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# European Union

# Biotechnology

# EU adopts Regulation for Cartagena Protocol

# 2003

**Approved by:**
Stan Cohen
U.S. Mission to the EU, Brussels

**Prepared by:**
Peter Talks

**Report Highlights:**
A Regulation on the transboundary movements of GMOs has been published in the Official Journal of the European Communities. It will enter into force twenty days from its publication, the 25th of November.
The new rules lay down strict labeling and consent rules for GMOs exported from the EU. The Regulation provides that the export of GMO material from the EU is only possible for authorized GMOs and with the explicit permission of the importing country. Exporters must notify importers in writing of GM shipments, that the exporter must comply with the importing countries legislation in this area, even if it goes beyond the requirements of the Cartagena Protocol and that the precautionary principle must be respected.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
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[E2]

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The full text of the Regulation (pdf format) can be found at the below link:

http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf

Alternatively, it can be accessed from Official Journal L287 of 5 November 2003:

http://europa.eu.int/eur-lex/en/archive/2003/l_28720031105en.html

Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms

Selected Text:

**CHAPTER II**

**EXPORTS OF GMOs TO THIRD COUNTRIES**

**Section 1**

**GMOs intended for deliberate release into the environment**

**Article 4**

Notification to Parties and non-Parties of import

The exporter shall ensure notification, in writing, to the competent authority of the Party or non-Party of import prior to the first intentional transboundary movement of a GMO intended for deliberate release into the environment and destined for the use specified in accordance with Annex I, point (i). The notification shall contain, as a minimum, the information specified in Annex I. The exporter shall ensure the accuracy of the information contained in the notification.

**ANNEX I**

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLE 4

(a) Name, address and contact details of the exporter.
(b) Name, address and contact details of the importer.
(c) Name and identity of the GMO, as well as the domestic classification, if any, of the biosafety level of the GMO in the State of export.

(d) Intended date or dates of the transboundary movement, if known.
(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO.
(i) Intended use of the GMO or products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through techniques listed in Annex I A, Part 1 of Directive 2001/18/EC.
(j) Quantity or volume of the GMO to be transferred.
(k) A previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC.
(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
(m) Regulatory status of the GMO within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the GMO is banned in the State of export, the reason or reasons for the ban.
(n) Result and purpose of any notification by the exporter to other States regarding the GMO to be transferred.
(o) A declaration that the abovementioned information is factually correct.

**Section 2**

**GMOs intended for direct use as food or feed, or for processing**

**Article 9**

Information to the BCH

1. The Commission on behalf of the Community or, where appropriate, the Member State which made the decision shall inform the BCH and other Parties through the BCH of any final decision regarding use, including placing on the market, within the Community or use within a Member State, of a GMO that may be subject to transboundary movements for direct use as food or feed or for processing. This information shall be sent to the BCH within fifteen days of the adoption of that decision.

This paragraph shall not apply to decisions regarding the deliberate release in accordance with Part B of Directive 2001/18/EC of a GMO which is not intended for direct use as food or feed or for processing in a third country without a subsequent decision.
2. The information referred to in paragraph 1 and sent to the BCH shall contain as a minimum the information specified in Annex II.

3. The Commission or the Member State referred to in paragraph 1 shall process requests submitted to them by any Party or non-Party for additional information regarding the decisions referred to in paragraph 1.

4. A copy of the information referred to in paragraphs 1, 2 and 3 shall be sent by the Commission or the Member State referred to in paragraph 1, in writing, to the focal point of each Party that informs the Secretariat in advance that it does not have access to the BCH.

## ANNEX II

INFORMATION REQUIRED UNDER ARTICLE 9

(a) The name and contact details of the applicant for a decision for domestic use.
(b) The name and contact details of the authority responsible for the decision.
(c) Name and identity of the GMO.
(d) Description of the gene modification, the technique used, and the resulting characteristics of the GMO.
(e) Any unique identification of the GMO.
(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
(i) Approved uses of the GMO.
(j) A risk assessment report consistent with Annex II to Directive 2001/18/EC.
(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

## CHAPTER III

## UNINTENTIONAL TRANSBOUNDARY MOVEMENT OF GMOs

### Article 14

1. Member States shall take appropriate measures to prevent unintentional transboundary movements of GMOs.

2. As soon as a Member State becomes aware of an occurrence, under its jurisdiction, resulting in a release of GMOs that leads, or may lead, to an unintentional transboundary movement that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, that Member State shall:
(a) take the appropriate measures to inform the public and inform without delay the Commission, all other Member States, affected or potentially affected States, the BCH, and, where appropriate, relevant international organisations;
(b) without delay consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures in order to minimise any significant adverse effects.

3. Any information arising from paragraph 2 shall include the information specified in Annex III.

**ANNEX III**

INFORMATION REQUIRED UNDER ARTICLE 14

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the GMO.
(b) Information on the circumstances and estimated date of the release, and on the use of the GMO in the originating Party.
(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures.
(d) Any other relevant information; and
(e) A contact point for further information.