Parliament proposed a new Article 18a making provision for a Commission report to be published every five years after the transposition of the Directive and for it to be forwarded to the Parliament and the Council (amendment 64).

The Commission incorporated the new Article as Article 16 in its amended proposal.

The Council also incorporated the provision (Article 16a of its common position). It restricted the reference to international agreements on human rights to those to which the Member States were parties and said that the Directive could not raise problems vis-à-vis agreements which had not yet come into force.

60. The European Parliament proposed two new recitals which also stipulate the preparation of reports by the Commission and their forwarding to the Parliament and the Council (amendments 38 and 39).

The Commission incorporated these new recitals (recitals 35 and 36 in its amended proposal).

While the Council agreed with the content of these recitals, it preferred to group in a single Article of the Directive all the provisions requiring the Commission to submit reports. It therefore incorporated the content of these two recitals in points (b) and (c) of Article 16 in its common position. It thought it would be useful to lay down that the annual report referred to in (c) covered not only the development of patent law in the field of biotechnology and genetic engineering but also the implications thereof.

IV. CONCLUSIONS

61. In its common position, the Council adopted the gist of almost all the amendments proposed by the European Parliament. The Commission could accept the common position of the Council on all the points.

(1) OJ C 296, 8.10.1996, p. 4.

(2) OJ C 286, 22.9.1997, p. 87.

(3) OJ C 311, 11.10.1997, p. 12.

(4) OJ C 295, 7.10.1996, p. 11.

(5) Unless otherwise stated, the numbering of Articles and recitals in this statement of reasons is that of the common position.

(6) Council Decision of 25 October 1993 on the conclusion of the Convention on Biological Diversity, OJ L 309, 13.12.1993, p. 1.

(7) Directive No 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, 23.11.1995.