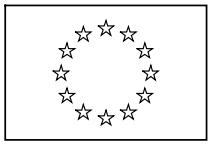

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18.02.2002
COM(2002) 85 final

2002/0046 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the transboundary movement of genetically modified organisms

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Background

On 24 May 2000, the European Community and its Member States signed up to the Cartagena Protocol on Biosafety. Implementing legislation must now be put in place, at the Community level, in order to conclude this international agreement, in accordance with Article 300 of the Treaty. Against this background, the Commission has committed to present a Proposal for an appropriate legal instrument to implement the provisions of the Protocol. In order to meet our international obligations, this should be presented as a matter of urgency and preferably before the end of 2001 since;

- *The Protocol will enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification by Parties to the Convention (Article 37.1 of the Protocol)*[1]*;*

- *There exists a strong political will in Member States to be amongst the first Parties to ratify the Protocol, a view supported by the European Parliament;*

- *The EU has played a leading role in the conclusion of the Protocol and a fast ratification would provide a strong political signal that its commitment to the Protocol is not diminishing.*

2. Objective

The overall objective of the Biosafety Protocol (BP) is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms 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 focussing on transboundary movements (Article 1 of the Protocol).

The Protocol especially refers to the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development (Article 1 of the Protocol). The European Union intends to implement the Protocol in its domestic legislation in the light of the precautionary principle, in accordance with the guidelines developed in the Communication from the Commission on the precautionary principle of 2 February 2000[2].

The definition of an LMO under the Protocol is largely consistent with the definition of a Genetically Modified Organism (GMO) under Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms[3]. The genetic modification techniques applicable to each definition under the two instruments are not the same, however, although this is not likely to impinge on operational aspects of the legislation.

---

1 At the current time (August 2001), only five Parties have ratified the Protocol, but some Parties have already announced their intention to ratify in 2001 (Small Island States for example) or by the beginning of 2002.

2 Communication from the Commission on the precautionary principle of 2 February 2000, COM(2000)1

3 OJ L 106, 17.4.2001, p. 1.

Furthermore, humans are explicitly excluded from the scope of Directive 2001/18/EC but this is not the case for the Protocol although again, this is unlikely to have any operational consequences.

The Protocol differentiates between and establishes different procedures for transboundary movements of (i) LMOs and (ii) LMO-FFPs (LMOs intended for direct use as food or feed, or for processing – GM commodities in EU terminology).

- For LMOs intended for intentional introduction into the environment, the Protocol establishes an *Advanced Informed Agreement* (AIA - Article 7 of the Protocol), which forms a central part of the procedure concerning transboundary movements. Full notification by the Exporter/Party of Export to the Party of Import is required under this procedure prior to the first transboundary movement. This procedure also requires the Party of Import to perform a risk assessment on the basis of the information provided in the notification and other available scientific evidence in order to identify and evaluate the possible adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking also into account risks to human health. This risk assessment has to be carried out in a scientific sound manner, in accordance with stringent requirements listed in Annex III of the Protocol. The provisions of the Protocol alternatively allow the Party of Import to use procedures under their national legislation provided that they are consistent with the requirements of the Protocol (Arts. 9.2.c and 9.3 of the Protocol).

- For LMO-FFPs, the procedure for transboundary movements is different and is founded on a pre-market '*product based' information sharing system* (Article 11 of the Protocol). This places an obligation on Parties granting authorisation for the placing on the market of new LMO-FFPs on their domestic markets to inform all Parties of these approvals through communication with the Biosafety Clearing House (BCH). The relevant information must be communicated within two weeks of the approval of a new LMO-FFP. This provides for the possibility for Parties intending to import such new LMO-FFPs to submit it to an appropriate authorisation procedure, under their national laws. Parties of import can either react to notifications, submitted through the BCH, on a case-by-case basis or take the decision to impose notification of all LMO-FFPs that will be imported on their territory (Article 11.4 of the Protocol).

3. Relationship with EC domestic legislation and bilateral agreements

Article 14 of the Protocol provides for a disconnection clause for bilateral, regional and multilateral agreements and arrangements. This would allow Member States of the European Union, on the proviso that Community legislation is consistent with the objectives of the Protocol and notified to the BCH, to:

- *Utilise the provisions of Community legislation, as opposed to those of the Protocol, for transboundary movements of LMOs in the European Union (as provided for by Article 14.3 of the Protocol) and ultimately for movements to and from EEA countries (although the latter requires further discussion with these countries);*

- *Utilise the provisions of Community legislation, as opposed to those of the Protocol, for imports of LMOs into the European Union, as provided for by Article 14.4 of the Protocol. This provision is further reinforced by Article 9.2c and 11.4 of the Protocol, which allow*

for Parties to use their national legal frameworks rather than the AIA procedures for importation of LMOs and LMO-FFPs[4].

After careful assessment of the Community legal framework relevant to the Cartagena Protocol on Biosafety, the Commission has concluded that EC legislation is consistent with the provisions of the Protocol and will therefore systematically be applied for both movements of GMOs between Member States and imports of GMOs into the European Union.

All relevant EC legislation and procedures will apply for imports of GMOs into the European Union. This will be clearly stated by the EU at the time of the ratification and relevant legislation will be notified to the Biosafety Clearing House, according to Article 20.3(a) of the Protocol. New legislation and amendments to existing legislation will also have to be notified to the Biosafety Clearing House once they enter into force.

4. Implementation strategy

In the first instance, it is paramount for reasons of legal clarity that the proposed measure to implement the Protocol clearly differentiates between the roles of the European Union as (i) an Exporter and (ii) an Importer since:

- *As a Party of Export, the European Union will have to introduce exporter obligations, which currently do not exist in Community legislation;*

- *As a Party of Import, the European Union will to a large extent be able to utilise existing Community legislation.*

For *Exporter obligations*, it will be necessary for the European Union to develop *new* legislation to meet the requirements of the Protocol. It would, however, seem appropriate to limit the provisions of this legislation to the *essential requirements of the Protocol* given the diversity of the import procedures to which the Exporter/Party of Export will have to conform.

It will be possible, on the other hand, to address *Importer obligations* under the *existing* Community legislation. The European Union should, in the main, be able to utilise the Community legislative framework on the basis that it is consistent with the requirements of the Protocol.

In addition, other essentially horizontal issues must be addressed, for example the repartition of responsibilities between the European Union and the Member States, with particular regard to notification obligations.

The Commission has proceeded so far to extensive consultation with interested parties (Member States, Industries, Environmental Organisations, Trade Associations) and it appears that the overall approach is largely agreed by those parties.

Against the above background, it appears that the most appropriate way to implement the Protocol within a reasonable timeframe is via a single, horizontal legal instrument and a

---

[4] Article 14.4 of the Protocol only refers to 'specific imports'. It can therefore be argued whether it can be applied as a general rule. However, Arts. 9.2 c and 9.3 of the Protocol give a clear choice between AIA and domestic regulatory framework when the latter is consistent with the Protocol.

Regulation as opposed to a Directive would allow for more rapid implementation. It will also avoid legislative gaps and inconsistencies between different community and national texts and allow for more consistent practical application.

5. Costs

According to preliminary discussions with representative from the industry and the environmental organisations, it appears that costs involved by administrative formalities linked to the implementation of the Biosafety Protocol are negligible. The implementation of the Protocol should not bring additional costs to those already imposed by existing Community legislation.

2002/0046 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the transboundary movement 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 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 on 24 May 2000;

(2) The Cartagena Protocol on Biosafety, in its Article 1, specifies that, in accordance with the precautionary approach contained in Principle 15 of the Rio declaration, 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 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 focussing 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 and repealing Council Directive 90/220/EC[5], as last amended by Regulation (EC) .../... of the European Parliament and of the Council concerning the traceability and

---

1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
5 OJ L 106, 17.4.2001, p. 1.

labelling 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 take account of conservation and sustainable use of biological diversity, taking also into account risks to human health;

(5) Since Community legislation does not contain 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) Exports of GMOs should be notified to the country of import, allowing it to make an informed decision, based on risk assessment carried out in a scientifically sound manner;

(7) The notification should be ensured by the exporter, which is legally responsible vis-à-vis its contracting party for the product it sells. The notifier, normally the exporter, should be responsible for the accuracy of the information provided in the notification;

(8) According to the Protocol, the Community 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 the Community's other obligations under international law;

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

(10) The Protocol provides that Parties may decide to apply either the procedures of the Protocol or their domestic regulations with respect to imports of GMOs. 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 objectives of the Protocol, there is no need to adopt supplementary provisions with regard to imports of GMOs into the Community;

(11) 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], as last amended by Commission Directive 2001/7/EC[8], 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[9],

---

6 OJ L [...]
7 OJ L 319 , 12.12.1994, p. 7.
8 OJ L 30, 1.2.2001, p. 43.
9 OJ L 235 , 17.09.1996, p. 25.

as last amended by Commission Directive 2001/6/EC[10], already contain appropriate rules, there is no need to adopt supplementary provisions in this respect;

(12) It is necessary to ensure the identification of GMOs being exported from or imported into the Community. With regard to imports into the Community existing Community legislation, in particular Regulation (EC) .../...of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms, already contain appropriate provisions. With regard to exports similar rules should apply;

(13) 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 account risks to human health, Member States from whose territory such a movement originates should take appropriate measures to inform affected or potentially affected states, the Biosafety Clearing House (the BCH) and, where appropriate, relevant international organisations when they become aware of such an occurrence under their jurisdiction;

(14) In order to help developing the BCH, the Community and its Member States should ensure that relevant information is communicated to the BCH on a regular basis, and that monitoring and reporting on the implementation of the Protocol in the Community are performed;

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

(16) This Regulation respects the fundamental rights and observes the principles rerecognised in particular by the Charter of Fundamental Rights of the European Union;

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVES, SCOPE AND DEFINITIONS

Article 1
Objective

In accordance with the precautionary principle, the objective of this Regulation is to establish a common system of notification and information for exports to third countries of genetically modified organisms (GMOs) 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 the sustainable use of biological diversity, taking also into account risks to human health.

---

[10] OJ L 30, 1.2.2001, p.42.

Article 2
Scope

1. This Regulation shall apply to the export and unintentional transboundary movement 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 human use are excluded from the scope of this Regulation.

3. 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 Section 1 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 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/EECon the contained use of genetically modified micro-organisms[11], 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 to limit their contact with the general population and the environment.

(6) "Product" means product as defined in Article 2(7) of Directive 2001/18/EC;

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

(7) "Food" means food as defined in [Article 2 of the Proposal for a Regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food[12]];

(8) "Feed" means feed as defined in [Article 3(4) of the Proposal for a Regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food];

(9) Notification" means the submission of the information required under this Regulation to the competent authority of a Party to the Protocol or to the relevant authorities of non-Parties;

(10) “The Biosafety Clearing House” or “the BCH” means the Biosafety Clearing House stablished under Article 20 of the Protocol;

(11) "Notifier" means the natural or legal person submitting the notification;

(12) "Export" means:

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

(b) the re-export of products not meeting the conditions referred to in (a) which are placed under a custom procedure other than transit procedure.

(13) "Import" means the placing under a customs procedure other than transit procedure of products introduced into the customs territory of the Community;

(14) “Exporter” means any natural or legal person 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 item 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 item out of the customs territory of the Community shall be decisive;

(15) "Party" means any country or regional organisation having concluded the Protocol;

(16) "non-Party" means any country or regional organisation not having concluded the Protocol;

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

(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;

---

12 OJ C 96 E, 27.03.2001, p. 247.

(19) "Competent national authority" means the competent authority designated by the Parties to the Protocol which is responsible for performing the administrative functions required by the Protocol and which shall be authorised to act on its behalf with respect to those functions;

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

(21) "Secretariat" means the Secretariat to the Protocol.

CHAPTER II

EXPORTS OF GMOs TO THIRD COUNTRIES

Section 1

Exports of GMOs intended for deliberate release into the environment

Article 4
Notification to Parties and non-Parties of Import

1. The exporter shall ensure notification, in writing, to the competent national 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 notifier shall ensure that the information contained in the notification is accurate.

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

Article 5
Cases of non-reply to notifications

In cases where the Party or non-Party of Import does not reply to a notification within 270 days from the date of receiving the notification, the exporter shall send a written reminder to the competent national authority of that Party or non-Party of Import, with copy to the Secretariat, with a deadline of 60 days from receipt for response.

Article 6
Informing the Party of Export

The exporter, or the notifier, shall keep a record of the notification and the acknowledgement of receipt and send a copy of these documents to the competent national authority of the Member State of Export and to the Commission.

Article7
Transit

The exporter ensure notification of the transit of GMOs intended for deliberate release into the environment to Parties that have taken the decision to regulate transit of GMOs through their territory and have notified this decision to the Biosafety Clearing House (the BCH).

Section 2

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

Article 8
Notification to the BCH

1. The Commission shall notify to the BCH, on behalf of the Community, any final decision regarding Community use, including placing on the market, of a GMO that may be subject to transboundary movements for direct use as food or feed or for processing. This notification shall be sent to the BCH within fifteen days of the adoption of that decision.

   This paragraph shall not apply to decisions regarding field trials.

2. The information referred to in paragraph 1 to the Biosafety Clearing House shall contain as a minimum the information specified in Annex II.

3. The Commission shall process requests made by any Party for additional information regarding the decisions referred to in paragraph 1.

4. A copy of this information shall be sent, 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.

Section 3

Common provisions

Article 9
Identification

1. Exporters shall ensure that the following information is transmitted to the operator receiving the product:

   (a) that it contains or consists of GMOs

   (b) the relevant unique code(s) assigned to those GMOs

   However, the information under (b) above may be replaced by a declaration by the operator that the product shall only be used as food or feed, or for processing, together with the unique codes for the GMOs that the product may contain.

2. Paragraph 1 is without prejudice to other specific requirements in Community legislation and to international identification requirement to be developed in accordance with article 18 of the Protocol.

CHAPTER III

Unintentional transboundary movement

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 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 notify without delay the Commission, other Member States, affected or potentially affected states, the BCH, and, where appropriate, relevant international organisations.

   (b) consult the affected or potentially affected State to enable it to determine appropriate responses and initiate necessary action, including emergency measures.

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

CHAPTER IV

COMMON PROVISIONS

Article 11
Participation to the international information procedure

1. The Member States shall in accordance with the provisions of the Protocol notify to the Commission:

   (a) national legislation and guidelines relevant for the implementation of the Protocol, in accordance with 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 regarding intentional transboundary movements of GMOs, in accordance with Article 20.3(b) of the Protocol;

   (d) information concerning cases of illegal transboundary movements pertaining to them, in accordance with Article 25 of the Protocol.

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

(a) information notified by the Member States pursuant to paragraph 1;

(b) Community legislation and guidelines relevant for the implementation of the Protocol, in accordance with Article 20.3(a) of the Protocol;

(c) 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;

(d) any final decision regarding the use within the Community, the release or the importation of a GMO, in accordance with Articles 11 and 20.3(d) of the Protocol;

(e) 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, 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;

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

(g) Community contact point for notification of unintentional transboundary movement, in accordance with Article 17 of the Protocol;

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

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

(j) reports submitted pursuant to Article 20 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 national authorities and focal points

1. The Commission shall designate one focal point.

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

3. The Commission, on behalf of the EC, and the Member States shall, no later than the date of entry into force of the Protocol for them, notify the Secretariat of the names and addresses of their focal points and their competent national authority or authorities. Where a Member State designates more than one competent national authority, it shall convey to the Secretariat, with its notification, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent national authority is responsible for which type of GMO. The Commission and the Member States shall forthwith notify the Secretariat of any changes in the designation of their national focal points or in the name and address or responsibilities of their competent national authority or authorities.

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 [180 days 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. Member States shall regularly forward to the Commission information on the implementation of the present Regulation.

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, 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	*For the Council*
The President	*The President*

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.

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES (SMEs)

TITLE OF PROPOSAL

Proposal for a Regulation of the European Parliament and of the Council on the transboundary movements of genetically modified organisms.

THE PROPOSAL

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

The Regulation lays down at Community level requirements for the implementation of the Cartagena Protocol on Biosafety. The overall 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 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 focussing on transboundary movements.

The Regulation aims at avoiding differences and overlap between national laws, regulations and administrative provisions concerning exports and unintentional transboundary movements of GMOs which may hinder the free movement of products, creating conditions of unequal and unfair competition.

A Community Regulation laying down a harmonised framework for transboundary movements of such products would, therefore, provide for legal certainty as well as a coherent and consistent approach that should contribute to the effective functioning of the internal market.

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

All sizes of businesses related to the international trade of GMOs for deliberate release in the environment or to be used as food, feed or for processing are affected. The proposal has a similar impact over the entire Community. It is not aimed at any particular region.

3. What will business have to do to comply with the proposal?

For imports into the Community, EC legislative framework will continue to apply and there will be therefore no additional obligations imposed by the Proposal.

For exports, the Proposal will implement the provisions of the Protocol. The main new additional obligations for business will be as follows:

- Ensure notification to the Party of Import prior to the first transboundary movement of a GMO intended for deliberate introduction into the environment;

- Ensure notification of the transit of GMOs intended for deliberate release into the environment to Parties that have taken the decision to regulate transit of GMOs through their territory and have notified this decision to the BCH;

- Ensure proper identification of GMOs subject to transboundary movements.

In practical terms, the new obligations will only extend to exports formalities that are already compulsory for the same type of operations inside the European Community, and that require the same type of data. Therefore, the Proposal should not imply substantial extra costs for the operators.

4. What economic effects is the proposal likely to have?

The Proposal will have no real impact on imports into the Community, which will continue to be subject to the provisions of EC legislation.

For exports, the new system arising from the implementation of the Protocol will impose additional obligations, but they will have (i) a minor effect on an economic point of view and (ii) will improve the legal security for exports of GMOs:

- The proposed requirements for exports largely build on the general requirements in the Community legislation in the field of Biotechnology. By streamlining procedures for imports, exports and intra-community movements, the procedure avoids setting up a multitude of different procedures that risk being cumbersome, costly and misleading. Additional notification formalities it generates should have a negligible impact, since they will not lead to any additional studies or trial other than those necessary for obtaining a Community authorisation for a GMO.

- This proposal will establish an effective, predictable and consistent framework for exports of GMOs for deliberate release into the environment and to be used as food, feed or for processing. The new system of notifications and the decision-making procedures arising from the Protocol will improve the transparency and security of exports.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

The scope of the proposal is entirely horizontal and its provisions are generic. Therefore, it does not contain measures specifically aimed at or adapted for small and medium-sized firms.

CONSULTATION

6. List the organisations which have been consulted about the proposal and outline their main views.

A "stakeholder dialogue" was organised on 29 June 2001, to which a large panel of organisation has been invited[1]. Biotech industries, environmental organisations, consumer organisations and agricultural organisation were consulted on two documents:

- A background information paper explaining the procedure the Commission intended to follow for the implementation of the Biosafety Protocol in EC law;

- A discussion paper on the main issues regarding the implementation of the Biosafety Protocol in EC legislation, namely; (i) definition of a GMO, (ii) content of a notification for an export of GMO, (iii) export procedure, (iii) case of non-reply by a Party of import, (iv) notifications to non parties, (v) information of the Party of export, (vi) Costs implications.

Amongst the various stakeholders invited, the following industrial and agricultural organisations participated to the meeting of the 29 June 2001: the European Seed Association (ESA), Coceral, Europabio, European Federation of Food Science and Technology (EFFoST) and European Seed Growers Group (ESGG).

The Commission approach for the implementation of the Protocol was globally approved by the stakeholders, who insisted on the necessity to adopt clear cut and reliable procedures for the implementation of the Protocol.

It was also considered essential to clearly insist on the fact that the Protocol only deals with living organisms capable of reproduction, bearing in mind that, at international level, different countries have different definitions for GMOs.

On the notifications, stakeholders insisted on the fact that the Protocol only deals with the first transboundary movement. Since every country has the possibility to require different information for imports on its territory, some representatives considered that information requested in notifications under the Community implementing legislation should not go beyond the minimum notification requirements of the Protocol. Furthermore, they considered that climatic and environmental differences make it difficult to consider everything in light of

[1] The list of consulted organisation is as follows: **Industries:** Advanta B.V., Aventis Crop Science, BASF Plant Science, Syngenta Seeds AG, Monsanto Europe; **Environmental NGOs:** Greenpeace Belgium, Friends of the Earth Europe, European Environmental Bureau, WWF-Belgium, European Centre for Nature Conservation; **Consumer organisations:** Bureau Européen des Unions de Consommateurs, Consumers International**; Trade associations:** Coceral, EuropaBio, Global Crop Protection Federation, European Seed Association, European Seed Growers Group, European Feed Manufacturers' Federation, EC Seed Crushers' and Oil Processors' Federation, Foreign Trade Association, Federation of European Wholesale and International Trade Associations, European Liaison Committee of Freight Forwarders, European Federation of Pharmaceutical Industries' Associations, European Federation of Food Science and Technology; **Trade Unions and Employers Federations:** Union des Confédérations de l'industrie et des employeurs d'Europe, European Confederation of Independant Trade Unions, European Trade Union Confederation; **Agricultural Organisations:** European Farmer's Coordination, COPA/COGECA

European standards and that in any case, what will be exported from the EU is also likely to have already received a Community authorisation.

Identification requirements were rapidly discussed, and one representative asked that these should be based on the recommendation of the "Article 18 working group" (expert group working on international identification requirements pursuant to the Protocol).

Some participants considered purely academic to discuss on the relevance of an obligation for the Exporters to follow the procedures of the Party of import, and that there could be a legal problem to refer in a Community proposal to legislation of third countries that may be contradictory. Some other considered that the implementing legislation could reflect that the exporter has to act in accordance with the legislation of the Party of Import.

For cases of non-reply to a notification by the Party of import, stakeholders pointed out that the exporter had a right to legal certainty but that it was also difficult to force the Party of import to act. A non-reply might not imply a refusal, and the situation should be examined in the light of the legislation of the Party of import. Some legislation might not even require explicit consent for imports. The Importer should have a responsibility on this issue and the Party of export should play a role of facilitation. The Exporter should also provide as much information as possible to help the Party of import making a decision.

Consulted organisations disagreed with the right of the Party of export to be informed of everything. The information should only concern the first transboundary movement and not subsequent movements. Once the first transboundary movement has been authorised, there shall not be any brake to exports. Stakeholders also pointed out the importance of the Biosafety Clearing House for the access to information.

Most of the stakeholders considered that procedures should be similar for Parties and non-Parties for reasons of simplifications.

Consulted organisations considered that additional costs generated by the Protocol should be negligible. However, they declared that there are already many document requirements and administrative formalities and that those should be kept as simple as possible to avoid that trade is only possible for large enterprises. The Biosafety Clearing House (BCH) should also have a key role and be communicated every relevant information which will help to keep costs down and have light administrative formalities.