COMMISSION OF THE EUROPEAN COMMUNITIES

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Amended proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

on the legal protection of biotechnological inventions

(presented by the Commission pursuant to Article 189 a (2)
of the EC-Treaty)

EXPLANATORY MEMORANDUM

GENERAL COMMENTS

In February 1996, the Commission presented to European Parliament and the Council a new proposal for a Directive on the legal protection of biotechnological inventions.[1]

The Economic and Social Committee adopted its opinion regarding this proposal on 11 July 1996.[2]

European Parliament adopted 66 amendments at its first reading of the proposal during its plenary part-session of 14-18 July 1997.[3]

These amendments reflect European Parliament's concerns regarding the need (a) to clarify the difference between discoveries and inventions where the patentability of elements of human origin is concerned and (b) to introduce an ethical dimension into the proposal for a Directive.

In this respect, this amended proposal takes account of all of European Parliament's amendments.

There is only one amendment, amendment 76, which the Commission is unable to accept. This proposed the introduction of an Article 8a. The first paragraph of this amendment required a patent application for an invention consisting of biological material of animal or plant origin to indicate the geographical place of origin of the material in question and to provide evidence that the material had been used in accordance with the legal access and export provisions in force in the place of origin. The second paragraph required that, if the biological material was of human origin, the patent application should publish the name and address of the person of origin or his or her legal representative and also provide evidence that the material had been used and the patent applied for with the agreement of the person of origin or of his or her legal representative.

The first paragraph of this amendment goes beyond the international commitments which the Community and its Member States have entered into in approving and ratifying the Convention on Biological Diversity of 5 June 1992.[4] Moreover, the second paragraph does not meet the requirements governing the protection of personal data.[5]

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1 OJ No C 296, 8.10.1996, p. 4.

2 OJ NO C 295, 7.10.1996, p. 11.

3 Not yet published.

4 Council Decision of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity, OJ No L 309, 13.12.1993, p. 1.

5 Directive 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 No L 281, 23.11.1995.

COMMENTS ON THE RECITALS

From a general point of view

The table below indicates the numbers of the recitals into which the amendments adopted by Parliament have been incorporated.

Recitals	Amendments
3	2
4	3
8a	5
9a	6
9b	7
9c	8
11	9
13	11
14	12
14a	13
14b	1
15	14
16	15
16a-e	16
16f	17
16g	99 and 79
17	18
17a	19
17b	20
17c	21
18	22
19	23
19a	24
19b-c	26
20	27
22	80
23	30
24	31
24a	new
24b	10 and 33
25	34
30	35
32	new
33	36
34	37
35	38
36	39
37	40,41,42,43,68,77
38	44

From an individual point of view

All the amendments to the recitals have been incorporated in full, except as far as the following aspects are concerned:

Recital 13 incorporates amendment 11. Its middle section has been slightly reworded in order to align it on the wording of Article 5(1).

Recital 14a incorporates amendment 13. The beginning has been slightly reworded in order to take better account of the need to finance research against rare or so-called orphan diseases.

Recital 15 incorporates amendment 14. It has been slightly reworded at the end because it is the rights conferred by a patent and not the patent itself which are concerned.

Recital 16b incorporates amendment 16b. It has been slightly reworded in order to make it clearer that it is a DNA sequence's lack of biological function which makes it unpatentable.

Recital 16f incorporates amendment 17. It has been slightly reworded in order to align it on point 2.4. of Opinion No 8 of the Group of Advisers on the Ethical Implications of Biotechnology.

Recital 16g summarises amendments 79 and 99 in the light of the consequences of Article 28(1)(a) of the TRIPs Agreement.

Recital 17 incorporates amendment 18, with one slight change: the word "practicability" has been replaced by "application".

Recital 19 incorporates amendment 23. Its wording has been amended to make it legally more certain.

Recital 19c incorporates the second part of amendment 26. The final clause has been left out because there is nothing to prevent the patent on a product, e.g. a medicinal product, whose commercial exploitation has been authorised from being annulled if a judge finds that one of the conditions for its patentability is not met. Annulment of the patent does not involve withdrawal of the authorisation to exploit the product commercially. The two procedures are independent of each other.

Recital 22 incorporates amendment 80. The end has been slightly reworded in order to avoid any incorrect scientific interpretation which would be inconsistent with the amendment's purpose.

Recital 23 incorporates amendment 30. The wording has been amended following the deletion of recital 21 by amendment 28 because recital 23 is linked to it.

Recital 24a is new. It refers to the definition of human reproductive cloning contained in Opinion No 9 of the Group of Advisers on the Ethical Implications of Biotechnology. At the same time, it incorporates what was intended by amendment 55, paragraph 2(bb). This subparagraph better explains why the patentability of human reproductive cloning is to be ruled out. In view of the need for proper drafting, any redundant information should be avoided in the operative part of the Directive and the explanation should be incorporated into the recitals.

Recital 24b is a summary of amendments 10 and 33.

Recital 32 has been given a new wording. It is aligned on the wording of Article 31(1)(i) of the TRIPs Agreement in view of the fact that amendment 67 expressly introduces a reference to the rights and obligations arising out of that agreement, *inter alia*, in Article 1(2) of the proposal for a Directive.

Recital 35 incorporates amendment 38. The words "because otherwise patenting would be precluded on the grounds of lack of novelty of the invention" have been left out for the sake of clarity and in order to avoid any incorrect technical interpretation.

Recital 37 summarises amendments 40, 41, 42, 43, 68 and 77. Some of these amendments proposed introducing complete quotations of articles from the Convention on Biological Diversity. It would appear more appropriate, in view of the fact that recital 40 states that this Directive does not affect the rights and obligations of Member States arising from international agreements, and that amendment 67, cited above, also refers to this Convention, to refer globally to the Council Decision of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity.

COMMENTS ON THE INDIVIDUAL ARTICLES

Article 1(2) incorporates amendment 67.

Article 2 incorporates amendment 48, paragraphs 2, 4, 5 and 6.

Article 3 incorporates amendment 48, paragraphs 1 and 3.

Amendment 48 has been divided into two articles for the sake of clarity.

Article 4 incorporates amendment 47. Paragraph 2 of this Article has been amended in the same way as recital 17, amended by amendment 18. The word "*practicability*" is replaced by "*application*".

Article 5 incorporates amendments 100 and 49. It corresponds to the former Article 3

Articles 4, 5, 6, 7 and 8 have been deleted in accordance with amendments 50, 51, 52, 53 and 54 respectively. This is basically because they have been incorporated into Article 2, 3 and 4 of the amended proposal.

Article 6 incorporates amendment 55. It corresponds to the former Article 9.

It should be noted that the word "*publication*" has not been included in paragraph 1. The paragraph is thus consistent with Article 27(2) of the TRIPs Agreement.

Paragraph 2(bb) of the amendment is not incorporated as such into Article 6. See the explanation given regarding the new recital 24a.

Article 7 incorporates amendment 78. As the Commission announced during the plenary debate, it considers that, in the context of the request for proposals to be formulated on the composition and terms of reference of an ethics committee before the Directive enters into force, its Group of Advisers on the Ethical Implications of Biotechnology should be made competent. In so doing, the Commission will take account of Parliament's Resolution B4-0484/97 of 13 June 1997 on the terms of reference of the Group of Advisers on the Ethical Implications of Biotechnology.

Article 8(1) is unchanged. It corresponds to the former Article 10.

Article 8(2) incorporates amendment 57.

Article 9 is inspired by amendment 58. It corresponds to the former Article 11. However, the reference in this amendment to Article 2a(1) (i.e. Article 4(1) of the amended proposal) is technically and legally incomprehensible in the light of Article 11 of the proposal, which introduces a derogation for farmers, and Article 12, which provides for a system of compulsory cross-licensing where a patent dominates a plant variety. It would therefore not be appropriate to include this reference because, in practice, this would limit the scope of protection conferred by a patent in such a way as to go against current practice under patent law.

Article 10 is unchanged. It corresponds to the former Article 12.

Article 11 incorporates amendment 59. It corresponds to the former Article 13.

It should be noted that amendment 95, which aimed to amend paragraph 2 of this Article, gives rise to a number of practical difficulties. The reference to Article 14(1) and (3) of Regulation No 2100/94 is incomplete. Those two paragraphs cannot function without paragraph 2 because it that would render meaningless the idea that the derogation provided for in Article 11 is in accordance with the provisions on plant varieties. Moreover, farmers might be confronted with different legal situations. This would not be desirable.

The final sentence of amendment 95 repeats the final sentence of amendment 59. However, this applies to plants what is specifically laid down for animals, which would not be appropriate.

Article 12(1) and (2) remain unchanged. They correspond to the former Article 14.

Article 12(3)(b) incorporates amendment 60, in accordance with Article 31(1)(i) of the TRIPs Agreement.

Article 12(4) incorporates amendment 61.

Article 13 is unchanged. It corresponds to the former Article 15.

Article 14 is unchanged. It corresponds to the former Article 16.

Article 17 of the initial proposal is deleted in accordance with amendment 62.

Article 15(1) incorporates amendment 63. It corresponds to the former Article 18.

Article 16 is new. It corresponds to amendment 64.

Articles 17 and 18 are unchanged. They correspond to the former Articles 19 and 20 respectively.

Amended proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

on the legal protection of biotechnological inventions

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Initial proposal	**Amended proposal**
Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,	Unchanged
Having regard to the proposal from the Commission,[1]	Unchanged
Having regard to the Opinion of the Economic and Social Committee,[2]	Unchanged
Acting in accordance with the procedure laid down in Article 189b of the Treaty, [3]	Unchanged
(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;	(1) Unchanged
(2) 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 be guaranteed effectively through adequate legal protection;	(2) Unchanged
(3) Whereas without effective and harmonised protection throughout the Member States such investments might well not be made;	(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

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1 OJ No C 296, 8.10.1996, p. 4.

2 OJ No C 295, 7.10.1996, p. 11.

3 European Parliament Opinion of

Initial proposal	Amended proposal
(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,[1] the European Parliament and the Council have determined that the legal protection of biotechnological inventions cannot be left as it currently stands;	(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, 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 Member States; whereas such differences could create barriers to trade and to the creation and proper functioning of the internal market;	(5) Unchanged
(6) 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;	(6) Unchanged
(7) 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 the industrial development of such inventions and of the smooth operation of the internal market;	(7) Unchanged

1 OJ No C 68, 20.3.1995, p. 26.

Initial proposal	Amended proposal
(8) 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; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions; whereas, however, they must be adapted or added to in certain specific respects in order to take full account of technological developments involving biological material which also fulfil the requirements for patentability;	(8) Unchanged
	(8a) Whereas in such cases 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;

Initial proposal	Amended proposal
(9) Whereas harmonisation of the laws of the Member States is necessary to clarify certain concepts in national laws originating in certain international patent and plant variety conventions which have led to some uncertainty as to the possibility of protecting biotechnological inventions concerning plant matter and certain 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;	(9) Deleted
	(9a) Having regard 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 land; whereas the patent system should be used to encourage research into, and the application of, such procedures;

Initial proposal	Amended proposal
	(9b) Having regard to the importance of the development of biotechnology 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;
	(9c) Whereas the TRIPs Agreement signed by the European Community and the Member States has entered into force and provides that patent protection shall be guaranteed for products and processes in all areas of technology;

Initial proposal	Amended proposal
(10) 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 - and can be further limited to defining the scope of the protection accorded by a patent on a biotechnological invention, to the right to use a deposit mechanism in addition to written descriptions, to a reversal of the burden of proof and to the option of obtaining non-exclusive compulsory licences in respect of interdependence between plant varieties and inventions;	(10) Unchanged
(11) 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 call into question national and Community law on 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;	(11) 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, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;

Initial proposal	Amended proposal
(12) Whereas no prohibition or exclusion exists in national or European patent law (Munich Convention) which precludes *a priori* the patentability of biological matter;	(12) Unchanged
(13) Whereas it should be specified that knowledge relating to the human body and to its elements in their natural state falls within the realm of scientific discovery and may not, therefore, be regarded as patentable inventions; whereas it follows from this that substantive patent law is not capable of prejudicing the basic ethical principle excluding all ownership of human beings;	(13) Whereas patent law must 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;
(14) Whereas significant progress in the treatment of diseases has already been made thanks to medicinal products derived or otherwise produced from elements isolated from the human body, and medicinal products resulting from a technical process aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, the patent system should promote research aimed at obtaining such elements;	(14) Whereas significant progress in the treatment of diseases has already been made thanks to medicinal products derived and/or otherwise produced from elements isolated from the human body, and medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, the patent system should promote research aimed at obtaining and isolating such elements valuable to medicinal production;

Initial proposal	Amended proposal
	(14a) Whereas, since the patent system provides insufficient incentive for financing 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;
	(14b) Having regard to Opinion No 8 by the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission;
(15) Whereas, therefore, it should be made clear that an invention capable of industrial application and based on an element isolated from the human body or otherwise produced by means of a technical process is patentable, even where the structure of that element is identical to that of a natural element, since no patent may be interpreted as covering an element of the human body in its natural environment forming the basic subject of the invention.	(15) 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 capable of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, while the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

Initial proposal	Amended proposal
(16) Whereas such an element isolated from the human body or otherwise produced may not be regarded as unpatentable in the same way as an element of the human body in its natural state, that is to say, may not be equated with a discovery, since the element isolated is the result of the 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;	(16) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability as it is, for example, the result of the technical process 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;
	(16a) 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 require the same criteria to be applied as in all other areas of technology;
	(16b) Whereas a mere sequence of DNA segments without indication of a biological function does not contain a technical teaching and is therefore not a patentable invention;
	(16c) Whereas a sequence or partial sequence can be the subject of a patentable invention when all the necessary conditions for a patent are satisfied: novelty, level of invention and industrial application;

Initial proposal	Amended proposal
	(16d) Whereas for the criterion of industrial application to be complied with, the genetic sequence or partial sequence and thus also the protein for which a DNA sequence codes must be determined; whereas for sequences which overlap, each sequence will be considered as an independent sequence in patent law terms;
	(16e) Whereas the requirements for disclosure of the industrial application of the sequences or partial sequences do not differ from those in other areas of technology; whereas at least an industrial application must be actually disclosed in the patent application;
	(16f) Whereas the free and informed consent of the person from whose body material is taken is required in order for an application to be made for a patent in respect of the use of that material;
	(16g) Whereas this Directive in no way affects the basis of current patent law, according to which a patent may be granted for any new application of a patented product;

Initial proposal	Amended proposal
(17) Whereas, in order to determine the extent to which plant and animal varieties are to be excluded from patentability, it should be specified that the exclusion concerns those varieties as such and that, consequently, it does not prejudice the patentability of plants or animals obtained by means of a process at least one stage of which is essentially microbiological, irrespective of the basic biological material to which that process is applied;	(17) Whereas this Directive shall be without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are in general patentable provided that the application of the invention is not technically confined to a single plant or animal variety;
	(17a) Whereas the concept 'plant variety' is defined by the law protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality; whereas it is clearly distinguishable from other varieties;
	(17b) Whereas a plant totality 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 plant varieties;

Initial proposal	Amended proposal
	(17c) Whereas, however, if an invention consists only in genetically modifying a particular plant variety, it shall be excluded from patentability even if the genetic modification is the result not of breeding but of a genetic engineering procedure;
(18) Whereas, for the purposes of determining whether or not it is possible to patent essentially biological processes for obtaining plants or animals, human intervention and the effects of that intervention on the result obtained must be taken into account;	(18) Whereas a procedure for the breeding of plants and animals is essentially biological if it is based on crossing whole genomes (with subsequent selection and perhaps further crossing of whole genomes);
(19) Whereas national patent laws for inventions contain provisions as to the criteria for allowing or excluding patentability, including provisions to the effect that a patent may not be granted in respect of inventions whose publication or exploitation would be contrary to public policy or morality;	(19) Whereas this Directive shall be without prejudice to concepts of invention and discovery, as developed by national, European or international patent laws;
	(19a) Whereas this Directive shall be without prejudice to the provisions of national patent law whereby surgical or therapeutic treatment procedures applicable to the human body or the bodies of animals and diagnostic procedures which are carried out on the human body or the bodies of animals are excluded from patentability;

Initial proposal	Amended proposal
	(19b) Whereas the TRIPs Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions whose commercial exploitation within their territory must be prevented in order to protect public policy or morality, including to protect human or animal life or health, to preserve plants or to prevent serious harm to the environment, provided that such an exclusion is not undertaken solely because exploitation is prohibited by their legislation;
	(19c) Whereas other prohibitions on exploitation under national law are not sufficient to exclude patentability; whereas such an exclusion presupposes that the commercial exploitation of the invention is prohibited in the Member State in question;
(20) Whereas such a reference to public policy and morality should be included in the operative part of this Directive in order to bring out the fact that some applications of biotechnological inventions, by virtue of some of their consequences or effects, are capable of offending against them;	(20) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against public policy or morality must also be stressed in this Directive;

Initial proposal		Amended proposal	
(21)	Whereas it must be determined whether applications offend against public policy and morality in each specific case, by means of an appraisal of the values involved, whereby the benefit to be derived from the invention, on the one hand, is weighed and evaluated against any risks associated therewith, and any objections based on fundamental principles of law, on the other hand;	(21)	Deleted
(22)	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 public policy or morality;	(22)	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 public policy and morality; whereas this list cannot presume to be exhaustive; whereas processes the use of which offend against human dignity, such as processes to produce chimeras from a mixture of human and animal genomes, are also excluded from patentability;

Initial proposal	Amended proposal
(23) Whereas such moral considerations must be given greater weight in appraising the patentability of biotechnological inventions, both on account of the subject-matter of this branch of science, namely living matter, and because of the often far-reaching implications of the inventions to be examined; whereas these considerations do not, however, change the nature of patent law as a primarily technical body of law and are no substitute for the other legal checks which biotechnological inventions are required to undergo from the start of their development or at the marketing stage, particularly with regard to safety;	(23) Whereas morality represents the ethical or moral principles generally observed in a Member State or accepted by the scientific or professional circles concerned; whereas it is particularly important that these principles be respected 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 checks of patent law regardless of the technical field of the invention;
(24) Whereas, in view of the importance and the controversial nature of the unprecedented questions raised by germ line gene therapy, it is important to exclude unequivocally from patentability methods of treatment of human beings based on it;	(24) Whereas in the European Union there is a consensus that interventions in the human germ line and the cloning of human beings offends against public policy and morality; whereas it is therefore important to exclude unequivocally from patentability methods for intervention in the germ line of human beings and processes for cloning human beings;

Initial proposal	Amended proposal
	(24a) Whereas in the European Union there is a consensus that interventions in the human germ line and the cloning of human beings offends against public policy and morality; whereas it is therefore important to exclude unequivocally from patentability methods for intervention in the germ line of human beings and processes for cloning human beings;

Initial proposal	Amended proposal
	(24b) Whereas this Directive does not affect the application of the Convention on Human Rights and Fundamental Freedoms of 4 November 1950, the Convention for 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, or any other international instrument concerning the protection of human rights on which the Member States have cooperated or to which they have acceded;
(25) 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 also animals resulting from such processes must be excluded from patentability insofar as the suffering or physical handicaps inflicted on the animals concerned are out of proportion to the objective pursued;	(25) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical (diagnostic or therapeutic) benefit to man or animal, and also animals resulting from such processes, must be excluded from patentability;

Initial proposal	Amended proposal
(26) 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-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;	(26) Unchanged
(27) 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;[1]	(27) Unchanged
(28) Whereas only the fee envisaged under Community plant variety rights as a condition for applying the derogation from Community plant variety rights can be required of the farmer;	(28) Unchanged

1 OJ No L 227, 1.9.1994, p. 1.

Initial proposal	Amended proposal
(29) Whereas, however, the holder of the patent may defend his rights against a farmer abusing the derogation or against the breeder who has developed the plant variety incorporating the protected invention if the latter fails to adhere to his commitments;	(29) Unchanged
(30) Whereas a second derogation from the rights of the holder of the patent must authorise the farmer to use the protected livestock for breeding purposes on his own farm, in order to replenish their numbers;	(30) Whereas a second derogation from the rights of the holder of the patent must authorise the farmer to use the protected livestock for agricultural purposes;
(31) Whereas the extent and the conditions of that second derogation may be determined by national laws, regulations and practices, since there is no Community legislation on animal variety rights;	(31) Unchanged
(32) 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 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;	(32) 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;

Initial proposal	Amended proposal
(33) 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,	(33) 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 the invention represents significant technical progress of considerable economic interest;
	(34) Whereas 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;
	(35) Whereas the Commission will investigate whether, in the field of basic genetic engineering research, free and unimpeded scientific exchanges are hampered because publications containing information which might be patentable are delayed or not undertaken, as a result of which patentability would be excluded because of the lack of novelty on the part of the inventor; whereas the Commission will carry out a comparison with the patent law of the United States and Japan in this respect and report to the European Parliament and the Council two years after the entry into force of this Directive;

Initial proposal	Amended proposal
	(36) Whereas the Commission will report [annually] to the European Parliament on the development of patent law in the field of biotechnology and genetic engineering;
	(37) Whereas the rights and obligations of the Member States derived from international agreements, particularly further to the Council Decision of 25 October 1993 on the conclusion of the Convention on Biological Diversity,[1] and Articles 3, 8(j), 16(2), second sentence, and 16(5) of the Convention on Biological Diversity of 5 June 1992, are not affected by this Directive;

[1] OJ No L 309, 13.12.1993, p. 1.

Initial proposal	Amended proposal
	(38) Whereas the Third Conference of the Parties of 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';

Initial proposal	Amended proposal
HAVE ADOPTED THIS DIRECTIVE:	HAVE ADOPTED THIS DIRECTIVE:
CHAPTER I	**CHAPTER I**
Patentability	**Patentability**
Article 1	*Article 1*
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.	1. Unchanged
2. This Directive shall be without prejudice to national and Community laws on the monitoring of research and of the use or commercialisation of its results.	2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the Convention on Biological Diversity and the TRIPs Agreement.
Article 2	*Article 2*
For the purposes of this Directive,	1. For the purposes of this Directive,
1. *Biological material* means any material containing genetic information and capable of self-reproduction or of being reproduced in a biological system;	(a) *Biological material* means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;
2. *Microbiological process* means any process involving or performed upon or resulting in microbiological material; 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;	(b) *Microbiological process* means any process involving or performed upon or resulting in microbiological material.

Initial proposal	Amended proposal
3. *Essentially biological process for the production of plants or animals* means any process which, taken as a whole, exists in nature or is not more than a natural plant-breeding or animal-breeding process.	2. A procedure for the breeding of plants or animals shall be defined as essentially biological if it is based on crossing and selection.
	3. The concept *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 novel, imply inventive activity and are capable of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a procedure by means of which biological material is produced, processed or used.
	2. Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature.
	Article 4
	1. The following shall not be patentable:
	(a) plant and animal varieties,
	(b) essentially biological procedures for the breeding of plants and animals.
	2. Inventions which concern plants or animals may be patented if the application of the invention is not technically confined to a particular plant or animal variety.

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

Initial proposal	Amended proposal
Article 3	*Article 5*
1. The human body and its elements in their natural state shall not be considered patentable inventions.	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. Notwithstanding paragraph 1, the subject of an invention capable of industrial application which relates to an element isolated from the human body or otherwise produced by means of a technical process shall be patentable, even if the structure of that element is identical to that of a natural element.	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 function of a sequence or a partial sequence of a gene must be disclosed in the patent application.
Article 4	Deleted
1. The subject 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, including plants and animals, as well as elements of plants and animals obtained by means of a process not essentially biological, except plant and animal varieties as such, shall be patentable.	
Article 5	Deleted
Microbiological processes and products obtained by means of such processes shall be patentable.	

Initial proposal	Amended proposal
Article 6	Deleted
Essentially biological processes for the production of plants or animals shall not be patentable.	
Article 7	Deleted
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 8	Deleted
The subject of an invention concerning a biological material shall not be considered a discovery or lacking in novelty merely on the grounds that it already formed part of the natural world.	
Article 9	*Article 6*
1. Inventions shall be considered unpatentable where exploitation would be contrary to public policy or morality; however, exploitation shall not be deemed contrary merely because it is prohibited by law or regulation.	1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to public policy 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 shall be considered unpatentable:	2. On the basis of paragraph 1, the following shall be considered unpatentable:
(a) methods of human treatment involving germ line gene therapy;	(a) procedures for human reproductive cloning;

Initial proposal	Amended proposal
(b) 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 also animals resulting from such processes, whenever the suffering or physical handicaps inflicted on the animals concerned are disproportionate to the objective pursued.	(b) processes for modifying the germ line genetic identity of human beings;
	(c) methods in which human embryos are used;
	(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 Group of Advisers on the Ethical Implications of Biotechnology shall assess all ethical aspects of biotechnology.

Initial proposal	Amended proposal
CHAPTER II	**CHAPTER II**
Scope of protection	**Scope of protection**
Article 10	*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 multiplication or propagation in an identical or divergent form and possessing those same characteristics.	1. Unchanged
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 using that process and to any other biological material derived from the biological material directly obtained through multiplication or propagation in an identical or divergent form and possessing those same characteristics. That protection shall not affect the exclusion from patentability of plant and animal varieties as such, pursuant to Article 4(2).	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 biological material directly obtained through multiplication or propagation in an identical or divergent form and possessing those same characteristics.
Article 11	*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 3(1), in which the product is incorporated and in which the genetic information is contained and expressed.	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 is incorporated and in which the genetic information is contained and expressed.

Initial proposal	Amended proposal
Article 12	*Article 10*
The protection referred to in Articles 10 and 11 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.	The protection referred to in Articles 8 and 9 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 13	*Article 11*
1. By way of derogation from Articles 10 and 11, the sale of 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 reproduction or propagation by him on his own farm, the scope of and procedure for this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.	1. By way of derogation from Articles 8 and 9, the sale of 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 reproduction or propagation by him on his own farm, the scope of and procedure for this derogation corresponding to those under Article 4 of Regulation (EC) No 2100/94.
2. By way of derogation from Articles 10 and 11, the sale of breeding stock to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for breeding purposes on his own farm, in order to replenish their numbers.	2. By way of derogation from Articles 8 and 9, the sale of breeding stock or other 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 the sale for the purposes of pursuing agricultural activities but not the sale within the framework or for the purpose of a commercial breeding activity.

Initial proposal	Amended proposal
3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.	3. Unchanged
CHAPTER III	**CHAPTER III**
Compulsory cross-licensing	**Compulsory cross-licensing**
Article 14	*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.	1. Unchanged
2. Where the holder of a patent on 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.	2. Unchanged

Initial proposal	Amended proposal
3. Applicants for the licences referred to in paragraphs 1 and 2 above must demonstrate that:	3. Unchanged
(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;	(a) Unchanged
(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.	(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest.
4. Each Member State shall designate the authority or authorities responsible for granting the licence. The licence shall be granted principally for the supply of the domestic market of the Member State which has granted the licence.	4. Each Member State shall designate the authority or authorities responsible for granting the licence.
CHAPTER IV	**CHAPTER IV**
Deposit, access and re-deposit of a biological material	**Deposit, access and re-deposit of a biological material**
Article 15	*Article 13*
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 reproduced by a person skilled in the art, the description shall be considered inadequate for the purposes of patent law unless:	1. Unchanged

Initial proposal	Amended proposal
(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 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 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:	2. Unchanged
(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.	

Initial proposal	Amended proposal
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 matter derived from it available to third parties and (b) not to use it or any matter derived from it except for experimental purposes, unless the patent holder or applicant, as applicable, expressly waives such an undertaking.	3. Unchanged
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.	4. Unchanged
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.	5. Unchanged
Article 16	*Article 14*
1. If the biological material deposited in accordance with Article 15 ceases to be available from the recognised depositary institutions, a new deposit of the material shall be permitted on the same terms as those laid down in the Budapest Treaty.	1. Unchanged

Initial proposal	Amended proposal
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.	2. Unchanged
CHAPTER V	Deleted
Burden of proof	
Article 17	
1. If the subject-matter of a patent is a process for obtaining a new product, then, when the same product is produced by any other party, it 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	**CHAPTER VI**
Final provisions	**Final provisions**
Article 18	*Article 15*
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 2000. They shall immediately inform the Commission thereof.	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 1999. They shall immediately inform the Commission thereof.

Initial proposal	Amended proposal
When Member States adopt these measures, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.	Unchanged
2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	2. Unchanged
	Article 16
	Every five years after the transposition of this Directive the Commission shall publish 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 or on which they have cooperated. The report shall be forwarded to European Parliament and the Council.
Article 19	*Article 17*
This Directive shall enter into force on the 20th day following that of its publication in the Official Journal of the European Communities.	Unchanged
Article 20	*Article 18*
This Directive is addressed to the Member States.	Unchanged

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