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

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.

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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

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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

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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.

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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.

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