

Basic information	
1995/0340(SYN) SYN - Cooperation procedure (historic) 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 Directive 90/219/EEC) Repealed by 2007/0259(COD) Subject 3.10.09.06 Agro-genetics, GMOs 4.60.04.04 Food safety	Procedure completed

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

Key events			

Date	Event	Reference	Summary
06/12/1995	Legislative proposal published	COM(1995)0640 	Summary
09/05/1996	Committee referral announced in Parliament		
26/06/1996	Debate in Council		
15/10/1996	Debate in Council		
09/12/1996	Debate in Council		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
12/06/1997	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
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
Amendments and repeals	Repealed by 2007/0259(COD)
Legal basis	EC Treaty (before Amsterdam) E 130S
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/4/09615

Documentation gateway				
European Parliament				
Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0070/1997 OJ C 115 14.04.1997, p. 0005	26/02/1997	

Text adopted by Parliament, 1st reading/single reading		T4-0085/1997 OJ C 115 14.04.1997, p. 0051-0059	12/03/1997	Summary
Committee recommendation tabled for plenary, 2nd reading		A4-0192/1998 OJ C 195 22.06.1998, p. 0004	20/05/1998	
Text adopted by Parliament, 2nd reading		T4-0332/1998 OJ C 210 06.07.1998, p. 0021-0033	16/06/1998	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	11542/1/1997 OJ C 062 26.02.1998, p. 0001	16/12/1997	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(1995)0640  OJ C 356 22.11.1997, p. 0014	06/12/1995	Summary
Modified legislative proposal	COM(1997)0240  OJ C 369 06.12.1997, p. 0012	12/06/1997	Summary
Commission communication on Council's position	SEC(1998)0042 	20/01/1998	Summary
Modified legislative proposal	COM(1998)0479 	29/07/1998	
Follow-up document	COM(2001)0263 	17/05/2001	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0887/1996 OJ C 295 07.10.1996, p. 0052	10/07/1996	Summary

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

[Directive 1998/0081](#)
[OJ L 330 05.12.1998, p. 0013](#)

[Summary](#)

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

1995/0340(SYN) - 12/03/1997 - Text adopted by Parliament, 1st reading/single reading

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)

1995/0340(SYN) - 09/12/1996

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)

1995/0340(SYN) - 12/06/1997 - Modified legislative proposal

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 committee 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)

1995/0340(SYN) - 16/12/1997 - Council position

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)

1995/0340(SYN) - 10/07/1996 - Economic and Social Committee: opinion, report

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)

1995/0340(SYN) - 26/10/1998 - Final act

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)

1995/0340(SYN) - 17/05/2001 - Follow-up document

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.

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

1995/0340(SYN) - 20/01/1998 - Commission communication on Council's position

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)

1995/0340(SYN) - 06/12/1995 - Legislative proposal

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)

1995/0340(SYN) - 16/06/1998 - Text adopted by Parliament, 2nd reading

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.