Basic information

2002/0046(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety **Subject** 3.10.09.06 Agro-genetics, GMOs 3.70.01 Protection of natural resources: fauna, flora, nature, wildlife, countryside; biodiversity 4.60.04.04 Food safety	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy	SJÖSTEDT Jonas (GUE/NGL)	27/03/2002

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy	SJÖSTEDT Jonas (GUE/NGL)	27/03/2002

Former committee for opinion	Former rapporteur for opinion	Appointed
ITRE Industry, External Trade, Research, Energy	The committee decided not to give an opinion.	
AGRI Agriculture and Rural Development	MÜLLER Emilia Franziska (PPE-DE)	20/03/2002

Council of the European Union

Council configuration	Meetings	Date
Environment	2413	2002-03-04
Environment	2439	2002-06-25
Environment	2517	2003-06-13
Environment	2457	2002-10-17
Environment	2491	2003-03-04

European

Commission DG	Commissioner

Commission	Environment	

Key events

Date	Event	Reference	Summary
18/02/2002	Legislative proposal published	COM(2002)0085	Summary
27/02/2002	Committee referral announced in Parliament, 1st reading		
04/03/2002	Debate in Council		
25/06/2002	Debate in Council		
10/09/2002	Vote in committee, 1st reading		Summary
10/09/2002	Committee report tabled for plenary, 1st reading	A5-0289/2002	
24/09/2002	Decision by Parliament, 1st reading	T5-0432/2002	Summary
24/09/2002	Debate in Parliament		
16/10/2002	Modified legislative proposal published	COM(2002)0578	Summary
04/03/2003	Council position published	15546/1/2002	Summary
13/03/2003	Committee referral announced in Parliament, 2nd reading		
30/04/2003	Vote in committee, 2nd reading		Summary
30/04/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0154/2003	
03/06/2003	Debate in Parliament		
04/06/2003	Decision by Parliament, 2nd reading	T5-0246/2003	Summary
13/06/2003	Act approved by Council, 2nd reading		
15/07/2003	Final act signed		
15/07/2003	End of procedure in Parliament		
05/11/2003	Final act published in Official Journal		

Technical information

Procedure reference	2002/0046(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	EC Treaty (after Amsterdam) EC 175-p1
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16797

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0289/2002	10/09/2002	
Text adopted by Parliament, 1st reading/single reading		T5-0432/2002 OJ C 273 14.11.2003, p. 0024-0104 E	24/09/2002	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0154/2003	30/04/2003	
Text adopted by Parliament, 2nd reading		T5-0246/2003 OJ C 068 18.03.2004, p. 0149-0292 E	04/06/2003	Summary

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	06272/1/2003	03/03/2003	
Council position	15546/1/2002 OJ C 107 06.05.2003, p. 0001-0016 E	04/03/2003	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2002)0085 OJ C 151 25.06.2002, p. 0121 E	18/02/2002	Summary
Modified legislative proposal	COM(2002)0578	16/10/2002	Summary
Commission communication on Council's position	SEC(2003)0282	07/03/2003	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2003)0360	12/06/2003	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofR	Committee of the Regions: opinion	CDR0033/2002 OJ C 278 14.11.2002, p. 0031	16/05/2002	
EESC	Economic and Social Committee: opinion, report	CES0846/2002 OJ C 241 07.10.2002, p. 0062	17/07/2002	

Additional information

Source	Document	Date

European Commission	EUR-Lex	

Final act

Regulation 2003/1946
OJ L 287 05.11.2003, p. 0001-0010 Summary

Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety

2002/0046(COD) - 12/06/2003 - Commission opinion on Parliament's position at 2nd reading

The Commission accepts all the Parliament's amendments in full. It considers that the compromise package constituted by these amendments will enable the Community to implement its obligations pursuant to the ratification of the Cartagena Protocol on Biosafety.

Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety

2002/0046(COD) - 18/02/2002 - Legislative proposal

PURPOSE : in accordance with the precautionary principle, the objective of the proposed regulation is to establish a common system of notification and information for exports to third countries of genetically modified organisms (GMOs). CONTENT : on 24 May 2000, the European Community and its Member States signed up to the Cartagena Protocol on Biosafety. Implementing legislation must now be put in place at Community level in order to conclude this international agreement, in accordance with Article 300 of the Treaty. Against this background, the Commission is committed to present a proposal for an appropriate legal instrument to implement the provisions of the Protocol. More specifically, the proposed Regulation lays down at Community level requirements for the implementation of the Cartagena Protocol on Biosafety. The overall objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer handling and use of genetically modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focussing on transboundary movements. It should be noted that pharmaceuticals for human use are excluded from the scope of this Regulation. The proposed regulation aims at avoiding differences and overlap between national laws, regulations and administrative provisions concerning exports and unintentional transboundary movements of GMOs which may hinder the free movement of products, creating conditions of unequal and unfair competition. A Community Regulation laying down a harmonised framework for transboundary movements of such products would, therefore, provide for legal certainty as well as a coherent and consistent approach that should contribute to the effective functioning of the internal market.

Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety

2002/0046(COD) - 04/06/2003 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution drafted by Jonas SJOSTEDT (EUL/NGL, Sweden) making a few amendments to the common position. These are as follows: - Parliament specified that exporters must await "prior written express consent" before proceeding with the first transboundary movement of a GMO intended for deliberate release into the environment. No such movement may be made without prior written express consent; - a new recital states that Pharmaceuticals for humans that are addressed by other international agreements, to which the Community or the relevant Member State is party, or organisations, of which the Community or the relevant Member State is a member, should be excluded from the scope of the Regulation; - the Commission will make available to the public documents on export notification records in accordance with the Community rules on access to environmental information; - information which may not be kept confidential should include the name and address of not only the exporter but also the importer.

Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety

2002/0046(COD) - 16/10/2002 - Modified legislative proposal

The European Commission can accept 15 amendments fully, 12 in principle and 2 partly out of the 48 amendments adopted by the European Parliament. The Commission cannot accept 19 amendments. As regards the amendments accepted by the Commission, these refer to those which : -

recognise the fundamental right of citizens to a free choice in regard to GMOs, which is in line with the Commission's general approach to biotechnology; - improve the editorial quality of the Proposal and are in line with the Cartagena Protocol. It proposes to move the exemption of notification for GMOs intended for deliberate release into the environment, which have been identified as being not likely to have adverse effects, from the article related to the scope to the article dealing with notification to Parties and non-Parties of Import; - clarify the objective of the information procedure for GMOs intended for direct use as food, feed, or for processing; - improve the provisions of the Proposal on the identification of GMOs, in line with article 18 of the Biosafety Protocol and in coherence with the Commission's Proposal for a Regulation on the Labelling and Traceability of GMOs; - ensures a better transposition of article 11(4) of the Biosafety Protocol; - adjusts the deadlines for monitoring and reporting obligations of the Proposal so that they conform to Art. 31 (4) of Directive 2001/18/EC on the deliberate release into the environment of GMOs; - clearly rules out re-notification of subsequent movements of a specific GMO that has already been approved in a given country, in line with the Biosafety Protocol and Community practices. With regard to the amendments accepted in part or in principle by the Commission, these refer to those which : - improve the consistency of the Proposal with the Protocol for GMOs that are pharmaceuticals for human use. The Commission can accept it in principle, but would prefer a simpler wording: "Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the scope of this Regulation"; - update the Proposal, in line with the adoption of Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; - delete the definition of "notifier" in Article 3(11) of the Proposal; - aim at simplifying the definition of "exporter"; - aim at providing a definition of "transboundary movements; - intend to develop the information obligation of exporters towards Member States and the European Commission regarding transboundary movements of GMOs; - reflect the provisions of Article 21 of the Biosafety Protocol that deals with confidential information; - aligning the proposal with the identification requirements of the Protocol, as well as with those of the Commission Proposal on Labelling and Traceability of GMOs; - clarify the procedure to be followed in cases of non-decision by a Party of Import on a notification of a GMO; - aim at clarifying the notification procedure for GMOs intendedfor deliberate release into the environment. As regards the amendments not accepted by the Commission, these concern : - deleting the reference to an amended proposal on Labelling and Traceability which is still mentioned an amendment of Directive 2001/18/EC; - raising the important issue of capacity building in developing countries, but do not provide for operational mechanisms; - raising the issue of environmental liability; - recognises the need for exporters to respect the importing country's regulatory framework for GMOs; - imposing on the Commission an obligation to notify to the Biosafety Clearing House, on behalf of the Community, any final decision regarding Community use, including placing on the market, of a GMO that may be subject to transboundary movements for release into the environment; - setting up procedures for GMOs intended for direct use as food or feed, or for processing, that does not fully reflect Article 11 of the Biosafety Protocol. More importantly, by limiting Community exports to GMOs that have been approved into the EU for direct use as food or feed, or for processing; - enlarging the scope of the Proposal to food and feed produced with the aid of GMOs; - the transit of GMOs which is not entirely in line with Article 6 (1) of the Biosafety Protocol, notably by confusing transport and transit and not mentioning the role of the Biosafety Clearing House; - detailing the obligation to transmit accompanying documentation throughout all the different steps of the transboundary movement of a GMO (notably transit and storage); - putting an obligation on Member States to take appropriate measures to prevent unintentional transboundary movements of living modified organisms; - putting an obligation on Member States to lay down, after joint consultation, rules on uniform penalties applicable to infringements of the provisions of this Proposal for a Regulation. This aspect is of Member State competence. If there is certainly a need for coordination and harmonisation of sanctions is to be encouraged, this goes legally beyond what can be inserted into a Community Regulation.

Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety

2002/0046(COD) - 07/03/2003 - Commission communication on Council's position

In general terms, the common position follows the structure of the original Commission's proposal. However, it broadens the original scope of the proposal and strengthens the obligations lying on Community exporters in a very substantial way, which goes beyond the requirement of the Biosafety Protocol. The Commission concludes by stating that despite a consequent improvement of the original proposal on many aspects, some of the changes introduced by the Council, especially with regard to the questions of explicit consent and of exports of GM commodities, do alter the coherence of the proposal with other pieces of Community legislation. Furthermore, these changes are also likely to create problems in terms of practical implementation of the proposal, notably in terms of international trade. Therefore, the Commission was not in a position to support the common position, which has been adopted by unanimity. Accordingly, the Commission has made a declaration to the minutes of the Environment Council.

Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety

2002/0046(COD) - 15/07/2003 - Final act

PURPOSE : to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and to ensure coherent implementation of the provisions of the Protocol on behalf of the Community in order to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. LEGISLATIVE ACT : Regulation 1946/2003/EC of the European Parliament and of the Council on transboundary movements of genetically modified organisms. CONTENT : this Regulation is designed to implement part of the Cartagena Protocol on Bio-safety in the Community. While existing Community legislation covers to a large extent imports and trade in GMOs, the proposal is intended to fulfil the requirements under the Protocol on exporters by establishing a common system of notification and information for transboundary movements of GMOs. As regards identification and accompanying documentation, the Regulations states that exporters shall ensure that the following information is stated in a document accompanying the GMO and is transmitted to the importer receiving the GMO: a) that it contains or consists of GMOs; b) the unique identification code(s) assigned to those GMOs if such codes exist. For GMOs intended for direct use as food or feed, or for processing, the information shall be supplemented by a declaration by the exporter: a) stating that the GMOs are intended for direct use as

food or feed, or for processing and indicating clearly that they are not intended for deliberate release into the environment; and b) giving details of the contact point for further information. Concerning the issue of confidentiality, the Commission and the Member States shall not divulge to third parties any confidential information received or exchanged under this Regulation. The Commission shall designate a Community focal point and shall, where appropriate, identify any Community competent authority. Each Member State shall designate one focal point, as well as one or more competent authorities. A single entity may fulfil the functions of both focal point and competent authority. On the issue of penalties, the Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measure necessary to ensure that they are implemented. The Member States shall notify those provisions to the Commission, by not later than 5 November 2004 and shall notify it without delay of any subsequent amendment affecting them. At regular intervals and at least every three years, unless otherwise determined under Article 33 of the Protocol, Member States shall forward to the Commission a report on the implementation of this Regulation. The Commission shall, at intervals to be determined by the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol, compile a report on the basis of the information provided by the Member States and present it to the Conferenceof the Parties to the Convention serving as the meeting of the Parties to the Protocol. As existing Community legislation, and in particular Directive 2001/18/EC and sectoral legislation providing for a specific risk assessment to be carried out in accordance with the principles set out in that Directive, already contain rules which are in line with the objective of the Protocol, there is no need to adopt supplementary provisions with regard to imports of GMOs into the Community. ENTRY INTO FORCE : 25 November 2003. This Regulation shall apply from the date of entry into force of the Protocol, or from the date of entry into force of this Regulation, which ever shall be the latest.

Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety

2002/0046(COD) - 24/09/2002 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Jonas SJOSTEDT (EUL/NGL, Sweden) on the transboundary movement of GMOs. (Please refer to the document dated 10/09/02.) Parliament put additional emphasis on the precautionary principle in the recitals. It provided that the Commission must notify to the BCH, on behalf of the Community any final decision regarding Community use, including placing on the market, of a GMO that may be subject to transboundary movements for release into the environment. Finally, it was made clear that no GMO that may be subject to transboundary movements for direct use as food or feed or for processing may be exported unless it is authorised for the same use within the EC.

Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety

2002/0046(COD) - 04/03/2003 - Council position

The Council adopted the common position with the Italian and German delegations abstaining. In 2002 it was decided, after consultation of the European Parliament, to conclude the Protocol on behalf of the European Community. The Protocol will enter into force when 50 Parties have deposited the necessary instrument. Against this background this proposal, which is based on Article 175, paragraph 1 of the EC treaty, is mainly concerned with the establishment of a common system of notification and information for transboundary movements of GMOs to third countries and with unintentional transboundary movements, which is needed in order to ensure implementation of the provisions of the Cartagena Protocol relating to those issues. Other provisions of the Protocol fall under other Community legislation. In general, the Council agreed upon an approach where the Protocol is followed closely. Within that context, there are nevertheless are concrete formulations, which follow EU practice where this has been seen as legally or politically necessary, e.g. the term "living modified organisms" used in the protocol is not used, since the EU internal terminology "genetically modified organism" is understood to be an equivalent term and is the generally applicable term within the EU. The Council finds it relevant to consider the relationship to possible non-Parties under the Regulation, since not all countries interested in the substance matter regulated under the Protocol nor all signatories to the Protocol will necessarily be Parties to the Protocol at the time of its entry into force. The Council has agreed, on the basis of the context of the various articles and paragraphs, upon those parts of the Regulation, which should also relate to non-Parties. It should be noted that out of 45 amendment to the proposal adopted at first reading by the European Parliament, 33 have been incorporated, either verbatim, in part or in spirit, into the Council's common position.