

Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms

(2002/C 151 E/04)

(Text with EEA relevance)

COM(2002) 85 final — 2002/0046(COD)

(Submitted by the Commission on 18 February 2002)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Protocol), was signed by the Community and its Member States on 24 May 2000.
- (2) The Cartagena Protocol on Biosafety, in its Article 1, specifies that, in accordance with the precautionary approach contained in Principle 15 of the Rio declaration, the 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.
- (3) The Protocol requires each Party to take necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC⁽¹⁾, as last amended by Regulation (EC) ... of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms invited the Commission to bring forward a legislative proposal for implementing the procedures laid down in the Protocol and, in accordance with the Protocol, requiring Community exporters to ensure that all requirements of

the Advance Informed Agreement Procedure, as set out in Articles 7 to 10, 12 and 14 of the Protocol, are fulfilled.

- (4) It is important to organise the supervision and control of transboundary movements of GMOs in order to take account of conservation and sustainable use of biological diversity, taking also into account risks to human health.
- (5) Since Community legislation does not contain requirements for exports of GMOs to third countries and in order to ensure compliance with the obligations in the Protocol regarding transboundary movements of GMOs, a common legal framework should be established for such exports.
- (6) Exports of GMOs should be notified to the country of import, allowing it to make an informed decision, based on risk assessment carried out in a scientifically sound manner.
- (7) The notification should be ensured by the exporter, which is legally responsible vis-à-vis its contracting party for the product it sells. The notifier, normally the exporter, should be responsible for the accuracy of the information provided in the notification.
- (8) According to the Protocol, the Community may take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol, provided that such action is consistent with the objective and the provisions of the Protocol and in accordance with the Community's other obligations under international law.
- (9) According to the Protocol, the Community may apply its domestic legislation in respect of the movements of GMOs within its customs territory.
- (10) The Protocol provides that Parties may decide to apply either the procedures of the Protocol or their domestic regulations with respect to imports of GMOs. 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 objectives of the Protocol, there is no need to adopt supplementary provisions with regard to imports of GMOs into the Community.

⁽¹⁾ OJ L 106, 17.4.2001, p. 1.

- (11) It is necessary to ensure the safe transport, handling and packaging of GMOs. As existing Community legislation, in particular Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road ⁽¹⁾, as last amended by Commission Directive 2001/7/EC ⁽²⁾, and Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail ⁽³⁾, as last amended by Commission Directive 2001/6/EC ⁽⁴⁾, already contain appropriate rules, there is no need to adopt supplementary provisions in this respect.
- (12) It is necessary to ensure the identification of GMOs being exported from or imported into the Community. With regard to imports into the Community existing Community legislation, in particular Regulation (EC) ... of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms, already contain appropriate provisions. With regard to exports similar rules should apply.
- (13) In order to respond efficiently to unintentional transboundary movements of GMOs that are likely to have a significant adverse effect on the conservation and sustainable use of biological diversity, taking account risks to human health, Member States from whose territory such a movement originates should take appropriate measures to inform affected or potentially affected States, the Biosafety Clearing House (the BCH) and, where appropriate, relevant international organisations when they become aware of such an occurrence under their jurisdiction.
- (14) In order to help developing the BCH, the Community and its Member States should ensure that relevant information is communicated to the BCH on a regular basis, and that monitoring and reporting on the implementation of the Protocol in the Community are performed.
- (15) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (16) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVES, SCOPE AND DEFINITIONS

Article 1

Objective

In accordance with the precautionary principle, the objective of this Regulation is to establish a common system of notification and information for exports to third countries of genetically modified organisms (GMOs) 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 the sustainable use of biological diversity, taking also into account risks to human health.

Article 2

Scope

1. This Regulation shall apply to the export and unintentional transboundary movement of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
2. Pharmaceuticals for human use are excluded from the scope of this Regulation.
3. GMOs intended for deliberate release into the environment identified in a decision of the Conference of the Parties serving as the Meeting of the Parties to the Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health are excluded from the scope of Section 1 of this Regulation.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

1. 'Organism' means organism as defined in Article 2(1) of Directive 2001/18/EC;
2. 'Genetically modified organism', or 'GMO', means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB of Directive 2001/18/EC;
3. 'Deliberate release' means deliberate release as defined in Article 2(3) of Directive 2001/18/EC;

⁽¹⁾ OJ L 319, 12.12.1994, p. 7.

⁽²⁾ OJ L 30, 1.2.2001, p. 43.

⁽³⁾ OJ L 235, 17.9.1996, p. 25.

⁽⁴⁾ OJ L 30, 1.2.2001, p. 42.

4. 'Placing on the market' means placing on the market as defined in Article 2(4) of Directive 2001/18/EC;
5. 'Contained use' means:
- (a) activities defined in Article 2(c) of Directive 90/219/EEC on the contained use of genetically modified micro-organisms⁽¹⁾, as last amended by Directive 98/81/EC,
 - (b) activities in which GMOs other than micro-organisms are genetically modified or in which such GMOs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures, based on the same principles of containment as in Directive 90/219/EEC, are used to limit their contact with the general population and the environment.
6. 'Product' means product as defined in Article 2(7) of Directive 2001/18/EC;
7. 'Food' means food as defined in [Article 2 of the Proposal for a Regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food⁽²⁾];
8. 'Feed' means feed as defined in [Article 3(4) of the Proposal for a Regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food];
9. 'Notification' means the submission of the information required under this Regulation to the competent authority of a Party to the Protocol or to the relevant authorities of non-Parties;
10. 'The Biosafety Clearing House' or 'the BCH' means the Biosafety Clearing House established under Article 20 of the Protocol;
11. 'Notifier' means the natural or legal person submitting the notification;
12. 'Export' means:
- (a) the permanent or temporary leaving of the customs territory of the Community of products meeting the conditions of Article 23(2) of the Treaty,
 - (b) the re-export of products not meeting the conditions referred to in (a) which are placed under a custom procedure other than transit procedure.
13. 'Import' means the placing under a customs procedure other than transit procedure of products introduced into the customs territory of the Community;
14. 'Exporter' means any natural or legal person on whose behalf a notification is made, that is to say the person who, at the time when the notification is sent, holds the contract with the consignee in the third country and has the power for determining the sending of the item out of the customs territory of the Community. If no export contract has been concluded or if the holder of the contract does not act on its own behalf, the power for determining the sending of the item out of the customs territory of the Community shall be decisive;
15. 'Party' means any country or regional organisation having concluded the Protocol;
16. 'non-Party' means any country or regional organisation not having concluded the Protocol;
17. 'The Protocol' means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;
18. 'Biological diversity' means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;
19. 'Competent national authority' means the competent authority designated by the Parties to the Protocol which is responsible for performing the administrative functions required by the Protocol and which shall be authorised to act on its behalf with respect to those functions;
20. 'Focal point' means the entity designed by a Party to be responsible on its behalf for liaisons with the Secretariat;
21. 'Secretariat' means the Secretariat to the Protocol.

⁽¹⁾ OJ L 117, 8.5.1990, p. 1.

⁽²⁾ OJ C 96 E, 27.3.2001, p. 247.

CHAPTER II

EXPORTS OF GMOs TO THIRD COUNTRIES

Section 1

Exports of GMOs intended for deliberate release into the environment

Article 4

Notification to Parties and non-Parties of Import

1. The exporter shall ensure notification, in writing, to the competent national authority of the Party or non-Party of Import prior to the first intentional transboundary movement of a GMO intended for deliberate release into their environment. The notification shall contain, at a minimum, the information specified in Annex I. The notifier shall ensure that the information contained in the notification is accurate.

2. Section 1 shall not apply to GMOs intended for direct use as food or feed, or for processing.

Article 5

Cases of non-reply to notifications

In cases where the Party or non-Party of Import does not reply to a notification within 270 days from the date of receiving the notification, the exporter shall send a written reminder to the competent national authority of that Party or non-Party of Import, with copy to the Secretariat, with a deadline of 60 days from receipt for response.

Article 6

Informing the Party of Export

The exporter, or the notifier, shall keep a record of the notification and the acknowledgement of receipt and send a copy of these documents to the competent national authority of the Member State of Export and to the Commission.

Article 7

Transit

The exporter ensures notification of the transit of GMOs intended for deliberate release into the environment to Parties that have taken the decision to regulate transit of GMOs through their territory and have notified this decision to the Biosafety Clearing House (the BCH).

Section 2

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

Article 8

Notification to the BCH

1. The Commission shall 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 direct use as food or feed or for processing. This notification shall be sent to the BCH within fifteen days of the adoption of that decision.

This paragraph shall not apply to decisions regarding field trials.

2. The information referred to in paragraph 1 to the Biosafety Clearing House shall contain as a minimum the information specified in Annex II.

3. The Commission shall process requests made by any Party for additional information regarding the decisions referred to in paragraph 1.

4. A copy of this information shall be sent, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the BCH.

Section 3

Common provisions

Article 9

Identification

1. Exporters shall ensure that the following information is transmitted to the operator receiving the product:

(a) that it contains or consists of GMOs,

(b) the relevant unique code(s) assigned to those GMOs.

However, the information under (b) above may be replaced by a declaration by the operator that the product shall only be used as food or feed, or for processing, together with the unique codes for the GMOs that the product may contain.

2. Paragraph 1 is without prejudice to other specific requirements in Community legislation and to international identification requirement to be developed in accordance with Article 18 of the Protocol.

CHAPTER III

UNINTENTIONAL TRANSBOUNDARY MOVEMENT

Article 10

1. 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 take the following action:

- (a) take the appropriate measures to inform the public and notify without delay the Commission, other Member States, affected or potentially affected States, the BCH, and, where appropriate, relevant international organisations,
- (b) consult the affected or potentially affected State to enable it to determine appropriate responses and initiate necessary action, including emergency measures.

2. Any information arising from paragraph 1 shall include the information specified in Annex III.

CHAPTER IV

COMMON PROVISIONS

Article 11

Participation to the international information procedure

1. The Member States shall in accordance with the provisions of the Protocol notify to the Commission:

- (a) national legislation and guidelines relevant for the implementation of the Protocol, in accordance with Article 20.3(a) of the Protocol;
- (b) national contact points for notification of unintentional transboundary movements, in accordance with Article 17 of the Protocol;
- (c) any bilateral, regional and multilateral agreement and arrangements regarding intentional transboundary movements of GMOs, in accordance with Article 20.3(b) of the Protocol;
- (d) information concerning cases of illegal transboundary movements pertaining to them, in accordance with Article 25 of the Protocol.

2. The Commission shall in accordance with the provisions of the Protocol notify, on behalf of the Community, to the BCH:

- (a) information notified by the Member States pursuant to paragraph 1;
- (b) Community legislation and guidelines relevant for the implementation of the Protocol, in accordance with Article 20.3(a) of the Protocol;
- (c) any bilateral, regional and multilateral agreement and arrangements at the Community level regarding intentional transboundary movements of GMOs, in accordance with Article 20.3(b) of the Protocol;
- (d) any final decision regarding the use within the Community, the release or the importation of a GMO, in accordance with Articles 11 and 20.3(d) of the Protocol;

- (e) any summary of risk assessments or environmental review of GMOs generated by the Community regulatory process and carried out in accordance with procedures similar to those laid down in Annex II to Directive 2001/18/EC, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, in accordance with Article 20.3(c) of the Protocol;

- (f) any information concerning cases of unintentional or illegal transboundary movements, in accordance with Articles 17 and 25 of the Protocol;

- (g) Community contact point for notification of unintentional transboundary movement, in accordance with Article 17 of the Protocol;

- (h) any review of decisions regarding an intentional transboundary movement, in accordance with Article 12 of the Protocol;

- (i) application of Community legislation instead of the procedures of the Protocol for movements of GMOs within the Community and imports of GMOs into the Community in accordance with Article 14(3) and 14(4) of the Protocol;

- (j) reports submitted pursuant to Article 20 of this Regulation, including those on implementation of the advanced informed agreement procedure, in accordance with Article 20.3(e) of the Protocol.

Article 12

Competent national authorities and focal points

1. The Commission shall designate one focal point.
2. Each Member State shall designate one national focal point, as well as one or more competent national authorities. A single entity can also fulfil the functions of both focal point and competent national authority.
3. The Commission, on behalf of the EC, and the Member States shall, no later than the date of entry into force of the Protocol for them, notify the Secretariat of the names and addresses of their focal points and their competent national authority or authorities. Where a Member State designates more than one competent national authority, it shall convey to the Secretariat, with its notification, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent national authority is responsible for which type of GMO. The Commission and the Member States shall forthwith notify the Secretariat of any changes in the designation of their national focal points or in the name and address or responsibilities of their competent national authority or authorities.

*Article 13***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 penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission, by (date) at the latest [180 days following the date of publication of this Regulation in the *Official Journal of the European Communities*] and shall notify it without delay of any subsequent amendment affecting them.

*Article 14***Monitoring and reporting**

1. Member States shall regularly forward to the Commission information on the implementation of the present Regulation.
2. The Commission shall, at intervals to be determined by the Conference of the Parties 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 Conference of the Parties serving as the meeting of the Parties to the Protocol.

*Article 15***Entry into force**

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.
2. This Regulation shall apply from the day of entry into force of the Protocol, according to Article 37(1) of the Protocol, or ninety days after the date of the deposit of the instrument of ratification by the Community, whichever shall be the later.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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 genetically modified organism, as well as the domestic classification, if any, of the biosafety level of the genetically modified organism 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 genetically modified organism.
 - (i) Intended use of the genetically modified organism or products thereof, namely, processed materials that are of genetically modified organism 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 genetically modified organism 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 genetically modified organism 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 genetically modified organism 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 genetically modified organism to be transferred.
 - (o) A declaration that the abovementioned information is factually correct.
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ANNEX II

INFORMATION REQUIRED UNDER ARTICLE 8

- (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 genetically modified organism.
 - (d) Description of the gene modification, the technique used, and the resulting characteristics of the genetically modified organism.
 - (e) Any unique identification of the genetically modified organism.
 - (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 genetically modified organism.
 - (j) A risk assessment report consistent with Annex II of 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.
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ANNEX III

INFORMATION REQUIRED UNDER ARTICLE 10

- (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 point of contact for further information.
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