Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2007/0259(COD)
Contained use of genetically modified micro-organisms (GMOs). Recast Repealing Directive 98/81/EC 1995/0340(SYN) Subject 3.10.09.06 Agro-genetics, GMOs	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	JURI Legal Affairs		19/12/2007
		PPE-DE SZÁJER József	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		06/03/2008
		PSE HEGYI Gyula	
Council of the European Union	Council configuration	Meeting	Date
	Transport, Telecommunications and Energy	2935	30/03/2009
European Commission	Commission DG	Commissioner	
	Legal Service	BARROSO José Manuel	

Key events

29/11/2007	Legislative proposal published	COM(2007)0736	Summary
19/02/2008	Committee referral announced in Parliament, 1st reading		
26/06/2008	Vote in committee, 1st reading		Summary
08/07/2008	Committee report tabled for plenary, 1st reading	A6-0297/2008	
21/10/2008	Results of vote in Parliament		
21/10/2008	Decision by Parliament, 1st reading	T6-0499/2008	Summary
30/03/2009	Act adopted by Council after Parliament's 1st reading		
06/05/2009	Final act signed		
06/05/2009	End of procedure in Parliament		

21/05/2009	Final act published in Official Journal		

Technical information

Procedure reference	2007/0259(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Directive
	Repealing Directive 98/81/EC 1995/0340(SYN)
Legal basis	EC Treaty (after Amsterdam) EC 175-p1
Stage reached in procedure	Procedure completed
Committee dossier	JURI/6/57065

Documentation gateway

For information		COM(2007)0740	23/11/2007	EC	
Legislative proposal		COM(2007)0736	29/11/2007	EC	Summary
Economic and Social Committee: opinion, report		CES0275/2008	13/02/2008	ESC	
Committee draft report		PE407.759	06/06/2008	EP	
Committee opinion	ENVI	PE404.617	20/06/2008	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0297/2008	08/07/2008	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0499/2008	21/10/2008	EP	Summary
Commission response to text adopted in plenary		SP(2008)6664	12/11/2008	EC	
Draft final act		03714/2008/LEX	06/05/2009	CSL	
Follow-up document		COM(2012)0398	17/07/2012	EC	Summary
Follow-up document		SWD(2012)0216	17/07/2012	EC	
Follow-up document		COM(2016)0808	20/12/2016	EC	Summary
Follow-up document		SWD(2016)0445	20/12/2016	EC	
Follow-up document		COM(2021)0266	31/05/2021	EC	
Follow-up document		SWD(2021)0114	31/05/2021	EC	
Follow-up document		COM(2023)0075	15/02/2023	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Directive 2009/41

OJ L 125 21.05.2009, p. 0075 Summary

Contained use of genetically modified micro-organisms (GMOs). Recast

PURPOSE: recast of Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms.

PROPOSED ACT: Directive of the European Parliament and of the Council

CONTENT: the codification of Council Directive 90/219/EEC has been initiated by the Commission, and a relevant proposal has been submitted to the legislative authority (see COD/2006/0100). The new Directive was to have superseded the various acts incorporated in it.

In the meantime Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission has been amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty (the co-decision procedure), including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.

In accordance with the joint statement of the European Parliament, the Council and the Commission on Decision 2006/512/EC, for this new procedure to be applicable to instruments adopted in accordance with the co-decision procedure which are already in force, those instruments must be adjusted in accordance with the applicable procedures.

The Commission feels that it is therefore appropriate to transform the codification of Directive 90/219/EEC into a recast in order to incorporate the amendments necessary for the adjustment to the regulatory procedure with scrutiny.

On comitology, the text now states the following:

-power should be conferred on the Commission in particular to adopt the amendments necessary to adapt Annex II, Part A, and Annexes III, IV and V to technical progress and to adapt Annex II, Part C. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, they should be adopted in accordance with the regulatory procedure with scrutiny;

-the new elements introduced into this Directive only concern the committee procedures. They therefore do not need to be transposed by the Member States;

-the Directive is without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex VI, Part B.

Contained use of genetically modified micro-organisms (GMOs). Recast

The Committee on Legal Affairs adopted a report drafted by József SZÁJER (EPP-ED, HU), and approved, in 1st reading of the codecision procedure, the proposal for a directive of the European Parliament and of the Council on the contained use of genetically modified micro-organisms (recast). The proposal is approve as adapted to the recommendations of the Consultative Working Party of the Legal Services of the European Parliament, the Council and the Commission. The Committee on Legal Affairs does not propose any amendments apart from those suggested by the sectoral committee with regard to Part B of Annex II. Amendments to Annex II, Part B should also be adopted in accordance with the regulatory procedure with scrutiny.

Contained use of genetically modified micro-organisms (GMOs). Recast

The European Parliament adopted, by 653 votes to 16 with 13 abstentions, under 1st reading of the codecision procedure, a legislative resolution approving the proposal for a directive of the European Parliament and of the Council on the contained use of genetically modified micro-organisms (recast.) The report had been tabled for consideration in plenary by József SZÁJER (EPP-ED, HU), on behalf of the Legal Affairs Committee. The Commission proposal was approved as adapted to the recommendations of the Consultative Working Party of the Legal Services of the European Parliament, the Council and the Commission. According to the Consultative Working Party, the proposal in question does not include any substantive amendments other than those identified as such in the proposal and, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

Contained use of genetically modified micro-organisms (GMOs). Recast

PURPOSE: to recast Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

LEGISLATIVE ACT: Directive 2009/41/EC of the European Parliament and of the Council on the contained use of genetically modified micro-organisms (Recast).

CONTENT: following a first reading agreement with the Parliament, the Council adopted this Regulation which recasts legislation on the contained use of genetically modified micro-organisms. The codification of Council Directive 90/219/EEC had been initiated by the Commission, when Council Decision 1999/468/EC was amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the co-decision procedure.

Accordingly, the codification of Directive 90/219/EEC was transformed into a recast in order to incorporate the amendments necessary for the

adjustment to the regulatory procedure with scrutiny.

On comitology, the text now states that the Commission is empowered to adopt the amendments necessary to adapt Annexes II, III, IV and V to technical progress, and to adapt Annex II, Part C.

The new elements introduced into this Directive concern only the committee procedures. They therefore do not need to be transposed by the Member States.

ENTRY INTO FORCE: 10/06/2009.

Contained use of genetically modified micro-organisms (GMOs). Recast

The Commission presents a report on the experience of Member States with Directive 2009/41/EC on the contained use of genetically modified micro-organisms (recast) for the period 2006 2009. This report is based on a sixth series of Member States' reports.

Activities: to recall, contained use activities are classified into four classes: class 1 represents activities of no or negligible risk; classes 2, 3 or 4 represent activities of low, moderate or high risk, respectively.

Most contained use activities fell within class 1 or class 2. Significantly fewer class 3 and 4 activities were being carried out, but the number is increasing. Most activities were related to research but several serve commercial purposes such as the manufacture of diagnostics, or veterinary or medicinal products. On the whole, the Member States applied the Directive in a similar fashion. Differences arose as Member States enacted additional legislation in almost all areas covered by the Directive.

Problems with interpretation of the provisions: some Member States named topics which need further clarification, in relation with a necessary update of technical and scientific advancement and/or further harmonization on the European level.

- In Austria, Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Malta, Portugal, Romania and Slovakia no specific problems with the interpretation of the provisions were reported. For the New Member States, in the majority of the cases the reason is the lack of activities due to the lack of notifications.
- Belgium, Czech Republic, Hungary and the Netherlands encountered problems in assessing whether the application of certain new techniques resulted in a genetically modified organism and fell within the scope of Directive 2009/41/EC. At the request of the Competent Authorities of Directive 2001/18/EC the Commission set up a New Techniques Working Group in October 2007 to assess a non-exhaustive list of techniques as to whether they result in the production of a genetically modified organism or microorganism as defined under Directives 2001/18/EC and 2009/41/EC. The outcome is expected to help to clarify whether certain new techniques result in genetically modified organisms and fall within the scope of Directive 2009/49/EC.
- The Netherlands, Spain, Hungary, Czech Republic, Belgium, Finland saw a need for clarification of the scopes of Directive 2009/41/EC and Directive 2001/18/EC with respect to clinical trials.

Other problems encountered in case of implementation of the Directive 2009/41/EC were the following:

- difficulties with the detection and identification of GMOs (Germany), lack of clarity of terminology (Germany, Finland);
- huge number of notifications of class 1 to be reviewed (Denmark), or huge number of inspections (Ireland);
- high number of notifications for viral vectors with low risk (United Kingdom) which created a significant administrative burden;
- difficulties in obtaining feedback from the users working with GMO/GMM (Spain). Member States proposed different measures such as including safe organisms in Part C of the Annex II of the Directive 2009/41/EC (Slovenia), to set up a EU GMM Working Group focusing on research activities from the perspective of Directive 2009/41/EC, and to change the requirements for notifying class 2 activities (United Kingdom).

Clinical trials: the national reports showed that the Member States addressed clinical trials in different ways. Some Member States (Denmark and Finland) applied Directive 2009/41/EC on the contained use of GMMs, others (for example, Sweden) used Directive 2001/18/EC on the deliberate release of GMOs into the environment, and yet others applied other national legislation. Other Member States (Spain, UK) decide on a case-by-case basis whether a clinical trial is regarded as contained use or as a deliberate release. These differences stem from differences in the interpretation of annexes of Directive 2001/18/EC and Directive 2009/41/EC, in particular, as the latter Directive had not been specifically designed for clinical trials.

However, both Directives attribute the competence to regulate clinical trials with GM microorganisms essentially to the Member States, Directive 2009/41/EC by setting minimum standards leaving it up to the Member States to go beyond those minimum standards, and Directive 2001/18/EC by attributing the competence for authorising part B notifications to the Member States. Some Member States raise the point that further harmonization would be useful. However, most importantly, both Directives share as common objective a high level of protection so that, from a safety point of view, further harmonisation at Union level is at present not a priority for the Commission.

Contained use of genetically modified micro-organisms (GMOs). Recast

This Commission report examines the experience acquired by Member States in the framework of Directive 2009/41/EC of the European Parliament and of the Council on the contained use of genetically modified micro-organisms (recast) for the period 2009-2014.

The document presents a summary of the information provided by 26 Member States for each of the following aspects:

Operations and facilities: Most of the contained use operations carried out in the Member States, according to the information provided, fall within Class 1 (zero or negligible risk) or 2 (low risk). Few Class 3 or 4 operations (moderate and high risk) have been carried out.

Most of the operations were related to research activities, but several pursued commercial objectives, such as the manufacture of diagnostics and veterinary and human medicines.

Notification and approval systems: national systems differ slightly with regard to the competent authorities.

In many Member States, the competent authority for notification and approval is the ministry of the environment or environmental agencies. In others, these functions are performed by other ministries, acting alone or in collaboration with other authorities, such as the Ministry of Health or Research. Overall, the notifications were processed within the deadlines set by the Directive.

Accidents: few Member States (Finland, the Netherlands, Slovakia, Sweden and the United Kingdom) reported accidents. Corrective actions have been taken in the case of accidents with respect to operational processes and procedures, as well as installations used for contained use operations. The institutions concerned have made the necessary changes to prevent similar events from occurring in the future.

Inspections and enforcement measures: control procedures include regular annual inspections, unannounced inspections, first-time facilities checks, material sampling, and document and procedure checks.

Several problems were raised during inspections (e.g. inappropriate waste management, inaccurate documentation, ignorance of the latest genetic modification technologies, inadequate staff training, and inadequate signage). Where the inspections have identified situations requiring corrective action, the competent authorities must ensure that the notifiers take the necessary measures to make the necessary changes within the time limits laid down.

Problems in interpreting the provisions of the Directive: there are problems in some Member States, particularly with regard to the definition of genetic modification laid down in the Directive, notifications of genetic modifications resulting from the use of new techniques, the assessment of the various classes of GMMs, the "next contained use" operation and clinical trials under the Directive.

Several Member States pointed out that the large number of notifications, the demanding information requirements for each notification, the detailed reporting system and the complexity of the various procedures can create a heavy administrative burden for authorities and notifiers.

Public consultation and information: practically all Member States apply the provisions on public consultation and public information on the results of operations within the framework of the Directive. Some States, however, restrict public consultation to Classes 3 and 4 operations. Although the Internet is the most common means of communication, other means (seminars, meetings, brochures, etc.) are also used. Overall, no response was received through public consultations.

Waste disposal: Member States state that they treat waste management by class or by waste category. Only a few Member States (Belgium, Lithuania, Poland and Portugal) plan to inactivate all types of waste before disposal. Some Member States have disposal facilities dedicated to the inactivation of GM waste, while others use general waste treatment facilities.