




# Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Directive	1988/0159(COD) Procedure rejected
Protection of biotechnological inventions	
Subject 3.50.08 New technologies; biotechnology 3.50.16 Industrial property, European patent, Community patent, design and pattern	

Key players			
European Parliament			
Council of the European Union			
Council configuration	Meeting	Date	
<a href="#">Economic and Financial Affairs ECOFIN</a>	<a href="#">1782</a>	19/09/1994	

Key events			
27/07/1989	Committee referral announced in Parliament, 1st reading		
21/01/1992	Vote in committee, 1st reading		
21/01/1992	Committee report tabled for plenary, 1st reading	A3-0050/1992	
10/02/1992	Debate in Parliament		Summary
10/02/1992	Decision by Parliament, 1st reading	COM(1988)0496	Summary
10/02/1992	Report referred back to committee		
20/02/1992	Vote in committee, 1st reading		
20/02/1992	Committee report tabled for plenary, 1st reading	A3-0126/1992	
06/04/1992	Debate in Parliament		Summary
08/04/1992	Decision by Parliament, 1st reading	T3-0223/1992	Summary
10/06/1992	Debate in Parliament		Summary
10/06/1992	Report referred back to committee		
23/09/1992	Vote in committee, 1st reading		
23/09/1992	Committee report tabled for plenary, 1st reading	A3-0286/1992	

26/10/1992	Debate in Parliament		
29/10/1992	Decision by Parliament, 1st reading	T3-0596/1992	Summary
16/12/1992	Modified legislative proposal published	COM(1992)0589	Summary
23/11/1993	Vote in committee, 1st reading		
23/11/1993	Committee report tabled for plenary confirming Parliament's position	A3-0364/1993	
02/12/1993	Decision by Parliament, 1st reading	T3-0681/1993	Summary
07/02/1994	Council position published	<a href="#">04065/1/1994</a>	Summary
24/02/1994	Committee referral announced in Parliament, 2nd reading		
27/04/1994	Vote in committee, 2nd reading		Summary
27/04/1994	Committee recommendation tabled for plenary, 2nd reading	A3-0321/1994	
03/05/1994	Debate in Parliament		Summary
05/05/1994	Decision by Parliament, 2nd reading	T3-0411/1994	Summary
19/09/1994	Parliament's amendments rejected by Council		
28/11/1994	Formal meeting of Conciliation Committee		Summary
12/01/1995	Formal meeting of Conciliation Committee		Summary
23/01/1995	Final decision by Conciliation Committee		Summary
23/01/1995	Joint text approved by Conciliation Committee co-chairs	<a href="#">3606/1995</a>	
22/02/1995	Report tabled for plenary, 3rd reading	<a href="#">A4-0028/1995</a>	
01/03/1995	Debate in Parliament		Summary
01/03/1995	Decision by Parliament, 3rd reading	T4-0078/1995	Summary
01/03/1995	End of procedure in Parliament		
01/03/1995	End of procedure in Parliament		

### Technical information

Procedure reference	1988/0159(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	Rules of Procedure EP 163; EC before Amsterdam E 100A
Stage reached in procedure	Procedure rejected
Committee dossier	CODE/4/05964

### Documentation gateway

Legislative proposal		<a href="#">COM(1988)0496</a> <a href="#">OJ C 010 13.01.1989, p. 0003</a>	21/10/1988	EC	Summary
Economic and Social Committee: opinion, report		<a href="#">CES0550/1989</a> <a href="#">OJ C 159 26.06.1989, p. 0010</a>	26/04/1989	ESC	
Committee report tabled for plenary, 1st reading/single reading		A3-0050/1992 <a href="#">OJ C 067 16.03.1992, p. 0007</a>	21/01/1992	EP	
Committee report tabled for plenary, 1st reading/single reading		A3-0126/1992 <a href="#">OJ C 125 18.05.1992, p. 0008</a>	20/02/1992	EP	
Text adopted by Parliament, partial vote at 1st reading/single reading		T3-0223/1992 <a href="#">OJ C 125 18.05.1992, p. 0112-0183</a>	08/04/1992	EP	Summary
Committee report tabled for plenary, 1st reading/single reading		A3-0286/1992 <a href="#">OJ C 305 23.11.1992, p. 0007</a>	23/09/1992	EP	
Text adopted by Parliament, 1st reading/single reading		T3-0596/1992 <a href="#">OJ C 305 23.11.1992, p. 0107-0173</a>	29/10/1992	EP	Summary
Modified legislative proposal		<a href="#">COM(1992)0589</a> <a href="#">OJ C 044 16.02.1993, p. 0036</a>	16/12/1992	EC	Summary
Reconsultation		<a href="#">COM(1993)0570</a>	10/11/1993	EC	
Committee final report tabled for plenary, 1st reading/single reading		A3-0364/1993 <a href="#">OJ C 342 20.12.1993, p. 0002</a>	23/11/1993	EP	
Text adopted by Parliament confirming position adopted at 1st reading		T3-0681/1993 <a href="#">OJ C 342 20.12.1993, p. 0015-0030</a>	02/12/1993	EP	Summary
Council position		<a href="#">04065/1/1994</a> <a href="#">OJ C 101 09.04.1994, p. 0065</a>	07/02/1994	CSL	Summary
Commission communication on Council's position		<a href="#">SEC(1994)0275</a>	22/02/1994	EC	
Committee recommendation tabled for plenary, 2nd reading		A3-0321/1994 <a href="#">OJ C 205 25.07.1994, p. 0008</a>	27/04/1994	EP	
Text adopted by Parliament, 2nd reading		T3-0411/1994 <a href="#">OJ C 205 25.07.1994, p. 0230-0307</a>	05/05/1994	EP	Summary
Commission opinion on Parliament's position at 2nd reading		<a href="#">COM(1994)0245</a>	09/06/1994	EC	Summary
Joint text approved by Conciliation Committee co-chairs		<a href="#">3606/1995</a>	23/01/1995	CSL/EP	
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		<a href="#">A4-0028/1995</a> <a href="#">OJ C 068 20.03.1995, p. 0013</a>	22/02/1995	EP	
Text adopted by Parliament, 3rd reading		T4-0078/1995 <a href="#">OJ C 068 20.03.1995, p. 0015-0026</a>	01/03/1995	EP	Summary

#### Additional information

European Commission

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## Protection of biotechnological inventions

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Since a compromise had been reached between the EP and the Commission, the EP approved the Commission's proposal subject to the amendments that it had made. The compromise amendment on the farmer's privilege provided that the farmers may use seeds gathered or any other reproducible plant material on their own farm. The EP also reserved the right to request the opening of the conciliation procedure in the event that the Council intended to depart from the text that it had approved.?

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The amended proposal took account of Parliament's debates and amendments, which sought to supplement the provisions on public policy and morality, to give more precise guidance to national patent offices and courts in determining what was or was not patentable: certain practices were deemed to be not patentable (the human body or parts of the human body as such, processes for modifying the genetic identity of the human body which had a non-therapeutic purpose and which were contrary to the dignity of man, processes for modifying the genetic identity of animals which were likely to cause them suffering or physical handicaps without any substantial benefit to man or animal). The amendment establishing the farmer's privilege was also incorporated.?

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The Council confirmed the approach taken by the Commission in its amended proposal by integrating Parliament's amendments that it had accepted. The Council thus recognised that the two main issues raised by Parliament, namely the ethical dimension of biotechnological inventions and the farmer's privilege, should be dealt with by patent law. On this last issue, the Council nevertheless felt that these regulations should take account of what future Community law on the production of plants would envisage in order to ensure that, when the patent or production law was invoked, the legal situation of the farmers concerned did not change. The Council also felt that at the moment there was no need to make provision for a farmer's privilege for livestock farming since the privilege would not be applied for many years and there was still no law on the production of animal varieties. Finally, the Council added, on its own initiative, several other amendments: it clarified the scope of the non-patentability of the human body or its elements, particularly nucleic acids; it did away with the concept of human dignity as a criteria to determine the exclusion from patentability of certain processes for modifying the genetic identity of human beings - under which chapter it raised the issue of so-called germ line gene therapy - and thus rejected association with it for therapy purposes; it strengthened the criteria of benefits in permitting an assessment of the acceptability of a procedure for determining the genetic identity of animals; it improved the consistency of certain elements in the proposal with the European Patent Convention. ?

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The Committee on Legal Affairs adopted the draft recommendation by Mr ROTHLEY, adopting several amendments that re-established Parliament's position at first reading in relation to certain issues that the Members considered essential: - the non-patentability of the human body: the recommendation reaffirmed very clearly the principle of the complete ban on patenting the human body or elements of the human body; Members rejected the term "as such" that the Council wished to add to the ban on patents for "the human body or elements of the human body", which could reduce the scope of this ban; the processes for modifying the genetic identity of humans should also be deemed non-patentable - except for therapeutic purposes; it should be remembered that the Council did not want to ban the processes for modifying the genetic identity of human beings that "offended against human dignity"; - the recognition of the non-patentability of surgical or therapeutic treatment procedures applicable to the human body or the bodies of animals, which was not included in the common position and which

Members wished to restore, with the exception of "ex vivo" therapeutic procedures; - the exclusion from patentability of processes for modifying the genetic identity of animals which were likely to cause them suffering or physical handicaps and also animals resulting from such processes. It rejected the restriction the Council wished to include in relation to this ban (in the Council's view, the processes in question would only be excluded from patentability in cases where they were "without any substantial benefit to man or animal" and "insofar as the suffering or physical handicaps inflicted on the animals concerned were out of proportion to the objective pursued"); - the "farmer's privilege" (in other words, farmers' rights): Members called for inclusion of the rule whereby the sale to a farmer of "patented animals and/or propagation material by the holder of the patent or with his consent" implied "authorisation for the farmer to use the animals produced in this way, as well as patented animals, for reproduction by him on his own farm". The scope and arrangements for this rule, which derogated from the principle whereby a patent on biological material covered all the biological materials obtained from that material through reproduction or propagation, should be set out by the Council on the basis of a Commission proposal and following consultation of the European Parliament. ?

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The EP adopted three amendments concerning the evaluation of inventions, the ethical and moral aspects in examining inventions and the non-patentability of the human body. ?

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Second meeting of the Conciliation Committee. There was a majority position in the EP delegation, although it was not unanimous, on Mr Rothley's proposal. The Council would respond at the next meeting of the Conciliation Committee due to be held on 23 January 1995.

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In relation to the common position of 7 February 1994, the joint text incorporated the amendments proposed by the EP at second reading, with the exception of the amendment concerning Recital 10 (patentability of parts of the human

Body). The Conciliation Committee reached agreement on a new wording of this key recital: ??an invention based on elements that were susceptible of industrial

application and produced from the human body by means of a technical process in such a way that they are no longer directly linked to a specific individual shall not be excluded from patentability due to the human origin of the elements, even where the structure of those elements is identical to those of a natural element, on the understanding that the parts of the human body from which those elements are derived shall be excluded from patentability?. In other words, parts of the human body were not patentable in principle, but they could be patentable when they formed part of an industrial invention and had been modified in such a way as to no longer be directly linked to an individual. However, problems of interpretation could arise in relation to the phrase ?in such a way that they are no longer directly linked to a specific individual?. After noting that there was disagreement, it was decided that the Council and the EP would each make a statement on their interpretation of this phrase. The EP also pointed out that where there were different interpretations of legislative texts, it would be up to the Court of Justice to take a decision. The other main aspects of the Parliament/Council compromise related to: - modification of the genetic identity of animals. Provision was made to exclude from patentability ?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, insofar as the suffering or physical handicaps inflicted on the animals concerned are out of proportion to the objective pursued?; - germ gene therapy. The EP, the Council and the Commission agreed on a joint statement that referred to the recent opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European

Commission. In this opinion, the Group had stated that ?having regard to the importance and the controversial nature of germ gene therapy and in light of the scientific knowledge available, human gene therapy is not currently acceptable from an ethical point of view?. - farmers?

rights. On this issue the Commission made the following statement: "When a Community legal provision on the breeding of animals enables farmers to use protected livestock for reproduction purposes on his farm in order to renew his stock, the Commission shall give due consideration to this for the purposes of incorporating such a derogation within the framework of the Directive".

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For the first time within the framework of the codecision procedure, Parliament rejected (by 240 votes to 188, with 23 abstentions) the joint EP/Council draft directive on the legal protection of biotechnological inventions. ?

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The rapporteur, Mr ROTHLEY, supported the draft text of the Directive, stating that it provided adequate guarantees and would fill the current legal vacuum. However, in spite of the rapporteur's position, most of the political groups rejected the joint text, pointing out that the proposed legal framework did not provide adequate protection of the fundamental values of the individual. Commissioner Monti confirmed the commitment made at the meeting of the Conciliation Committee on the "farmer's privilege" and warned that rejection of the text by the EP would prevent the establishment of guarantees for respect for human dignity and the introduction of the farmer's privilege. He also felt that the joint text was a good compromise as the ban on patenting elements of the human body as such and the modification of genetic identity was included not only in the recitals but also in Article 2 of the joint text. In his view, rejection of the text would leave the EU lagging behind Japan and the United States in the area of biotechnological research. His position was not supported.