COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 16 December 1992

Amended proposal for a

COUNCIL DIRECTIVE

on the legal protection of biotechnological inventions

(presented by the Commission pursuant to Article 149(3) of the EEC-Treaty)

EXPLANATORY MEMORANDUM

BACKGROUND

In November 1988 the Commission presented to the Council a proposal for a Council Directive on the legal protection of biotechnological inventions.[1]

The Economic and Social Committee delivered its opinion on 26 April 1989.[2]

Parliament discussed the proposal at length in committee and in plenary in April and October 1992.[3]

The amended proposal is intended to take account of these opinions.

Parliament concentrated mainly on the ethical dimension of biotechnological inventions. As the discussions progressed, it became clear that a mere reference to the concepts of public policy ("ordre public") and morality was not enough and that this traditional framework for exclusion from patentability needed to be supplemented by more precise guidelines for national patent offices and courts. Such is the object of Article 2 of the amended proposal.

Parliament adopted by a very large majority an amendment concerning what is commonly known as farmer's privilege. The Commission, though initially opposed to the amendment, has finally accepted it to allow the Council to discuss it as part of a continuing cooperation procedure. This amendment by Parliament is to be found in Article 13 of the amended proposal.

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1 OJ No C 10, 13.1.1989, p. 3.

2 OJ No C 159, 26.6.1989, p. 10.

3 OJ No C

The question of the compatibility between the proposal for a Directive and the Nairobi Convention on Biological Diversity, which was signed at the Earth Summit in Rio de Janeiro on 5 June 1992, was also discussed in depth by Parliament. The conclusion reached was that the proposal for a Directive was perfectly compatible with the Convention's objectives.

COMMENTARY ON THE RECITALS

Fourth and fifth recitals

These two new recitals replace the fourth recital of the original proposal. Their purpose is to make clear that the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions. The proposal for a Directive therefore in no way seeks to create a separate body of law, but is intended only to clarify the existing law in order that it might be applied correctly to such inventions.

Seventh to thirteenth recitals

These new recitals, which were not in the original proposal, deal with the "ethical question" raised by the Commission's proposal. Although this ethical question was not mentioned explicitly at the outset, this does not mean that the Commission did not consider it important or that it denied it existed. In the first place, the traditional exceptions to patentability, including that relating to public policy and morality, are enshrined in national law and can therefore still apply. And in the second place, the ethical question is essentially covered by rules for safeguarding human rights in relation to the applications of research and the monitoring of its results or their commercialization. Such rules fall outside the scope of patent law. The best known example is that of the body of rules concerning authorizations to market medicinal products, which exist separately from, and must be complied with independently of, the patent law provisions applicable to that area of technology. It can, of course, be argued that, in so far as the technology to be protected might affect the genetic make-up of living matter, including that of human beings, controls must be introduced or prohibitions laid down. The Commission agrees with this point of view.

The Commission recognizes, however, that, although the purpose of the proposal for a Directive is merely to harmonize laws on patents protecting biotechnological inventions and not to establish a set of European ethical principles, it is essential, in the light of all that has been said since the original proposal was published, not least within Parliament, that patent law should contain certain impassable barriers so as to provide guidance for those interpreting the concepts of public policy and morality.

Consequently, the Commission considers that three types of invention must be excluded from patentability: the human body or parts of the human body per se, certain processes for modifying the genetic identity of human beings, and certain processes for modifying the genetic identity of animals.

Questions relating to the monitoring of the applications of research and of the use or commercialization of its results are reserved for other national or Community laws. Patent law should go no further than it does as rules on these matters are out of place in it: Member States may enact such rules as they see fit, subject to any Community measures that may be in force. For example, Council Decision 90/395/EEC of 29 June 1990 adopts a specific research and technological development programme in the field of health: human genome analysis (1990 to 1991) and provides for a study of the ethical, social and legal aspects.

A number of specific programmes implementing the third framework programme for research and technological development (1990 to 1994) include evaluations of the economic and social impact and of any technological risks. For example, Council Decision 91/505/EEC of 9 September 1991 adopting the specific programme in the field of biomedicine and health pays particular attention to the ethical, social

and legal aspects, and includes research on biomedical ethics; and Council Decision 92/218/EEC of 26 March 1992 adopting the specific programme in the field of biotechnology takes into account the ethical, social and ecological implications of research. On 20 November 1991 the Commission set up an advisory body for all questions to do with the ethical implications of biotechnology.

Twenty-fifth and twenty-seventh recitals

These new recitals reflect the new wording of the corresponding articles.

The Commission has not accepted Parliament's amendments Nos 1 to 8 introducing new recitals as it considers that they are unrelated to the proposal's objective and do not shed any light on its substantive terms.

COMMENTARY ON THE ARTICLES

Article 1

The new wording seeks to bring out more clearly the fact that the ordinary rules of patent law apply, subject to the provisions of the Directive.

The proposed wording reproduces the terms of Parliament's amendment No 9.

The Commission has not accepted Parliament's amendments Nos 10, 11 and 12. It considers amendment No 10 unnecessary in the light of existing law, notably Article 69 of the Munich Convention on the Grant of European Patents. As for amendments Nos 11 and 12, these are out of place in a directive harmonizing national laws as the latter already have to take account of the conventions referred to therein.

Article 2

In paragraph 1 the concept of biological material replaces that of living matter.

The proposed wording reproduces the terms of Parliament's amendment No 13.

Paragraph 2 defines the concept of biological material and replaces Article 19 of the original proposal.

The proposed wording is based on Parliament's amendment No 14.

Paragraphs 3 and 4 are the concrete formulation of the explanations given in connection with the sixth to thirteenth recitals.

The first subparagraph of paragraph 3 is based on Parliament's amendment No 16. The examples given in the second subparagraph of paragraph 3 are intended as an aid to interpreting the concept of public policy or morality.

With regard to the unpatentability of the human body or parts of the human body, the Commission wishes to make it quite clear, in keeping with the discussions that have taken place within Parliament, that "parts of the human body" per se means parts of the human body as found inside the human body. It is important that this be spelled out so as to remove all possible ambiguity with respect to the position of certain products or parts of the human body which are already covered by patents granted in connection with the development of medicinal products: e.g. a human lymphoblastoid cell line (European patent No 0113.769 B1 granted on 15 February 1989); a recombinant DNA molecule capable of inducing the expression in a unicellular host of a polypeptide displaying the immunological or biological activity of human ß-interferon (European patent No 0041.313 B1 granted on 12 September 1990); a human hepatocyte culture process (European patent No 0143.809 B1 granted on 18 January 1989); the molecular cloning and characterization of a gene sequence coding for human relaxin (European patent No 0101.309 B1 granted on 16 September 1991); a method for producing human antibody (European patent No 0096.839 B1 granted on 25 January 1989); and a process for producing a human protein of therapeutic value (French patent No 2.637613 B1 granted on 27 September 1991).

It goes without saying that, if the applicant simply wishes to patent a mere part of the "human body" per se, e.g. a human gene neither the function of which nor the protein for which it codes is known, exclusion from patentability would apply.

The proposed wording is based on Parliament's amendment No 15.

The second exclusion in principle from patentability concerns processes for modifying the genetic identity of human beings for a non-therapeutic purpose which is contrary to the dignity of man (point (b) of the second subparagraph of paragraph 3). Nowadays the tools of genetic engineering can be used to diagnose genetic diseases at gene level, whether directly or indirectly and at any stage in the development of a human being, starting from conception. Consequently, it is possible to envisage the application of genetic engineering techniques to manipulations of the human genome with a view to obtaining a lasting modification thereof. In the case of human beings, these manipulations would be designed above all to correct selectively a genetic defect by introducing a normal gene, if possible in place of the corresponding defective gene. However, such "germinal" gene therapy is still more or less at the stage of experimentation on animals and human cell cultures. In practice, such manipulations can be carried out only in the context of in vitro fertilization, and genetic correction at the stage preceding implantation of the embryo is still some way off as the proper functioning of a foreign gene has yet to be mastered.

The other type of gene therapy is known as "somatic" gene therapy. It consists in trying to cure the somatic cells of an existing human being without modifying his germ cells. Hence the genetic change brought about in the patient is not hereditary, in contrast to what might happen in the case of germinal gene therapy. The proposed exclusion from patentability does not cover the processes used in somatic gene therapy.

Through the proposed wording, the Commission is seeking to leave open the possibility of granting legal protection to inventions capable of improving considerably the lot of certain human beings suffering from deep-seated illness. The fact that it will still be some time before this type of invention actually sees the light of day is no bar to its being already contemplated in the proposal for a Directive. On the contrary, the prospect of protection cannot but

encourage investment in this field. As regards the spectre of eugenics which is sometimes raised by those who warn against this type of research and the uncontrolled applications it would permit, it is important to note the coupling of the condition of the therapeutic purpose of those processes for modifying the genetic identity of human beings which are capable of being patented with that of conformity with the dignity of man.

In the course of the discussions within Parliament, it became apparent that a distinction had to be drawn between, on the one hand, methods for treatment by surgery or therapy and diagnostic methods, which are not considered inventions susceptible of industrial application and which are therefore unpatentable, and, on the other, biotechnological processes involving modification of the genetic identity of human beings which have a therapeutic purpose in keeping with the dignity of man. Use of the expression "therapeutic purpose" to describe an invention which may be patentable from an ethical point of view could create the impression that that which is declared technically unpatentable, notably in Article 52(4) of the Munich Convention on the Grant of European Patents, would become patentable in the case of biotechnological inventions. In order to avoid this ambiguity due to an overlapping of the similarly worded technical standard and ethical standard, it seems appropriate to stress the unpatentability of certain methods, whatever their technical characteristics, in the sphere of biotechnology. The amended proposal accordingly reproduces the wording of Article 52(4) of the Munich Convention in Article 8 and not in Article 2, which has been specifically extended compared with the original proposal to include the ethical dimension capable of being dealt with by patent law. Thus the ethical control introduced by point (b) of the second subparagraph of Article 2(3) of the amended proposal may exclude certain inventions from patentability even if they are patentable under Article 8.

The proposed wording is based on the second and fourth paragraphs of Parliament's amendment No 20.

The third exclusion in principle from patentability concerns processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal (point (c) of the second subparagraph of paragraph 3). The techniques for producing transgenic animals are well known and have been described in detail, and seek, among other things, to create laboratory animals (e.g. Harvard University's "onco-mouse") or animals which produce, via a tumour cell developing as a result of gene therapy, effective secretions of foreign proteins of therapeutic value, for example neutrophil elastase inhibitor intended for the treatment of pulmonary emphysema, thrombotic disorders and hypertension (as is the case with the transgenic mouse of the French company Transgène, patent No 2.637613 B1 referred to above).

In view of the usefulness of this type of invention to man's well-being, in this instance his health, the Commission considers it only right and proper that investment in research thereon should be capable of being duly protected. The Commission also considers that the borderline between what is acceptable and what is not acceptable must take account of the criterion of animal suffering. The Commission acknowledges that this criterion may be difficult to evaluate, but it believes that its inclusion is necessary in order to avoid the gratuitousness of certain experiments which may be inflicted on animals in so far as they are out of all proportion to the objectives pursued. While it is concerned about certain extreme situations in which animals may find themselves in some laboratories, the Commission must neverthless point out that patent law is not the appropriate field in which to legislate thereon. The preamble to the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes signed at Strasbourg on 18 March 1986 sets out clearly the framework within which vertebrate animals may be used with reference to their usefulness to man and to the suffering they may endure as a result:

"Recognising that man has a moral obligation to respect all animals and to have due consideration for their capacity for suffering and memory;

Accepting nevertheless that man in his quest for knowledge, health and safety has a need to use animals where there is a reasonable expectation that the result will be to extend knowledge or be to the overall benefit of man or animal, just as he uses them for food, clothing and as beasts of burden;

Resolved to limit the use of animals for experimental and other scientific purposes, with the aim of replacing such use wherever practical, in particular by seeking alternative measures and encouraging the use of these alternative measures;

Desirous to adopt common provisions in order to protect animals used in those procedures which may possibly cause pain, suffering, distress or lasting harm and to ensure that where unavoidable they shall be kept to a minimum."

Besides Belgium, Denmark, France, Germany, Greece, the Netherlands, Spain and the United Kingdom, the European Communities as such signed the Convention, and on 24 November 1986 the Council adopted Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.[1] In 1992, moreover, the Commission set up at the JRC's Ispra establishment a laboratory responsible for validating, at Community level, alternative methods for reducing the number of animals used for experimental purposes and their degree of suffering.

The wording proposed for point (c) of the second subparagraph of Article 2(3) thus reproduces the two basic ideas underlying amendments Nos 17 and 18 and amendment No 19 and already sanctioned by the Council Directive of 24 November 1986: an invention which has the effect of inflicting suffering on an animal is excluded from patentability, unless it may be beneficial.

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1 OJ No L 358, 18.12.1986, p. 1.

As far as the scope of paragraph 4 is concerned, the following instruments can be mentioned by way of example: Directives 90/219/EEC and 90/220/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms and on the deliberate release into the environment of genetically modified organisms; French Decree No 83 132 setting up a National Advisory Committee on Ethics in Life and Health Sciences; the German Act of 30 October 1990 on the protection of embryos; the Danish Act of 3 June 1987 on an Ethics Council and the regulation of certain forms of biomedical experimentation; the United Kingdom Human Fertilization and Embryology Act 1990; the Spanish Act of 28 December 1988 on the donation and utilization of human embryos and foetuses and their cells, tissues and organs; the Portuguese Act of 9 June 1990 setting up a National Council on Ethics in Life Sciences; the Italian Decree of 28 March 1990 setting up a National Committee for Bioethics; the German Act of 20 June 1990 on gene technology; and the Belgian Act of 14 August 1986 on the protection and welfare of animals.

It should be noted, moreover, that a framework convention on bioethics is being prepared by the Council of Europe. Mention should also be made of Parliament's Resolution of 16 March 1989 on the ethical and legal problems of genetic engineering.

The Commission has not accepted Parliament's amendment No 21 as it goes beyond what patent law can monitor by way of the examination of patent applications filed with national offices. As already indicated in the comments on the seventh to thirteenth recitals, a global ethic of research and of the information it generates must not be drawn up within the specialized framework of patent law. If necessary, a suitable set of rules meeting the concerns which motivated amendment No 21 could bring its influence to bear in the light of Article 2(4) of the amended proposal.

The Commission has not accepted the second part of Parliament's amendment No 47 as it contains a traditional principle already enshrined in the Munich Convention on the Grant of European Patents (Article 52(2)(a)) and incorporated in the laws of the Member States.

Article 3

The new wording proposed for Article 3 simplifies and corrects the original proposal as regards the patentability of biological material.

The proposed wording is based on Parliament's amendment No 22.

Article 4

The wording proposed for Article 4 is intended to be more precise.

The Commission has not accepted Parliament's amendment No 23 relating to Article 4. This article does not deal as such with processes for the production of the biological material forming the subject-matter of Articles 5 and 6 of the amended proposal. It simply states that use of plant or animal varieties or of the processes for their production does not imply the unpatentability of the invention in which it occurs.

Article 5

The wording proposed for Article 5 groups together Articles 5 and 6 of the original proposal dealing with microbiological processes consisting of one or more steps.

The wording proposed for paragraph 2 reproduces the terms of Parliament's amendment No 24.

Article 6

The wording proposed for Article 6 is drawn from the terms of Article 7 of the original proposal concerned with essentially biological processes which are not patentable.

The proposed wording is based on Parliament's amendment No 25.

Article 7

The wording proposed for Article 7 corresponds to that of Articles 8 and 9 of the original proposal regarding biological material forming part of an existing material and capable of being patented.

Article 8

As already indicated in connection with point (b) of the second subparagraph of Article 2(3) of the amended proposal, this article reproduces, in the interests of clarity, the terms of Article 52(4) of the Munich Convention on the Grant of European Patents. The article replaces Article 18 of the original proposal.

The proposed wording is based on the first and third paragraphs of Parliament's amendment No 20.

Article 9

The wording proposed for Article 9 takes up again the question of surgical or diagnostic methods covered by Article 8 in so far as they constitute a step in a process patentable as a whole.

Article 10

The wording proposed for Article 10 deals, using a different phraseology from Article 12 of the original proposal, with the question of the extent of the protection conferred by a patent on a biological material having specific characteristics or of the protection conferred by a patent on a process for the production of a biological material having specific characteristics.

The proposed wording is based on Parliament's amendments Nos 29 and 31.

Article 11

The wording proposed for Article 11 deals, using a different phraseology, with the principle of a specific exhaustion in certain circumstances of a patentee's rights in a biological material. This question was dealt with in Article 11 of the original proposal.

The proposed wording reproduces the terms of Parliament's amendment No 30.

Article 12

The wording proposed for Article 12 reproduces in a corrected form that proposed for Article 13 of the original proposal concerning the extent of the protection conferred on a product containing or consisting of genetic information, irrespective of its parentage, which is dealt with in Article 10. The Commission has therefore not accepted Parliament's amendment No 33 aimed at deleting Article 13 of the original proposal.

Article 13

During the discussions within Parliament, the question of "farmer's privilege", that is to say the possibility for a farmer to use part of his harvest to resow his fields, became the key issue, so much so that Parliament twice referred the proposal for a Directive back to its legal affairs Committee because the Commission, for legal, technical and economic reasons, did not accept farmer's privilege.

However, the fact that the vast majority of Parliament's members are in favour of introducing farmer's privilege into patent law is a political sign which the Commission cannot ignore in the context of a cooperation procedure. This is all the more true as the lack of a solution to the problem would prevent work from continuing on the proposal for a Directive as a whole despite its having been before the Council and Parliament since the beginning of 1989. By accepting farmer's privilege, the Commission is seeking first and foremost to unblock the cooperation procedure so as to enable the Council to state its position on the proposal as amended in the light of Parliament's amendment and to examine Parliament's reasons.

The first argument put forward by Parliament concerns the current farming practice of using part of the harvest as seeding material. This practice could be called into question in the case of seeds patented following genetic manipulations because the patent holder would enforce his rights against certain usages established and recognized as part of the legal protection already available to the farming community, namely breeders' rights.

The second argument put forward by Parliament relates to the ability of the patent holder to monitor closely what might be happening on a farm.

The third argument put forward by Parliament is an economic one. If there were no farmer's privilege, the scope of patent law would be such that farmers might have to pay a royalty on each generation of seed.

Since the vast majority within Parliament are in favour of farmer's privilege, and since this view was expressed with vigour, the Commission has accepted Parliament's amendment No 32 so as to unblock the cooperation procedure, as indicated above.

It is important to note that, in Parliament's amendment and in the text of the amended proposal, the concept of farmer's privilege does not appear as such, but takes the form of a derogation from the extent of the protection conferred by a patent. Like Parliament, the Commission acknowledges, moreover, that the subject-matter of the harvests and the livestock of a farmer must be dealt with in the same way.

The Commission is fully aware, however, that farmer's privilege must not make possible under patent law that which is forbidden under plant variety protection law, resulting in certain areas of agriculture or horticulture, such as ornamental plants, fruit trees or vines, being affected. It has therefore rejected the oral amendment added by Parliament's legal affairs Committee with a view to inserting the words "or other propagatable material" after the first occurrence of the word seed. Thus, as far as the Commission is concerned, "seed" is to be understood in the narrow sense.

Article 14

The new wording proposed for Article 14 concerning compulsory licences envisages only the possibility of granting such licences where it is in the public interest.

The proposed wording is based on Parliament's amendment No 34.

Article 15

The new wording proposed for Article 15 concerning the deposit, under certain conditions, of the biological material forming the subject-matter of an invention has been greatly simplified compared with Article 15 of the original proposal. In this highly technical field, which is of concern mainly to patent offices in their daily work when they are called upon to consider whether the requirement as to sufficient disclosure of an invention is satisfied, it is much better to apply existing, time-tested principles. Hence the reference to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977, such reference being both necessary and sufficient.

The proposed wording is based on Parliament's amendments Nos 35 to 40.

Article 16

The new wording of Article 16 is a highly simplified version of Article 16 of the original proposal, the reference to the Budapest Treaty of 28 April 1977 being sufficient to deal with the question of new deposits of biological material in so far as all Member States will have to become parties to that Treaty by virtue of the proposal for a Directive.

The proposed wording reproduces the terms of Parliament's amendment No 41.

Article 17

The new wording of Article 17 concerning reversal of the burden of proof has been brought fully into line with Article 35 of the Luxembourg Convention for the Community Patent.

The proposed wording is based on Parliament's amendment No 42.

Article 18

The proposed wording reflects Parliament's amendment No 45.

The content of Article 10 of the original proposal - use for experimental purposes - has not been included as it has become apparent, following discussion of Parliament's amendment No 26, which the Commission has rejected, that it is inappropriate in view of the ordinary rules of patent law. Parliament's amendments Nos 27 and 28, which also concern Article 10 of the original proposal, have likewise been rejected by the Commission, the former because it is unnecessary in the light of present-day patent law, and the latter because it is incompatible with the current position with regard to patents for pharmaceutical products and hence would give rise to discrimination.

AMENDED PROPOSAL FOR A COUNCIL DIRECTIVE ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

(presented by the Commission pursuant to Article 149(3) of the EEC Treaty)

ORIGINAL PROPOSAL	AMENDED PROPOSAL
THE COUNCIL OF THE EUROPEAN COMMUNITIES,	THE COUNCIL OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof;	Unchanged
Having regard to the proposal from the Commission,	Having regard to the proposal from the Commission,[1]
In cooperation with the European Parliament,	In cooperation with the European Parliament,[2]
Having regard to the opinion of the Economic and Social Committee,	Having regard to the opinion of the Economic and Social Committee,[3]
(1) Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the Member States and such differences could create barriers to trade and to the creation and proper functioning of the internal market;	(1) Unchanged

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[1] OJ No C 10, 13.1.1989, p. 3.

[2] OJ No

[3] OJ No C 159, 26.6.1989, p. 10

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

ORIGINAL PROPOSAL	AMENDED PROPOSAL
(3) Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions can be considered of fundamental importance for the Community's industrial development;	(3) Unchanged
(4) Whereas the patent system must adapt to new technological developments which may involve living matter but which also fulfil the requirements for patentability;	(4) Whereas the legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law;
	(5) Whereas the rules of national patent law remain the essential basis as far as the legal protection of biotechnological inventions is concerned; whereas, however, they must be adapted or supplemented in certain specific respects in order to take fully into account new technological developments which may involve biological material but which also fulfil the requirements for patentability;
(5) Whereas no prohibition or exclusion exists in national or international patent laws which precludes the patentability of living matter as such;	(6) Unchanged

ORIGINAL PROPOSAL

AMENDED PROPOSAL

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

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

(9) Whereas it is important also to set out in the body of the Directive a list of inventions excluded from patentability so as to provide national courts and patent offices with an essential guide to interpreting the reference to public policy or morality;

ORIGINAL PROPOSAL

AMENDED PROPOSAL

(10) Whereas, in the light of the general principle that the ownership of human beings is prohibited, the human body or parts of the human body per se must be excluded from patentability;

(11) Whereas processes for modifying the genetic identity of human beings for a non-therapeutic purpose which is contrary to the dignity of man must also be excluded from patentability;

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

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

ORIGINAL PROPOSAL	AMENDED PROPOSAL
(6) Whereas national patent systems have in the past successfully adapted to technical developments and scientific breakthroughs in according patent protection to such developments where appropriate;	(14) Unchanged
(7) Whereas the investments required in research and development particularly for genetic engineering are especially high and especially risky and the possibility of recouping that investment can only effectively be guaranteed through adequate legal protection;	(15) Unchanged
(8) Whereas without effective and approximated protection throughout the Member States of the Community such investments might well never be made;	(16) Unchanged
(9) Whereas some inventions developed through biotechnology and genetic engineering are at present not clearly protected in all Member States by existing legislation, administrative practice and court jurisprudence; and such protection, where it exists, is not the same or has different attributes;	(17) Unchanged

ORIGINAL PROPOSAL	AMENDED PROPOSAL
(10) Whereas the uncoordinated development in the Community of the legal protection of biotechnological inventions in the Member States could result in the creation of new disincentives to trade to the detriment of further industrial development in such inventions and of the completion of the internal market;	(18) Unchanged
(11) Whereas existing differences having such effects need to be removed and new ones having a negative impact on the functioning of the common market and the development of trade in biotechnological goods and services prevented from arising;	(19) Unchanged
(12) Whereas international developments in the field of legal protection of the results of biotechnology and genetic engineering demonstrate the advantages to be gained from approximation of national legislation;	(20) Unchanged
(13) Whereas scientific and technological developments are often a result of international collaboration on research and, in consequence, need exists to ensure that biotechnological inventions may benefit from comparable protection on an international level;	(21) Unchanged

ORIGINAL PROPOSAL	AMENDED PROPOSAL
(14) Whereas although international instruments exist or are under consideration to harmonize various aspects of the legal protection of biotechnological inventions, they are not sufficient for Community purposes which must take account of the needs of Community science and industry and a Community market;	(22) Unchanged
(15) Whereas the patent laws applicable at present in the Member States contain disparities which hinder the development of trade in biotechnological goods and services, distort competition within the common market and therefore directly affect the establishment and functioning of that market; whereas it is particularly important to remove these disparities because, at the stage reached at present in establishing the common market, there would appear to be an urgent need to ensure that undertakings will be offered the possibility of obtaining effective and equivalent legal protection in all Member States for the results of their research activities in any part of the Community;	(23) Unchanged

ORIGINAL PROPOSAL	AMENDED PROPOSAL
(16) Whereas an approximation of the legislation of the Member States is also necessitated by existing language in national laws originating in certain international patent and plant variety conventions which have given rise to considerable uncertainty as to the possibility of protecting biotechnological inventions concerning plant matter and microbiological inventions, language such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals;	(24) Unchanged
(17) Whereas it is necessary to encourage potential innovation in the full range of human endeavours by recognizing that human intervention which consists of more than the selection of biological material and allowing such material to perform inherently biological functions under natural conditions should be considered patentable subject-matter and should not be regarded essentially biological;	(25) Whereas it is necessary to encourage potential innovation in the full range of human endeavours by recognizing that human intervention and its impact on the result achieved must be taken into account in determining whether the exclusion from patentability of essentially biological processes applies, it being understood that a process which, taken as a whole, does not exist in nature and is more than a mere production process is patentable;

ORIGINAL PROPOSAL	AMENDED PROPOSAL
(18) Whereas it is seemly that the legislation of the Member States should be harmonized in such a way so as not to conflict with the existing international conventions on which many Member States' patent and plant variety laws are based;	(26) Unchanged
(19) Whereas the Community's legal framework on the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of living matter as such; to the ability to use a deposit mechanism in lieu of written descriptions to satisfy the enabling disclosure requirements for patent application procedures; to a reversal of the burden of proof where release of self-replicable matter has occurred and to the right to a non-exclusive dependency licence for plant and animal varieties;	(27) Whereas the Community's legal framework on the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of biological material as such; to the ability to use a deposit mechanism in lieu of written descriptions to satisfy the enabling disclosure requirements for patent application procedures; to a reversal of the burden of proof; and to the right to a non-exclusive compulsory licence for plant varieties;

ORIGINAL PROPOSAL	AMENDED PROPOSAL
(20) Whereas, in view of the fact that the function of a patent is to reward the inventor with an exclusive but time-bound right for his creative efforts and thereby encourage inventive activities, the rightholder should be entitled to prohibit the use of patented self-replicable material in situations analogous to those where it would be permitted to prohibit such use of patented, non-self-replicable products, i.e. in respect of the production of the patented product itself;	(28) Unchanged
(21) Whereas, in the area of agricultural exploitation of new plant characteristics resulting from genetic engineering, guaranteed remunerated access in the form of licences of right must be provided for as an exception to the general principles of patent law,	Deleted
	(29) Whereas complementary measures of Community law can be adopted later, if necessary, in order to ensure consistency between patent law and the plant varieties protection regime.
HAS ADOPTED THIS DIRECTIVE:	HAS ADOPTED THIS DIRECTIVE:

ORIGINAL PROPOSAL	AMENDED PROPOSAL
CHAPTER I	CHAPTER I
Patentability of Living Matter	**Patentability of biological material**
Article 1	Article 1
Member States shall ensure that their national patent laws comply with the provisions of this Directive.	Member States shall ensure that legal protection for biotechnological inventions on the basis of their national patent laws complies with the provisions of this Directive.
Article 2	Article 2
A subject-matter of an invention shall not be considered unpatentable for the reason only that it is composed of living matter.	1. A subject-matter of an invention shall not be considered unpatentable for the reason only that it is composed of, uses or is applied to biological material. 2. "Biological material" within the meaning of this Directive means any self-replicating living matter and any matter capable of being replicated through a biological system or by any indirect means. 3. Inventions shall be considered unpatentable where publication or exploitation thereof would be contrary to public policy or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Member States.

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

(a) the human body or parts of the human body per se;

(b) processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man;

(c) processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal.

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

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Article 3	Article 3
1. Micro-organisms, biological classifications other than plant or animal varieties as well as parts of plant and animal varieties other than propagating material thereof of the kind protectable under plant variety protection law shall be considered patentable subject-matter. Claims for classifications higher than varieties shall not be affected by any rights granted in respect of plant and animal varieties.	Biological material, including plants and animals, as well as parts of plants and animals, except plant and animal varieties, shall be patentable.
2. Notwithstanding the provisions of paragraph 1, plants and plant material shall be considered patentable subject-matter unless such material is produced by the non-patentable use of a previously known biotechnological process.	Deleted
Article 4	Article 4
Uses of plant or animal varieties and processes for the production thereof shall be considered patentable subject-matter.	Uses of plant or animal varieties or of processes for their production, other than essentially biological processes, shall be patentable.

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Article 5	Article 5
Microbiological processes shall be considered patentable subject-matter. For purposes of this Directive, this term shall be taken to mean and to include a process (or processes) carried out with the use of or performed upon or resulting in a micro-organism.	1. Microbiological processes shall be patentable. For the purposes of this Directive, "microbiological process" means a process involving or performed upon or resulting in microbiological material. 2. A process consisting of a succession of steps shall be treated as a microbiological process if at least one essential step of the process is microbiological.
Article 6	Deleted
A process consisting of a succession of steps shall be regarded a microbiological process, if the essence of the invention is incorporated in one or more microbiological steps of the process.	
Article 7	Article 6
A process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions shall be considered patentable subject-matter.	Essentially biological processes shall not be patentable. In determining whether this exclusion applies, human intervention and its impact on the result achieved shall be taken into account. A process which, taken as a whole, does not exist in nature and is more than a mere production process shall be patentable.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
Article 8	Article 7
A subject-matter of an invention, including a mixture, which formed an unseparated part of a pre-existing material, shall not be considered unpatentable for the reason only that it formed part of said natural material.	An invention concerning a biological material shall not be considered a discovery or lacking in novelty for the reason only that, although not known, it formed part of an existing material.
Article 9	Deleted
A subject-matter of an invention, including a mixture, which formed an unseparated part of a pre-existing material, shall not be considered as an unpatentable discovery or as lacking novelty for the reason only that it formed part of said natural material.	

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CHAPTER II	
Scope of Protection	
Article 10	**Deleted**
The use of a product protected by a patent comprising or consisting of genetic information to develop another such product or the use of a patented process to obtain such a product shall not be regarded experimental for purposes of establishing patent infringement, if the developed product obtained from the experiments or its progeny in identical or differentiated form, is used for other than private or experimental purposes.	
Article 11	**Deleted**
If a product enjoying patent protection and put on the market by the patentee or with his consent is self-replicable, the rights conferred by the national patent shall not extend to acts of multiplication and propagation only where such acts are unavoidable for commercial uses other than multiplication and propagation.	

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Article 8

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be patentable. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 9

A process comprising a succession of steps shall not be excluded from patentability for the reason only that one or more of the steps involve a surgical, therapeutic or diagnostic method practised on the animal body. The treatment or diagnostic method shall not, however, be protected per se.

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Article 12

1. If the subject-matter of a patent is a process for the production of living matter or other matter containing genetic information permitting its multiplication in identical or differentiated form, the rights conferred by the patent shall not only extend to the product initially obtained by the patented process but also the identical or differentiated products of the first or subsequent generations obtained therefrom, said products being deemed also directly obtained by the patented process.

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CHAPTER II

Scope of protection

Article 10

1. The protection conferred by a patent on a biological material possessing, as a result of the invention, specific characteristics shall extend to all biological materials derived from that biological material through multiplication or propagation and possessing the same characteristics.

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2. Any extension of the protection conferred by the patent to a process as indicated under paragraph 1 to a product obtained thereby shall not be affected by an exclusion of plant or animal varieties from patentability.

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

Article 11

The protection referred to in Article 10 shall not extend to biological material derived from biological material that has been marketed by the patent holder or with his consent if the multiplication or propagation result from the application for which the material was marketed.

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Article 13

The protection for a product consisting of or containing particular genetic information as an essential characteristic of the invention shall extend to any products in which said genetic information has been incorporated and is of essential importance for its industrial applicability or utility.

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Article 12

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

Article 13

1. By way of derogation from Chapter II of this Directive, farmers may use for purposes of multiplication or propagation on their own farms the seeds obtained from crops cultivated on their own farms using seeds protected by patent. Only multiplication or propagation with a view to producing crops for the farmers concerned can be authorized.

2. By way of derogation from Chapter II of this Directive, farmers rearing livestock protected by patent may use it for multiplication purposes on their own farms to renew their stock.

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CHAPTER III

Dependency Licence for Plant Varieties

Article 14

1. If the holder of a plant breeders' right or a variety certificate can exploit or exercise his exclusive rights only by infringement of the rights attached to a prior national patent, a non-exclusive licence of right shall be accorded to the breeders' right holder to the extent necessary for the exploitation of such breeders' right where the variety protected represents a significant technical progress, upon payment of reasonable royalties having regard to the nature of the patented invention and consistent with giving the proprietor of such patent due reward for the investment leading to and developing the invention.

2. A licence under paragraph 1 shall not be available prior to the expiration of three years from the date of the grant of the patent or four years from the date on which the application for a patent was filed, whichever period last expires.

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CHAPTER III

Compulsory licence

Article 14

1. If the holder of a patent on a biotechnological invention refuses to allow another party who is the holder of a plant variety right to use the invention in return for an appropriate royalty, a non-exclusive compulsory licence may be sought from the competent authority and it shall be granted upon payment of an appropriate royalty if this is in the public interest.

2. Each Member State shall designate the authority competent to grant licences and shall inform the Commission of each licence granted.

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3. If a licence according to paragraph 1 has been granted, and if a variety protected by a plant breeders' right or variety certificate can be exploited by the patentee only by infringement of the rights attached to such variety, a non-exclusive licence shall be accorded to the original patentee to the extent necessary for the exploitation of the breeders' right or variety certificate, upon payment of reasonable royalties having regard to the nature of the improvement and consistent with giving the proprietor of the breeders' right due reward for the investment leading to and developing the new variety.	3. If the holder of a plant variety right refuses to allow another party who is the holder of a patent to engage in activities requiring his consent on reasonable terms, a non-exclusive compulsory licence may be sought from the competent authority and it shall be granted upon payment of an appropriate royalty if this is in the public interest.
4. Where disagreements arise with regard to the significance of the technical progress and as to the level of royalties, Member States shall provide for a court of competent jurisdiction to resolve the dispute.	4. An appeal shall lie from decisions of the competent authority to the courts.

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CHAPTER IV

Deposit, Access and Re-Deposit

Article 15

1. If an invention involves the use of a micro-organism or other self-replicable matter which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, or if it concerns such matter per se, the invention shall only be regarded as being disclosed for purposes of national patent law if:

   (a) the micro-organism or other self-replicable matter has been deposited with a recognized depositary institution not later than the date of filing of the application;

   (b) the application as filed gives such relevant information as is available to the applicant on the characteristics of the micro-organism or other self-replicable matter;

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CHAPTER IV

Deposit, access and re-deposit

Article 15

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

   (a) the biological material has been deposited, no later than the date on which the patent application was filed, at least with an authorized institution in accordance with the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977;

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

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(c) the depositary institution and the file number of the deposit are stated in the application.

2. The information referred to in paragraph 1(c) may be submitted:

(a) within a period of sixteen months after the date of filing of the application or, if priority is claimed, after the priority date;

(b) up to the date of submission of a request for early publication of the application;

(c) within one month after the national patent office has communicated to the applicant that a right to inspection of the files exists pursuant to paragraph 3(a)(ii) below.

The ruling period shall be the one which is the first to expire. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the deposited matter being available to the public in accordance with this Article.

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(c) the patent application states the name of the authorized depositary institution and the accession number identifying the deposited biological material.

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3.(a) Unless the application has been refused or withdrawn or is deemed to be withdrawn, the deposited matter shall be available upon request:

(i) to any person from the date of publication of the patent application, and

(ii) to any person having a right to inspect the files under the provisions of national patent law relating to applications under which rights are invoked against such a party, prior to the date of publication;

(b) Subject to the provisions of paragraph 4, such availability shall be effected by the issue of a sample of the deposited matter to the person making the request (hereinafter referred to as the "requester"). Said issue shall be made only if the requester has undertaken vis-à-vis the applicant for or proprietor of the patent:

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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, to only those persons who are authorized under national patent law;

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

(c) after the patent has been granted, to anyone requesting it.

3. Unless the patent holder or applicant, as applicable, abandons his rights, the sample can be supplied only if the person requesting it undertakes, for the duration of the validity of the patent:

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(i) not to make the deposited matter or any matter derived therefrom available to any third party;

(ii) to use the deposited matter or any matter derived therefrom in any country only for experimental purposes concerning the invention, with the proviso that this restriction will cease, in the country of the patent right on the basis of which the sample of the deposited matter was obtained, with the grant of a patent or other enforceable right in the invention involved. This provision shall not apply in the country of the patent right on the basis of which the sample of the deposited matter was obtained in so far as the requester is using the matter under a compulsory licence. The term "compulsory licence" shall be construed as including ex officio licences and the right to use patented inventions in the public interest.

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

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

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4. Until the date on which the technical preparations for publication of the application are deemed to have been completed, the applicant may inform the national patent office that, until the publication of the mention of the grant of the patent, the availability referred to in paragraph 3 shall be effected only by the issue of a sample to an expert nominated by the requester.	Deleted
5. The following may be nominated as an expert: (a) any natural person provided that the requester furnishes evidence, when filing the request, that the nomination has the approval of the applicant; (b) any natural person recognized as an expert by the national patent office. The nomination shall be accompanied by an undertaking from the expert vis-à-vis the applicant; paragraphs 3(b)(i) and (ii) shall apply, the requester being regarded as a third party.	Deleted

ORIGINAL PROPOSAL	AMENDED PROPOSAL
6. For the purposes of paragraph 3(b), any matter derived from the deposited matter shall be deemed to be any matter derived therefrom by culturing or in any other way of replication which matter still exhibits those characteristics of the deposited matter which are essential to or for carrying out the invention. The undertaking referred to in paragraph 3(b) shall not impede a deposit of derived matter, necessary for the purposes of patent procedure.	Deleted
7. The request provided for in paragraph 3 shall be submitted to the national patent office on a form recognized by that office. The national patent office shall certify on the form that a national patent application referring to the deposit of the micro-organism or other self-replicable matter has been filed, and that the requester or the expert nominated by him is entitled to the issue of a sample of the micro-organism or other self-replicable matter.	Deleted
8. The national patent office shall transmit a copy of the request, with the certification provided for in paragraph 7 ... to the depositary institution as well as to the applicant for, or the proprietor of, the patent.	Deleted

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9. Member States shall designate recognized depositary institutions for purposes of this Article.

10. If a micro-organism or other self-replicable material has been deposited in accordance with paragraphs 1 and 2 and has become available to any person or an expert in accordance with paragraphs 3 or 4, it shall henceforth be regarded available to the public in accordance with paragraph 1.

Article 16

1. If a micro-organism or other self-replicable matter deposited in accordance with Article 15 ceases to be available from the institution with which it was deposited because:

   (a) the micro-organism or other self-replicable matter is no longer viable, or

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4. At the depositor's request, where an application is refused or withdrawn or a patent is revoked or cancelled, 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 the above-mentioned case, the provisions of paragraph 3 shall apply.

Article 16

If the biological material deposited in accordance with Article 15 ceases to be available from the authorized depositary institution, a new deposit of the material shall be permitted in accordance with the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977.

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(b) for any other reason the depositary institution is unable to supply samples, and if the micro-organism or other self-replicable matter has not been transferred to another depositary institution recognized for the purposes of Article 15, from which it continues to be available, an interruption in availability shall be deemed not to have occurred if a new deposit of the micro-organism or other self-replicable matter originally deposited is made within a period of three months from the date on which the depositor was notified of the interruption by the depositary institution and if a copy of the receipt of the deposit issued by the institution is forwarded to the national patent office within four months from the date of the new deposit stating the number of the application or of the national patent.

2. In the case provided for in paragraph 1(a), the new deposit shall be made with the depositary institution with which the original deposit was made; in the cases provided for in paragraph 1(b), it may be made with another depositary institution recognized for the purposes of Article 15(9).

Deleted

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3. Where the institution with which the original deposit was made ceases to be recognized for the purposes of the application of Article 15, whether entirely or for the kind of micro-organism or other self-replicable matter to which the deposited micro-organism or other self-replicable matter belongs, or where that institution discontinues, temporarily or definitively, the performance of its functions as regards deposited micro-organisms or other self-replicable matter, and the notification referred to in paragraph 1 from the depositary institution is not received within six months from the date of such event, the three-month period referred to in paragraph 1 shall begin on the date on which this event is announced in the official publication of the national patent office.	Deleted
4. Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited micro-organism or other self-replicable matter is the same as that originally deposited.	Deleted
5. If the new deposit provided for in the present Article has been made under the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure of 28 April 1977, the provisions of that Treaty shall prevail in case of conflict.	Deleted.

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6. If a deposit is not accepted or if the deposited material is no longer available from the depositary institution and a re-deposit according to paragraphs (1) through (5) does not or could not remedy the unavailability, such unavailability shall not affect the patentability of the invention if the applicant/patentee provides the requesting party entitled to receive a sample with such same certifying its identity with the material used in the invention or obtained as the invention or with the originally deposited material, as the case may be.	Deleted
7. If a patent is deemed invalid because the patentee can no longer provide for a sample of the deposited material in accordance with this article, such invalidity shall in no case have retroactive effects.	Deleted

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CHAPTER V

Reversal of the Burden of Proof

Article 17

1. If the subject-matter of a patent is a process for obtaining a new or known product, the same product when produced by any other party shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process, if a necessary means to carry out the process had been deposited in accordance with Article 14 and had been released to a third party.

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.

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CHAPTER V

Reversal of the burden of proof

Article 17

1. If the subject-matter of a patent is a process for obtaining a new product, any identical product produced by any person other than the patent holder shall, in the absence of proof to the contrary, be deemed to have been obtained by means of 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.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
CHAPTER VI	CHAPTER VI
Miscellaneous	**Final provisions**
Article 18	Deleted
Any exclusion from patentability or from the field of industrial applicability of surgical or diagnostic methods practised on an animal body shall apply to such methods only if practised for a therapeutic purpose.	
Article 19	Deleted.
For the purposes of this Directive:	
(a) the word "micro-organism", where used, shall be interpreted in its broadest sense as including all microbiological entities capable of replication, e.g. as comprising, inter alia, bacteria, fungi, viruses, mycoplasmae, rickettsiae, algae, protozoa, and cells; and	
(b) the words "self-replicable matter", where used, shall be interpreted to comprise also matter possessing the genetic material necessary to direct its own replication via a host organism or in any other indirect way, e.g. as comprising, inter alia, seeds, plasmids, DNA sequences, protoplasts, replicons and tissue cultures.	

ORIGINAL PROPOSAL	AMENDED PROPOSAL
Article 20	Article 18
1. Member States shall bring into force the laws necessary to comply with this Directive not later than 31 December 1990.	1. The Member States shall adopt the laws, regulations and administrative provisions necessary for their compliance with this Directive not later than When they adopt such measures the Member States shall include references to this Directive or shall make such references when they effect official publication. The manner in which such references are to be made shall be laid down by the Member States.
2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in this field covered by this Directive.	2. The Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
Article 21	Article 19
This Directive is addressed to the Member States.	Unchanged
Done at Brussels,	
	For the Council
	The President

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