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(Acts whose publication is obligatory)

REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 July 2003 on transboundary movements of genetically modified organisms

(Text with EEA relevance)

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 [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4],

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 in 2000 and Council Decision 2002/628/EC [5] to conclude the Protocol, on behalf of the Community, was taken on 25 June 2002.

(2) Article 1 of the Protocol specifies that, in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, 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 (GMOs) 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 focusing 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 [6] 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 contribute to ensuring the conservation and sustainable use of biological diversity, taking also into account risks to human health, and so as to enable citizens to make a free and informed choice in regard to GMOs.

(5) Since Community legislation does not contain specific 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) It is necessary to recognise the need to respect the Party or non-Party of import's regulatory biosafety framework, in a manner consistent with the Protocol.

(7) 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 this Regulation.

(8) Exports of GMOs intended for deliberate release into the environment should be notified to the Party or non-Party of import, allowing it to make an informed decision,

[1] OJ C 151 E, 25.6.2002, p. 121.
[2] OJ C 241, 7.10.2002, p. 62.
[3] OJ C 278, 14.11.2002, p. 31.
[4] Opinion of the European Parliament of 24 September 2002 (not yet published in the Official Journal), Council Common Position of 4 March 2003 (OJ C 107 E, 6.5.2003, p. 1), Decision of the European Parliament of 4 June 2003 (not yet published in the Official Journal) and Council Decision of 16 June 2003.
[5] OJ L 201, 31.7.2002, p. 48.
[6] OJ L 106, 17.4.2001, p. 1.

based on a risk assessment carried out in a scientifically sound manner.

(9) The notification should be ensured by the exporter. The exporter should be responsible for the accuracy of the information provided in the notification.

(10) Exporters should await the prior written express consent of the Party or non-Party of import before proceeding with the first transboundary movement of a GMO intended for deliberate release into the environment.

(11) Recognising that some developing countries, and some countries with economies in transition, may lack the capacities which would enable them to take such informed decisions, the Commission and Member States should make sustained efforts to enable them to develop and strengthen human resources and institutional capacities.

(12) According to the Protocol, the Community or any other Party 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 that Party's other obligations under international law.

(13) According to the Protocol, the Community may apply its domestic legislation in respect of the movements of GMOs within its customs territory.

(14) 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.

(15) 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] 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 [2], already contain appropriate rules, there is no need to adopt supplementary provisions in this respect.

(16) It is necessary to ensure the identification of GMOs being exported from or imported into the Community. With regard to traceability, labelling and identification of imports into the Community, such GMOs are subject to rules in Community legislation. With regard to exports similar rules should apply.

(17) The Commission and Member States support the process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of GMOs, to be agreed, as provided for in Article 27 of the Protocol, at the first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

(18) The Commission and the Member States support the further development and the application of the common formats for accompanying documentation on identification of GMOs, which is undertaken in accordance with Article 18 of the Protocol.

(19) 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 into account risks to human health, a Member State should, as soon as it becomes aware of an event under its jurisdiction resulting in a release that may lead to an unintentional transboundary movement of a GMO that is likely to have such effects, take the appropriate measures to inform the public and inform without delay the Commission, all other Member States, affected or potentially affected States, the Biosafety Clearing-House (BCH) and, where appropriate, relevant international organisations. Also, that Member State should consult without delay affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action.

(20) In order to help develop the BCH, the Community and its Member States should ensure that relevant information is communicated to the BCH, and that monitoring and reporting on the implementation of the Protocol in the Community are performed.

(21) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(22) The precautionary principle should be taken into account when applying this Regulation.

(23) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

[1] OJ L 319, 12.12.1994, p. 7. Directive as last amended by Commission Directive 2003/28/EC (OJ L 90, 8.4.2003, p. 45).
[2] OJ L 235, 17.9.1996, p. 25. Directive as last amended by Commission Directive 2003/29/EC (OJ L 90, 8.4.2003, p. 47).

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVES, SCOPE AND DEFINITIONS

Article 1

Objectives

In accordance with the precautionary principle, and without prejudice to the provisions of Directive 2001/18/EC, the objectives of this Regulation are 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.

Article 2

Scope

1. This Regulation shall apply to the transboundary movements of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health.

2. Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the scope 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 to Directive 2001/18/EC;

3. 'deliberate release' means deliberate release as defined in Article 2(3) of Directive 2001/18/EC;

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 [1];

   (b) activities in which organisms 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 appropriately to limit their contact with the general population and the environment;

6. 'food' means food as defined in Article 2 of Regulation (EC) No 178/2002 [2];

7. 'feed' means feed as defined in Article 3(4) of Regulation (EC) No 178/2002;

8. 'notification' means the submission of the information required from the exporter under this Regulation to the competent authority of a Party to the Protocol or to the competent authority of a non-Party;

9. 'the Biosafety Clearing-House' or 'the BCH' means the Biosafety Clearing-House established under Article 20 of the Protocol;

10. 'export' means:

    (a) the permanent or temporary leaving of the customs territory of the Community of GMOs meeting the conditions of Article 23(2) of the Treaty;

    (b) the re-export of GMOs not meeting the conditions referred to in (a) which are placed under a customs procedure other than transit procedure;

11. 'import' means the placing under a customs procedure, other than transit procedure, of GMOs introduced into the customs territory of a Party or non-Party outside the Community from a Party within the Community;

12. 'exporter' means any natural or legal person by whom or 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 to determine that the GMO is to be sent 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 to determine that the GMO is to be sent out of the customs territory of the Community shall be decisive;

13. 'importer' means any natural or legal person, under the jurisdiction of the Party or non-Party of Import, who arranges for a GMO to be imported;

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[1] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (OJ L 117, 8.5.1990, p. 1). Directive as last amended by Decision 2001/204/EC (OJ L 73, 15.3.2001, p. 32).

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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 (OJ L 31, 1.2.2002, p. 1).

14. 'transboundary movement' means the intentional or unintentional movement of a GMO between one Party or non-Party and another Party or non-Party, excluding intentional movements between Parties within the Community;

15. 'Party' means any country or regional economic integration organisation being a Party to the Protocol;

16. 'non-Party' means any country or regional economic integration organisation not being a Party to the Protocol;

17. 'the Protocol' means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Convention);

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 authority' means a competent authority designated by a Party to the Protocol, or the relevant equivalent body of a non-Party, which is responsible for performing the administrative functions required by the Protocol, or equivalent functions in the case of a non-Party, and is authorised to act on its behalf with respect to those functions;

20. 'focal point' means the entity designated by a Party to be responsible on its behalf for liaising with the Secretariat;

21. 'Secretariat' means the Secretariat to the Protocol.

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.

Article 5

Cases of non-decision

1. A failure by the Party of import to acknowledge receipt of a notification or to communicate its decision shall not imply its consent to an intentional transboundary movement. No first intentional transboundary movement may be made without prior written express consent of the Party or, where appropriate, non-Party of import.

2. In cases where the Party of import does not communicate its decisions in response to a notification within 270 days from the date of receiving the notification, the exporter shall send a written reminder, with a deadline for response of 60 days from receipt of this reminder, to the competent authority of that Party of import, with a copy to the Secretariat, to the Member State of export, and to the Commission. In calculating the time within which a Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account.

3. Without prejudice to paragraph 1, the exporter shall not proceed with the first intentional transboundary movement of a GMO intended for deliberate release unless the procedures determined by the Party of import in accordance with Articles 9 and 10 of the Protocol or, where appropriate, equivalent procedures required by a non-Party of import have been followed.

4. Paragraphs 1, 2 and 3 shall not apply to cases of transboundary movements covered by simplified procedures or bilateral, regional and multilateral agreements or arrangements entered into in accordance with Article 13 and 14 of the Protocol.

5. The Commission and the Member States shall, in consultation with the Secretariat, take appropriate action in accordance with any appropriate procedures and mechanisms to facilitate decision-making or to promote compliance with the provisions of the Protocol by the Parties of import as decided by the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

Article 6

Informing the Party of export

The exporter shall for a period of a minimum of five years keep a record of the notification referred to in Article 4 and the acknowledgement of receipt and the decision of the Party or, where appropriate, non-Party of import and send a copy of these documents to the competent authority of the Member State from which the GMO is exported and to the Commission.

Without prejudice to Article 16, the Commission shall make these documents available to the public in accordance with the Community rules on access to environmental information.

Article 7

Review of decisions

1. If the exporter considers that a change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based or that additional relevant scientific or technical information has become available, he may ask the Party or, where appropriate, non-Party of import to review a decision it has made concerning notification pursuant to Article 10 of the Protocol.

2. Where a Party or non-Party of import does not respond to such a request within 90 days, the exporter shall send a written reminder to the competent authority of that Party or, where appropriate, non-Party of import, with a copy to the Secretariat, requesting a response within a set period following receipt of the reminder.

Article 8

Exceptions to Section 1 of this Chapter

1. GMOs intended for deliberate release into the environment identified in a decision of the Conference of the Parties to the Convention 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, shall be excluded from the scope of section 1 of this Chapter.

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

3. The obligations referred to in section 1 of this Chapter shall not apply if the Party of import has specified in advance to the BCH, in accordance with Article 13(1)(b) and Article 14(3) of the Protocol, that such imports of GMOs are to be exempted from the Advance Informed Agreement Procedure, as set out in Articles 7 to 10, 12 and 14 of the Protocol, provided that adequate measures are applied to ensure their safe intentional transboundary movement in accordance with the objective of the Protocol.

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 15 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.

Article 10

Parties' and non-Parties' national decisions on import

1. The exporter shall respect any decision on the import of GMOs intended for direct use as food or feed, or for processing, taken by a Party in accordance with Article 11(4) of the Protocol, or by a non-Party of import under its domestic regulatory framework that is consistent with the objective of the Protocol.

2. If a developing country Party or non-Party of import or a Party or non-Party of import with an economy in transition has declared through the BCH that it will take a decision prior to an import of a specific GMO intended for direct use as food or feed, or for processing, in accordance with Article 11(6) of the Protocol, the exporter shall not proceed with the first export of such GMO unless the procedure provided for under that provision has been followed.

3. Failure by the Party or non-Party of import to acknowledge receipt of a notification or to communicate its decision in accordance with paragraph 2 shall not imply its consent or refusal to the import of a GMO intended for direct use as food or feed, or for processing. 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 within the Community or the competent authority of a third country has expressly agreed to the import as required under Article 12 of Regulation (EC) No 178/2002.

Section 3

GMOs intended for contained use

Article 11

1. The provisions of Chapter II, section 1 shall not apply to transboundary movements of GMOs intended for contained use where such transboundary movements are undertaken in accordance with the standards of the Party or non-Party of import.

2. Paragraph 1 shall be without prejudice to any right of a Party or non-Party to subject all GMOs to risk assessment prior to decisions on import and to set standards for contained use within their jurisdiction.

Section 4

Common provisions

Article 12

Identification and accompanying documentation

1. 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.

2. For GMOs intended for direct use as food or feed, or for processing, the information referred to in paragraph 1 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.

Paragraph 1(b) shall not apply to products consisting of or containing mixtures of GMOs to be used only and directly as food or feed, or for processing. These products shall be subject to the traceability requirements of Directive 2001/18/EC and, when applicable, future Community legislation covering traceability, labelling and identification of such GMOs.

3. For GMOs intended for contained use, the information referred to in paragraph 1 shall be supplemented by a declaration by the exporter which shall specify:

(a) any requirements for the safe handling, storage, transport and use of these GMOs;

(b) the contact point for further information, including the name and address of the individual or institution to whom or which the GMOs are consigned.

4. For GMOs intended for deliberate release into the environment and any other GMO to which this Regulation applies, the information referred to in paragraph 1 shall be supplemented by a declaration by the exporter which shall set out:

(a) the identity and relevant traits and characteristics of the GMOs;

(b) any requirements for the safe handling, storage, transport and use of these GMOs;

(c) the contact point for further information and, as appropriate, the name and address of the importer and exporter;

(d) a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

5. Paragraph 1 to 4 shall be without prejudice to other specific requirements imposed by Community legislation and to international identification requirements to be developed in accordance with Article 18 of the Protocol.

Article 13

Transit

The exporter shall ensure notification of the transit of GMOs to Parties that have taken the decision to regulate transit of GMOs through their territory and have informed the BCH of this decision.

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.

CHAPTER IV

COMMON PROVISIONS

Article 15

Participation in the international information procedure

1. The Member States shall, without prejudice to the protection of confidential information in accordance with the provisions of the Protocol, inform the BCH and the Commission of:

(a) national legislation and guidelines relevant to the implementation of the Protocol, in accordance with Article 11(5) and 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 entered into by the Member State regarding intentional transboundary movements of GMOs, in accordance with Article 20(3)(b) of the Protocol;

(d) any information concerning cases of unintentional or illegal transboundary movements pertaining to them, in accordance with Articles 17 and 25 of the Protocol;

(e) any final decision taken by a Member State, on the use of GMOs within that Member State, including decisions:

— on contained use classified in risk class 3 or 4 of GMOs which are likely to be subject to transboundary movements,

— on the deliberate release of GMOs in accordance with part B of Directive 2001/18/EC, or

— on import into the Community of GMOs,

in accordance with Article 11 and Article 20(3)(d) of the Protocol, within 15 days of the adoption of that decision;

(f) any summary of risk assessments or environmental reviews of GMOs generated by the Community's regulatory process and carried out in accordance with Article 15 of the Protocol, 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;

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

(h) any decision taken by a Member State on safeguard measures under Article 23 of Directive 2001/18/EC or emergency measures taken by a Member State under Community legislation on genetically modified food and feed.

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

(a) Community legislation and guidelines relevant for the implementation of the Protocol, in accordance with Article 11(5) and Article 20(3)(a) of the Protocol;

(b) any bilateral, regional and multilateral agreement and arrangements at Community level regarding intentional transboundary movements of GMOs, in accordance with Article 20(3)(b) of the Protocol;

(c) any final decision taken at Community level regarding the use of a GMO within the Community, including decisions on the placing on the market or the importation of a GMO, in accordance with Article 11 and Article 20(3)(d) of the Protocol;

(d) 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;

(e) any review of decisions at Community level regarding an intentional transboundary movement, in accordance with Article 12 of the Protocol;

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

(g) reports submitted pursuant to Article 19 of this Regulation, including those on implementation of the advanced informed agreement procedure, in accordance with Article 20(3)(e) of the Protocol.

Article 16

Confidentiality

1. The Commission and the Member States shall not divulge to third parties any confidential information received or exchanged under this Regulation.

2. The exporter may indicate the information in the notification submitted under Article 4 which should be treated as confidential. Justification shall be given in such cases upon request.

3. In no case may the following information when submitted according to Articles 4, 9 or 12 be kept confidential:

(a) name and address of the exporter and importer,

(b) general description of the GMO or GMOs,

(c) a summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and

(d) any methods and plans for emergency response.

4. If, for whatever reasons, the exporter withdraws the notification, the Member States and the Commission must respect the confidentiality of commercial and industrial information, including research and development information, as well as information on which the Party or non-Party of import and the exporter disagree as to its confidentiality.

Article 17

Competent authorities and focal points

1. The Commission shall designate a Community focal point and shall, where appropriate, identify any Community competent authority.

2. 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.

3. The Commission, on behalf of the Community, and each Member State respectively shall, no later than the date of entry into force of the Protocol for them, inform the Secretariat of the names and addresses of their focal points and their competent authorities. Where a Member State or the Commission designates more than one competent authority, it shall, when conveying this to the Secretariat, include relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, as a minimum, specify which competent authority is responsible for which type of GMO. The Commission and the Member States shall forthwith inform the Secretariat of any changes in the designation of their focal points or in the name and address or responsibilities of their competent authority or authorities.

Article 18

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 not later than 5 November 2004 and shall notify it without delay of any subsequent amendment affecting them.

Article 19

Monitoring and reporting

1. 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.

2. 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 Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

Article 20

Entry into force

1. This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

2. This Regulation shall apply from the date of entry into force of the Protocol, in accordance with Article 37(1) of the Protocol, or from the date of entry into force of this Regulation, whichever shall be the later.

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

Done at Brussels, 15 July 2003.

For the European Parliament
The President
P. COX

For the Council
The President
G. TREMONTI

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.

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.

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.