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

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

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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, 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 [(7)] and Council Directive 96/ 49/EC of 23

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July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail [(8)], 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,

HAVE ADOPTED THIS REGULATION:

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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 [(9)];

(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

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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 [(10)];

(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;

(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