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OUTCOME OF PROCEEDINGS

from :	General Secretariat
to :	Delegations
No. prev. doc:	12125/02 ENV 493 MI 174 WTO 108 ONU 64 AGRI 210 CODEC 1177
No. Cion prop.	6447/02 ENV 106 MI 33 WTO 14 ONU 9 AGRI 45 CODEC 225 COM(2002) 85 final
Subject :	Proposal for a Regulation of the European Parliament and of the Council on the **transboundary movement of genetically modified organisms**

Delegations will find in the Annex the text as it stands after the meeting of the Working Party on the Environment on 24 September 2002 and on the basis of comments received from delegations by September 27 in accordance with the Presidency's request.

Text elements, which were underlined in the previous version of the text and which received full support, are no longer underlined.

In general, the text reflects, by underlining, text elements introduced in line with the discussion and conclusions drawn in the meeting on 24 September. Eliminated text is indicated by [...].

Certain new proposals by the Presidency are also set out in the text by underlining and are accompanied by separate comments in a footnote.

The need to add "or non-Party" has been examined once again by the Presidency and some delegations have given comments on this issue. Solutions are set out concretely in the text. On this basis, delegations are kindly invited to present their views on the issue before 2 October.

In view of comments received, it is suggested to maintain the terminology "transboundary movement".

The Presidency suggests to insert an new Article covering item to which Chapter II, Section shall not apply. This new Article 3a should contain the former Article 2(3) as well as Article 4(2) and (3).

As requested by the Presidency at the meeting on 24 September, delegations are invited to send their possible comments in writing to the text as it stands in this new working document before 12h00, 3 October 2002, ie. one day later than originally announced by the Presidency. On the basis on possible requests for changes received during that second round of written comments, a subsequent working document will be established which will serve as the basis for the discussion in the Working Party on 8 October, ie. one day later than originally announced by the Presidency.

It is the intention of the Presidency to take this dossier to Coreper on 11 October with a view to enabling the Council (Environment) on 17 October to establish a political agreement on a common position. With that in mind the Presidency urges delegations to focus on issues of major importance both in the written comments and in preparing for the meeting on 7 October.

ANNEX

Proposal for a [1]

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on transboundary[2] 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 [*],

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 [****],

HAVE ADOPTED THIS REGULATION:

[recitals omitted]

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[1] D/UK: general scrutiny reservation.
DK/F: parliamentary scrutiny reservation.

[2] F: From a customs law perspective the term "transboundary" should be avoided with regard to movements between the EU Member States since there are no internal borders.

[*] OJ C , , p. .

[**] OJ C , , p. .

[***] OJ C , , p. .

[****] OJ C , , p. .

CHAPTER I
OBJECTIVES, SCOPE AND DEFINITIONS

Article 1

Objective

In accordance with the precautionary principle, and without prejudice to the provisions of Directive 2001/18/EC, the objective of this Regulation is to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) to third countries and to ensure coherent implementation of the provisions of the Cartagena 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 [3].

Article 2

Scope

1. This Regulation shall apply to the transboundary movements[4] 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 humans that are addressed by other relevant international agreements or organisations are excluded from the scope of this Regulation.

[…][5]

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[3] Cion: Reservation on "and without prejudice to the provisions of Directive 2001/18/EC".
B/F/A suggest to delete "to third countries".
F suggests to insert "et mouvements non intentionnels d'OGM à l'intérieur de la Communauté".

[4] F suggests to add: "et aux mouvements intra-communautaires non intentionnels".

[5] See footnote 16.

Article 3

Definitions[6]

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;

(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 [*], 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 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;

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

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[6] B/F suggest to revise the sequence of the definitions.

[*] OJ L 117, 8.5.1990, p. 1.

[**] 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. 1–24.

(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 relevant authority of a non-Party [7];

(9) "The Biosafety Clearing-House" or "the BCH" means the Biosafety Clearing-House established under Article 20 of the Protocol;

(10) [...] [8];

(11) "Export" means [9]:

(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 custom procedure other than transit procedure.

(12) [10]"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;

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7 D: suggests to add as final words "and to the BCH".

8 SECRETARIAT: The term "notifier" has been replaced by "exporter" in all of this text. As a consequence the definition of "notifier" has been deleted.

9 D/F: replace all of the Commission's proposed wording by: " 'Export' means intentional transboundary movement from a Party within the Community to a Party or non-Party outside the Community.".

10 B/UK point out that imports will not necessarily go into the European Community.
D/F: replace all of the Commission's proposed wording with: " 'Import' means intentional transboundary movement into a Party within the Community from a Party or non-Party outside the Community or, as the case may be, into a Party or non-Party outside the Community from a Party within the Community.".

(13) "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 for determining the sending of the GMO 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 GMO out of the customs territory of the Community shall be decisive [11];

(13a) "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.[12]

(13b) "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.[13]

(14) "Party" means any country or regional economic integration organisation having concluded the Protocol;[14]

(15) "non-Party" means any country or regional economic integration organisation not having yet concluded the Protocol;[15]

(16) "The Protocol" means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

(17) "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;

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11 B/D/F/UK: replace all of the Commission's proposed wording with: " 'Exporter' means any legal or natural person, under the jurisdiction of a Party within the Community, who arranges for a genetically modified organism to be exported."

12 Cion: positive scrutiny reservation.

13 F: In line with its comment on the title of the Regulation (cf footnote 2), F suggests to reconsider the use of the term "transboundary".
F does not support the addition of the word "intentional".

14 A suggests to delete “having concluded the Protocol” and to insert as the final part of the sentence “being Party to the Protocol.”

15 A suggests to delete “having not yet concluded the Protocol” and to insert as the final part of the sentence “not being Party to the Protocol.”

(18) "Competent authority" means a competent authority designated by a Party to the Protocol, or the relevant equivalent body appointed by 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 which shall be authorised to act on its behalf with respect to those functions;

(19) "Focal point" means the entity designated by a Party to be responsible on its behalf for liaisons with the Secretariat;

(20) "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 3a[16]

Exceptions from Chapter II, section 1 of this Regulation

1. 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 Chapter II, section 1 of this Regulation.

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

3. The obligations referred to in Chapter II, section 1 shall not apply if the Party of import has specified in advance to the BCH, in accordance with Article 13 of the Protocol, that such imports of GMOs are to be exempted from the advance informed agreement procedure provided that adequate measures are applied to ensure their safe intentional transboundary movement in accordance with the objective of the Protocol.

[16] PRESIDENCY: A new article that contains all exceptions to chapter II, section 1 is suggested to accommodate several delegations (Art 3(1) is the text of the former Art 2(3). , Art 3(2) is the text of the former Art 4(2). Art 3(3) is the text of the former Art 4(3)).

Article 4

Notification to Parties and non-Parties of Import

1. For the intended uses in accordance with Annex I [17] 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 their environment […]. The notification shall contain, at a minimum, the information specified in Annex I. The exporter shall ensure that the information contained in the notification is accurate.

[…]

[…][18]

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.

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 to the competent authority of that Party […] of Import, with a copy to the Secretariat, the Member State of Export, and to the Commission.[19] 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.

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17 D/NL/FIN/UK: scrutiny reservation.

18 See also footnote 16.

19 PRESIDENCY: suggests to add "with a deadline of 60 days from receipt for response." in order to accommodate proposals from NL/A as wll as the European Parliament Amd 21.

3. [20]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 pursuance of article 9 and 10 of the Protocol or equivalent procedures required by a non-Party[21] of import have been followed.

4. Paragraph 1 to 3 shall not apply to cases of transboundary movements covered by simplified procedures or bilateral, regional and multilateral agreements or arrangements in pursuance of article 13 and 14 of the Protocol.

5. The Commission shall, in consultation with the Secretariat, take appropriate action in accordance with any appropriate procedures and mechanisms to facilitate decision-making 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.[22]

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[23] 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.

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20 UK/Cion: scrutiny reservation regarding Art 5(3).
F/UK/Cion suggest to replace the current Art 5(3) and (4) by the following single paragraph: "Les dispositions du paragraphe 1 sont sans préjudice d'autres exigences pouvant être élaborées au niveau international, par des décisions de la Réunion des Parties en application des articles 10, paragraphe 7, ou 34 du protocole."

21 F suggests to delete "a non-Party".

22 FIN: scrutiny reservation.

* PRESIDENCY: It should attempted to ensure consistency with the time frame in *[Art. 4, para. 4 of the Proposal for a Regulation on traceability and labelling of GMOs]*.

23 F suggests to add: "where appropriate"

Article 6a

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[24] 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[25] non-Party of import, with a copy to the Secretariat, requesting a response within a set period following receipt of the reminder.

~~Article 7~~

~~Transit~~ [26]

[24] F suggests to add: "where appropriate"
[25] F suggests to add: "where appropriate"
[26] PRESIDENCY: the content of Article 7 has been moved to a new Article 9(a).

Section 2

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

Article 8

Information to the BCH

1. The Commission on behalf of the Community or, where appropriate, the Member State, which made the decision, shall forward to the BCH 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 fifteen days of the adoption of that decision. [27]

   This paragraph shall not apply to decisions regarding the deliberate release according to 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 subsequent decision.[28]

2. The information referred to in paragraph 1 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 paragraph 1 to 3 shall be sent by the Commission or the Member State referred to in paragraph 1, 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.

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[27] A/D/P/FIN/Cion: scrutiny reservation on the first part of this paragraph.

[28] NL/S/UK/Cion/FIN: scrutiny reservation on the new addition.

Article 8a[29]

Parties' and non-Parties' national decisions on import

1. The exporter shall respect any decision in accordance with Article 11.4 of the Protocol on the import of GMOs intended for direct use as food, feed, or for processing, taken by a Party or non-Party of import under its domestic regulatory framework that is consistent with the objective of the Cartagena Protocol.

[29] I/S/Cion/P/UK/D/A: scrutiny reservation. F: reservation
Cion: Art.8a could be replaced with the following text:
"1. The exporter shall act in accordance with decisions on the import of GMOs intended for direct use as food, feed, or for processing, taken by a Party or non-Party of import under its domestic regulatory framework that is consistent with the objective of the Cartagena Protocol or under the procedures provided for under article 11(6) of the Protocol.
2. Where the procedure provided for under Article 11(6) of the Protocol has been followed, failure by the Party or non-Party of import to acknowledge receipt of a notification or to communicate its decision according to paragraph 1 shall not imply its consent or refusal to the import of a GMO intended for direct use as food, feed, or for processing, unless otherwise specified by the Party or non-Party."

2. If a developing country Party or non-Party of import or a Party or non-Party 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, according to Article 11.6 of the Protocol, the exporter shall not proceed with the first export of such GMO unless the process 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 according to paragraph 2 shall not imply its consent or refusal to the import of a GMO intended for direct use as food, feed, or for processing. The exporter shall not proceed with the first export of such GMO unless otherwise specified by the Party or non-Party of import.

Section 2a

GMOs intended for contained use

Article 8b[30]

1. The provisions of section 1 of this Regulation shall not apply to transboundary movements of GMOs destined for contained use where such transboundary movements are undertaken in accordance with the standards of the Party or non-Party of Import.[31]

2. Paragraph 1 is 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.

[30] PRESIDENCY: The compromise proposal is suggested by the Presidency on the basis of the work by a group of countries (UK/D/F) during the meeting of the 24th September 2002. All delegations: scrutiny reservation.

[31] A suggests to delete the final part of the sentence "where such transboundary movements are undertaken in accordance with the standards of the Party or non-Party of import."

Section 3

Common provisions

Article 9[32]

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 the first paragraph shall be supplemented by a declaration by the exporter stating also:

   (a) 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;
   (b) and which gives details of the contact point for further information.

   However, in the case of GMO mixtures the information under 1(b) above may be replaced by a declaration by the exporter stating the unique identification codes for the GMOs used to compose the GMO mixture and which are supposed to be in the mixture.

[32] FIN: scrutiny reservation. Cion: reservation.
UK: reservation. UK proposes to replace all of Art 9(2) to (5) by the following: "Paragraph 1 shall be without prejudice to other specific requirements in Community legislation and to decisions on the detailed requirements on handling, transport, packaging and identification in accordance with Article 18 of the Protocol adopted by the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Protocol."
F cannot support UK proposal.

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

(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 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 also state:

(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 are without prejudice to other specific requirements in Community legislation and to international identification requirements to be developed in accordance with Article 18 of the Protocol.

6. [33]

[33] B suggests adding new paragraphs: "6. The accompanying document described in paragraph 1, possibly supplemented by the declarations described in paragraphs 2, 3, or 4, shall be presented to the customs authority of any Member States when the export or the re-export is validated or on request of this authority during the export or re-export movement. 7. Detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in new Article 12a.2"

Article 9a[34]

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.

[34] PRESIDENCY: The text on transit has been moved to its new position from the original Article 7 (and it was most recently in Art 9(5)).
D/Fin suggest to replace context of Art 9a with the following text: "In accordance with Article 6(1) of the Protocol, notwithstanding the other paragraphs of Article 2 of this Regulation, and without prejudice to any right of a Party of transit to regulate the transport of GMOs through its territory and make available to the BCH any decision of that Party regarding the transit through its territory of a specific GMO, the provisions of this Regulation with respect to the notification procedure prior to the first intentional transboundary movement of a GMO shall not apply to GMOs in transit."
NL proposes the following: "The exporter shall ensure that the transit of GMOs intended for deliberate release into the environment, or for direct use as food or feed, or for processing, takes place in accordance with any decision taken by a party of transit to regulate the transit of such GMOs."

CHAPTER III

UNINTENTIONAL TRANSBOUNDARY MOVEMENT OF GMOS

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[35] 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 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.

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

[35] F suggests to add "ou un mouvement non intentionnel intra-communautaire".

CHAPTER IV
COMMON PROVISIONS

Article 11

Participation in the international information procedure [36]

1. The Member States shall in accordance with the provisions of the Protocol inform the BCH and the Commission of:

   (a) national 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) 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[37] pertaining to them, in accordance with Article 17 and 25 of the Protocol;
   (e) any final decision taken by a Member State, regarding the use within that Member State, including decisions on contained use, deliberate release according to part B of Directive 2001/18/EC or import to the Community of GMOs, in accordance with Articles 11 and 20.3 (d) of the Protocol, within [15] days of the adoption of that decision;[38]

[36] B: add a new point at the end of Art 11(1):
"(i) reports submitted pursuant to Article 14(1) of this regulation."

[37] F suggests to add "et des mouvements non intentionnels intra-communautaires".

[38] I/A/FIN/Cion: scrutiny reservation on point (e), in particular relating to "contained use". FIN suggests to delete the reference to contained use.

(f) any summary of risk assessments or environmental reviews of GMOs carried out in accordance with procedures similar to those laid down in Annex II to Directive 2001/18/EC and Annex III to Directive 90/219/EEC as amended, most recently by Directive 98/81/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;[39]

(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 according to Article 23 of Directive 2001/18/EC or emergency measures taken by a Member State according to [*Article [35] of the Proposal for a Regulation 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 the 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 within the Community, including decisions on the placing on the market or the importation of a GMO, in accordance with Articles 11 and 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;

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[39] NL/FIN: Scrutiny reservation on point (f).
FIN/A suggest to delete "and Annex III to Directive 90/219 ... by Directive 98/81/EC".

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

(f) application of Community legislation instead of the procedures of the Protocol for transboundary[40] movements of GMOs within the Community and imports of GMOs into the Community in accordance with Article 14(3) and[41] 14(4) of the Protocol;

(g) reports submitted pursuant to Article 14 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 authorities and focal points

1. The Commission shall designate a Community focal point[42].

2. Each Member State shall designate one focal point, as well as one or more competent authorities. A single entity can also fulfil the functions of both focal point and competent authority.

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[40] Cion does not support inclusion of the word "transboundary"
F suggests to delete "transboundary" and to insert "intentional".

[41] A: delete the reference to Art 14(3) of the Protocol.

[42] F: suggests to add "and shall, where appropriate, identify any Community 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, at 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.[43]

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 [12 months][44] 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. Regularly and at least every 3 years, unless otherwise established under article 33 of the Cartagena Protocol, Member States shall forward to the Commission a report on the implementation of the present Regulation.

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[43] B suggests to insert a new Art 12a, "*Committee",* with the following text:
"1. The Commission shall be assisted by the committee instituted by Article 30 of Directive 2001/18/EC. 2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply. 3. The period provided for in Article 5 (6) of Decision 1999/468/EC shall be three months."

[44] Cion: positive scrutiny reservation on this replacement.

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 [45], whichever shall be the later.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

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[45] PRESIDENCY: Add "or at the date of entry into force of the Regulation" or similar wording. I/P: progress on the dossier could make this redundant.

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 above-mentioned information is factually correct.

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.

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.