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 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.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are outstanding changes not yet made to REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.