Procedure file

Basic information

SYN - Cooperation procedure (historic)	1995/0340(SYN)	Procedure completed
Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC) Repealed by 2007/0259(COD) Subject 3.10.09.06 Agro-genetics, GMOs 4.60.04.04 Food safety		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Consumer Protection	PPE TRAKATELLIS Antonios	20/03/1996
	Former committee responsible		
	ENVI Environment, Public Health and Consumer Protection	PPE TRAKATELLIS Antonios	20/03/1996
	Former committee for opinion		
	ENER Research, Technological Development and Energy	UPE POMPIDOU Alain	06/02/1996
	JURI Legal Affairs, Citizens' Rights	PSE COT Jean-Pierre	10/03/1997
Council of the European Union	Council configuration	Meeting	Date
	General Affairs	2126	26/10/1998
	Environment	2062	16/12/1997
	Environment	1978	09/12/1996
	Environment	1956	15/10/1996
	Environment	1939	26/06/1996

Key events

06/12/1995	Legislative proposal published	COM(1995)0640	Summary
09/05/1996	Committee referral announced in Parliament		
26/06/1996	Debate in Council	1939	
15/10/1996	Debate in Council	1956	
09/12/1996	Debate in Council	1978	Summary

26/02/1997	Vote in committee		Summary
26/02/1997	Committee report tabled for plenary, 1st reading/single reading	A4-0070/1997	
11/03/1997	Debate in Parliament		Summary
12/03/1997	Decision by Parliament	T4-0085/1997	Summary
12/06/1997	Modified legislative proposal published	COM(1997)0240	Summary
16/12/1997	Council position published	11542/1/1997	Summary
19/02/1998	Committee referral announced in Parliament, 2nd reading		
20/05/1998	Vote in committee, 2nd reading		Summary
20/05/1998	Committee recommendation tabled for plenary, 2nd reading	A4-0192/1998	
15/06/1998	Debate in Parliament		Summary
16/06/1998	Decision by Parliament, 2nd reading	T4-0332/1998	Summary
29/07/1998	Modified legislative proposal published	COM(1998)0479	
26/10/1998	Act adopted by Council after consultation of Parliament		
26/10/1998	End of procedure in Parliament		
05/12/1998	Final act published in Official Journal		

Technical information

Procedure reference	1995/0340(SYN)
Procedure type	SYN - Cooperation procedure (historic)
Procedure subtype	Legislation
	Repealed by 2007/0259(COD)
Legal basis	EC before Amsterdam E 130S
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/4/09615

Documentation gateway

Legislative proposal		COM(1995)0640 OJ C 356 22.11.1997, p. 0014	06/12/1995	EC	Summary
Economic and Social Committee: opinion, report		CES0887/1996 OJ C 295 07.10.1996, p. 0052	10/07/1996	ESC	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0070/1997 OJ C 115 14.04.1997, p. 0005	26/02/1997	EP	
Text adopted by Parliament, 1st reading/single reading		T4-0085/1997 OJ C 115 14.04.1997, p. 0051-0059	12/03/1997	EP	Summary
Modified legislative proposal		COM(1997)0240 OJ C 369 06.12.1997, p. 0012	12/06/1997	EC	Summary

Council position		11542/1/1997 OJ C 062 26.02.1998, p. 0001	16/12/1997	CSL	Summary
Commission communication on Council's position		SEC(1998)0042	20/01/1998	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A4-0192/1998 OJ C 195 22.06.1998, p. 0004	20/05/1998	EP	
Text adopted by Parliament, 2nd reading		T4-0332/1998 OJ C 210 06.07.1998, p. 0021-0033	16/06/1998	EP	Summary
Modified legislative proposal		COM(1998)0479	29/07/1998	EC	
Follow-up document		COM(2001)0263	17/05/2001	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Directive 1998/81
OJ L 330 05.12.1998, p. 0013 Summary

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

OBJECTIVE: to rectify the shortcomings of Directive 90/219/EEC in the light of scientific progress and new experience while guaranteeing the same level of protection for the environment and human health. CONTENT: the proposal for a Council directive provides for: - notification procedures and requirements to be linked to the risk of operations involving the use of genetically-modified micro-organisms. Provision is made for four risk classes, taking account of scientific knowledge and international experience; - administrative procedures to be simplified, provided that this does not compromise safety; - minimum containment and control measures applicable to each risk class to be specified at a later date in order to guarantee harmonization and adequate environmental protection; - the possibility of introducing other derogations for safe genetically-modified micro-organisms in order to safeguard rapid adaptation to technical progress and avoid unreasonable administrative charges for users; - all the Annexes to be amended under a regulatory committee procedure, which will increase flexibility. In addition to the main changes outlined above, the proposal also updates certain technical sections of the directive in the light of scientific and technical progress.?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

The Committee feels that, in a field of technological development where risk assessment involves a number of unknown factors and where public acceptance is of fundamental importance, decisions to amend the existing rules should be taken with great caution, and be subject to maximum safety measures with a view to risk prevention. Only in this way can a sector offering considerable growth potential from the standpoint of production and employment gain the confidence of users and consumers and attract the necessary investment. It is precisely at the marketing stage that consumer concerns become apparent, as demonstrated by certain reactions to foodstuffs produced by genetic modification or genetically modified plants. The Committee welcomes an updating of Directive 219/90 to keep pace with technical and scientific progress, in terms of better definition and classification of risk levels, and hence of procedural simplification and of better technical protection, provided that the basic premises and philosophy of the Directives adopted in 1990 remain unchanged. It therefore regards the present proposal as an amendment of the existing legislation in the light of experience gained at Community and international level and not as a deregulation measure. It should be pointed out that the reason for adoption of specific Directives for genetically modified micro-organisms was acceptance of the idea that the risks associated with GMMs are not fully recognized in that a potential risk can derive from possible unforeseen effects of the building of new combinations of otherwise harmless components. ?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

The Council reached agreement on the basis of a compromise text. A common position was to be adopted once Parliament had delivered its opinion.

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

The Committee wants to enhance safety aspects of a Commission proposal on genetically modified micro-organisms (GMMs), which include

the Aids and Embola viruses. GMMs, which also include salmonella and rickettsia, are important tools of biotechnology. Some can produce useful substances, such as human insulin. On the other hand, an accidental release of GMMs into the environment could jeopardize whole ecosystems. The Commission proposal is for a Council Directive amending Directive 90/219/EEC on the contained use of GMMs, ie their use within an enclosed area (eg specially insulated laboratories). The committee adopted a number of amendments on safety tabled by the rapporteur, Mr Antonios TRAKATELLIS (EPP, Gr), who stressed the need to learn from the BSE crisis. One of these placed GMMs in separate graded categories according to health risk. This will give the general public protection equivalent to that already afforded to biotechnology workers. It will also help the industry by removing any doubt about the category to which a particular GMM belongs so that there is no uncertainty about what precautions must be taken. The committee also adopted an amendment by the rapporteur to the effect that a contained environment must prevent, not simply limit (as the Commission had proposed), contact between GMMs and the general population and the environment. However, the committee rejected many amendments which it considered were too stringent and likely to act as an unnecessary bureaucratic break on industry's freedom to experiment. The committee's report (first reading) was adopted under the cooperation procedure (Article 130s of the EC Treaty). However, against the Commission's wishes, the committee accepted Mr Trakatellis's argument - subject to agreement by the Legal Affairs Committee - that the legal basis should be changed to 100a (codecision procedure), which will give Parliament more clout. The committee also want the proposed directive to be monitored by a management committee rather than a regulatory committee. This will give more leeway to Parliament and the Commission vis-a-vis the Council. The aim of other amendments adopted by the committee, is for GMM users to take out adequate accident insurance and for the disposal of GMMs to be taken into account when assessing risks. The public should be better informed. Users must keep appropriate records and a register of serious accidents needs to be compiled. ?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

Having stressed that codecision should be applied to all issues relating to health, the rapporteur pointed out that the organisms in question (GMOs) were one of the most important tools in biotechnology. However, he stressed the need for work with these GMOs to take place in areas appropriately designed to cope with every kind of risk, in order to ensure human safety. The rapporteur also considered that the former definition of microorganism was more appropriate than that currently proposed by the Commission. He also said that not all projects in category 2 could be regarded as risk-free. Commissioner Bjerregaard emphasised the highly technical nature of the area in question which was in a process of very rapid development and could have considerable implications for employment in the EU. She then explained that the amendments made to the directive mainly concerned the administrative procedures in relation to the precautions to be taken when handling GMOs, in order to simplify the procedures without increasing the risks. As regards the amendments tabled, the Commissioner said that Amendments Nos 2, 3, 9, 10, 16, 17, 19, 31, 41, 42, 49 and 56 could be accepted. Amendments Nos 4, 11, 27, 30, 35, 37, 38, 39, 43, 47, 48, 54 and 55 could be partially accepted and Amendments Nos 7, 8, 14, 15, 17, 21-25, 64 and 68 could be accepted in principle.

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

In adopting the report by Mr Antonios TRAKATELLIS (EPP, GR) Parliament amended the proposal amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms (GMM) mainly with the aim of specifying the way in which the risk should be assessed. An amendment thus classes the GMMs in different categories according to the risk to human health. Parliament considers that for all activities involving GMMs the principle of good microbiological practice and of safety and health at work must apply in accordance with the relevant Community laws. Furthermore specific measures should be adopted and used for the control of the disposal of material from the activities of the contained use of GMMs. Parliament considers that a contained environment should avoid and not simply limit (as proposed by the Commission) contact between GMMs and the general population and the environment. According to other amendments legally responsible users of GMMs shall have full civil and criminal liability for any damage to humans or the environment. Before the activities begin they must take out sufficient liability insurance to cover accidents. Furthermore users must draw up appropriate reports and keep a register of any serious accidents. The Commission should set up and keep at the disposal of the Member States a register of accidents involving possible serious damage to public health or the environment. Parliament also hopes that monitoring of the implementation of the directive will be by a management committee rather than a regulatory committee, which would increase the freedom of action of Parliament and the Commission vis-à-vis the Council. Lastly, Parliament called for the co-decision procedure to apply to this proposal, which should therefore be based on Articles 100a and 189b of the EC Treaty,. ?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

The Commission's modified proposal incorporates several amendments adopted by the European Parliament at first reading, particularly those intended to: - reiterate the fact that for all operations involving genetically modified micro-organisms the principles of good microbiological practice and safety and health at work apply in accordance with the relevant Community laws; - emphasize the need to adopt and use specific measures for controlling the disposal of material from activities involving the contained use of genetically modified micro-organisms; - stress the need to provide a high level of safety for the general population and the environment; - place emphasis on the need to take account of the question of disposal when assessing the risk entailed in an activity involving genetically modified micro-organisms; - ensure that the applicant can himself request a decision on a formal authorization from the competent authority, this decision having to be made within a maximum of 45 days from the notification; - redraft the requirement on safety measures, which must be consistent with emergency plans; - limit the number of annexes which may be amended through the committee procedure; - request that, within six months of the implementation date of the directive, the criteria for the inclusion of certain types of genetically modified micro-organisms in Annex II, Part B, be laid down in accordance with Article 130s(1) of the EC Treaty; - apply commitology procedure type IIa, which allows the Council to adopt measures other than those proposed by the Commission. Regarding the annexes, the Commission agrees to add to Annex III a specific reference to Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work. In the case of Annex IV, it agrees to amend the requirements on surfaces in laboratories, which must be resistant to water and decontamination agents and must be easy to clean. On a general note, the Commission has not accepted the amendments limiting the information given to the public or the Commission, introducing specific requirements on liability insurance, changing the legal basis of the directive or complicating its operation. ?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

The common position provides for administrative measures, notification rules and containment and other protective measures applied to the contained use of genetically modified micro-organisms (GMMs). The Council adopted 28 of the 35 amendments proposed by the European Parliament and incorporated by the Commission in its proposal. As a result, certain aspects of the text have been strengthened: - the disposal of waste is specifically taken into account; - in cases of doubt of the classification of an activity, more stringent safety measures are applied; - the administrative control has been reinforced by the requirement to obtain explicit consent for all class 3 and class 4 work with GMMs; - the requirement for emergency plans has been extended to all cases where failure of containment could lead to serious danger; - the containment and control measures have been strengthened by the incorporation of a requirement to apply the principles of good occupational safety and hygiene; - references to the identification of potentially harmful effects to hand washing facilities and to surfaces resistant to water and decontamination agents have been introduced. The common position also provides for the possibility of specific exclusion from disclosure, after justification, for items mentioned in article 3(2) of directive 90/313/EEC on freedom of access to information on the environment to accommodate concerns on national security. The common position does not incorporate the amendments: - seeking to change the definition of contained utilisation; - making it possible for the notifier to request a decision within 45 days; - seeking the addition of the words "safety measures" as part of emergency plans with regard to information provided to organisations possibly at risk from accidents; - seeking to implement type II instead of a type III b procedure with regard to the Regulatory Committee. ?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

The Commission considers that the common position does not modify the approach or basic objectives of the proposal and that certain aspects of the text have even been strengthened or clarified. While it considers that the common position is technically acceptable, it cannot endorse the exclusion of the European Parliament from the process of adopting or modifying annexe II B, which affects the scope of the directive. The Commission also opposes the type III b regulatory committee procedure instead of the type II a procedure put forward in the amended Commission proposal. ?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

The safe use in laboratories of genetically modified micro-organisms, which include the Aids and Embola viruses, was a priority for the Committee when it adopted a recommendation on the subject by Mr Antonios TRAKATELLIS (EPP, Gr). The recommendation is for a second reading in the House, under the cooperation procedure, on the Council's common position on genetically modified micro-organisms (GMMs). It was adopted by 19 votes to one with two abstentions. The accidental release into the environment of GMMs (which also include salmonella and rickettsia) could jeopardize whole ecosystems. On the other hand, some GMMs can be used by scientists to produce valuable substances, such as human insulin. The dual aim of the measure proposed, therefore, is to provide a common framework for the development of this new technology while at the same time protecting human health and the environment. The common position embodies the Council's stance on a Commission proposal for a directive amending Directive 90/219/EEC on the contained use of GMMs, ie within an enclosed area (eg a specially insulated laboratory). The common position incorporates - entirely, partly or in principle - 29 of the 57 amendments adopted by Parliament at its first reading in March 1997. However, according to Mr Trakatellis, substantive EP amendments have been omitted. Hence the committee's decision to reinstate amendments from the first reading. One key amendment retabled aims to change the legal base from 130s(1) (environment, cooperation procedure) to 100a (internal market, codecision procedure). The committee also reinserted in the directive precise criteria for assessing risk - something which lies at the heart of the proposal - in place of the more general guidelines preferred by the Council. Moreover, according to the committee, a contained environment must avoid (not, as the Council wants, merely limit) contact between GMMs and the general population and the environment. In addition, the committee believes that official inspections must be carried out to ensure that users are complying with the directive and GMM users must keep appropriate records. Other amendments provide for users to take out adequate accident insurance. The committee is of the view that "legally responsible users of genetically modified micro-organisms shall have full civil liability for any damage to human health and the environment caused by the uses in question". It also wants improved information for the public. ?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

Commissioner Brittan said that the Commission could accept Amendments Nos 5, 6, 17, 19, 25, 32 and 36. It could also partially accept Amendments Nos 8, 12, 13 and 14 and Amendments Nos 2, 18, 20, 21, 28, 33, 34 and 35 which, however, should be reworded. With particular regard to Amendment No 13, the Commission could accept a comitology procedure (2a) which was more flexible than that proposed by the Commission (3b). On the other hand, the Commission could not accept 17 amendments, particularly No 1 which proposed changing the legal basis from Article 130s to Article 100a. The scope of the directive in question did not impact on the functioning of the single market. As for Amendments Nos 4 and 9 on liability, the Commission preferred to deal with this problem in a horizontal manner to avoid any kind of fragmentation. Likewise, Amendment No 11 had to be rejected because technical amendments to Annex III needed to be made rapidly and flexibly without recourse to the ordinary legislative procedure. Finally, the Commissioner rejected Amendments Nos 3, 7, 10, 15, 16, 22, 23, 24, 26, 27, 29 and 30 to ensure consistency with the proposal as a whole and for technical reasons, namely the need to ensure that the burden of control measures was not increased.

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

Adopting the report by Mr Antennas TRAKATELLIS (PPE, GR), the European Parliament called for legal basis of this directive to be changed (from article 130 S, 1 to article 100 A, so that the Parliament/Council co-decision procedure applied). Although the Council retained 28 of the 35 amendments adopted by Parliament in its common position, the rapporteur re-presented a number of amendments for second reading. These amendments, which were accepted by the plenary, called for a more accurate definition of the term "contained use" and for the risks to

be re-assessed where the competent authority was aware that the assessment was no longer adequate. Parliament called for the possibility for the applicant to obtain a decision within 45 days. It called for the public to be informed of emergency plans and relevant health and environmental safety measures before contained use commenced. Parliament called for inspections and controls in order to ensure that the directive was properly applied. It also insisted that users of GMMs assume full civil and criminal liability for any damage to human health or the environment caused and proposed in particular that they take out sufficient liability insurance to cover any losses occasioned before beginning their activities. With reference to the criteria for exclusion from the field of application of the directive of certain GMMs which are not considered to present a risk to human health or to the environment, the European Parliament called for the participation of the European Parliament in this procedure. The same applied to the participation of Parliament in the risk assessment procedure. The European Parliament also called for a clear definition of the risk assessment procedure which users of GMMS were required to apply. However, the European Parliament rejected the amendment tabled by the Committee on the Environment calling for users to provide a certificate of sufficient liability insurance cover to compensate everyone who may suffer as the result of GMM containment measures.?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

OBJECTIVE: to revise Directive 90/219/EEC in the light of scientific progress and to simplify the administrative procedures applicable to the contained use of genetically modified micro-organisms (GMMs), while maintaining an adequate level of protection for the environment and human health which is at least equal to that achieved under the present directive. COMMUNITY MEASURE: Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms. CONTENT: the directive makes provision for administrative procedures, rules of notification and containment and protection measures based on the risk presented by the contained use of GMMs. GMMs are classified in four classes of risk (no risk, low risk, moderate risk, high risk). The rationalised procedure will be followed where safety is not affected. The minimum containment and control measures applicable to each of the four risk classes are specified and the method for adapting the directive to future technical progress is simplified. The directive provides for the authorities to ensure that emergency plans are established before contained use commences and for information on these emergency plans to be supplied to the bodies and authorities likely to be affected by an accident. Member States are also required: - where they may be affected by an accident, to consult other Member States on the implementation of emergency plans; - to inform the Commission as quickly as possible of any accident which comes under the scope of the directive. Member States must submit summary reports on experiences acquired within the framework of the directive to the Commission every three years, starting on 5 June 2003. ENTRY INTO FORCE: 5 December 1998. DEADLINE FOR TRANSPOSITION: 5 June 2000.?

Contained use of genetically modified micro-organisms GMM (amend. Directive 90/219/EEC)

This is the third summary report to be published by the Commission and covers the period 1996-1999. The Commission report is based upon a third series of reports from Member States that were due in September 1999 but only received during a period from October 1999 to November 2000. The contents of these national reports were largely based upon an outline of submitted by the Commission to Member States in an attempt to improve the quality of information and harmonisation of responses. On the whole, national reports were vastly improved in comparison to previous submissions and contained detailed information on relevant issues and experiences concerning both Directive 90/219/EEC and transposition of the amending Directive 98/81/EC into national laws. The main themes dealt with in the report concern an overview of installations and activities of the Member States, classification and risk assessment, notification and approval system, accidents, inspection and enforcement issues, European enforcement project, problems with the interpretation of the provisions, public consultation and information, accident and emergency plans, protection of confidential information and waste disposal in the different Member States. Lastly, the report highlights the progress made by Member States with the transposition of Directive 98/81/EC into national legislation (before 5 June 2000 at the latest). It is interesting to note that at the time of writing this report, Finland, Denmark and Sweden has transposed the amended Directive into national law but the transposition was still on going in the other Member States.?