UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/BSWG/4/Inf.5
28 January 1998

ORIGINAL: ENGLISH

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Fourth meeting
Montreal, 5-13 February 1998

ENGLISH

THE CONSOLIDATED TEXT FROM THE THIRD MEETING OF THE OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY

/...

Annex I

CONSOLIDATED TEXT OF DRAFT ARTICLES

CONTENTS

TITLE

Option 1

Protocol on Biosafety

Option 2

Protocol for the Safe Transfer, Handling and Use of Living Modified Organisms.

Option 3

Biosafety Protocol

Option 4

Protocol for the Safe Transfer, Handling and Use of Living Modified Organisms

Option 5

Protocol for the Manipulation, Use, Transboundary Movement and Release into the Environment of Living Modified Organisms

PREAMBLE

A. Aide-mémoire from the Chair

1. Should the Preamble draw on language from decision II/5 adopted by the Conference of the Parties to the Convention on Biological Diversity at its second meeting?

2. Should the language set out the aspirations of the parties?

3. Should Article 19, paragraphs 3 and 4, and Article 8(g) of the Convention on Biological Diversity be recognized in the Preamble?

4. Should the Rio Declaration on Environment and Development, the UNEP International Technical Guidelines for Safety in Biotechnology, the United Nations Recommendations on the Transport of Dangerous Goods, and chapter 16 of Agenda 21 ("Environmentally Sound Management of Biotechnology") be referred to in the Preamble?

5. Should the Preamble recognize the limited capabilities of developing countries to cope with the risks associated with LMOs and the need for capacity-building?

6. Should the Preamble recognize that the Protocol is not duplicating other existing legal instruments?

7. Should the Preamble reflect the issue of socio-economic considerations?

8. Should the Preamble reflect the issue of liability and compensation?

9. Other?

B. Options

Option 1

The Parties to this Protocol:

Being Parties to the Convention on Biological Diversity,

Mindful of their obligation under Article 8 (g) of that Convention to establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, including risks to human or animal health,

Considering the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on human or animal health, biological diversity, the environment, and social and economic welfare,

Recognizing the need to establish a minimum condition of safety and a procedure for the assessment and management of the potential risks arising from the development, use, release and transfer of living modified organisms and products thereof,

Mindful of the obligation imposed by Article 19, paragraph 4, of the Convention on Biological Diversity on any Contracting Party, directly or by requiring any natural or legal person under its jurisdiction, to provide any available information about the use, the potential adverse impacts and the safety regulations required by that Contracting Party in handling such organisms to the Contracting Party into which those organisms are to be introduced,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms resulting from biotechnology,

Noting that States should make sure that the user of living modified organisms or products thereof should conduct its activities with respect to the development, handling, transport, use, release and transfer of living modified organisms in a manner that is consistent with the safety of human health and animal health, biological diversity, the environment, and social and economic welfare,

Acknowledging that any State has the sovereign right to ban the entry or release of living modified organisms into its territory,

Considering the importance of promoting international cooperation in the exchange of information on the transboundary transfer and release of

living modified organisms and the development of appropriate containment measures and emergency plans required to deal with accidents,

Noting that, in accordance with the precautionary principle, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize risk where such a risk is posed by living modified organisms resulting from biotechnology,

Noting also that safety measures and decisions on the development, use, handling, release and transfer of living modified organisms and products thereof need to be based on up-to-date and most comprehensive technical and scientific knowledge available,

Recalling chapter 16 of Agenda 21 adopted by the 1992 United Nations Conference on Environment and Development, which provides for the "Environmentally Sound Management of Biotechnology", and which further seeks to ensure safety in biotechnology development, application, exchange and transfer through international agreement,

Desirous of affirming the responsibility of States to fulfil their obligations under Article 19, paragraph 3, of the Convention on Biological Diversity in setting out appropriate procedures, in particular advance informed agreement, in the field of the safe transfer, handling and use of living modified organisms resulting from biotechnology,

Recalling also the commitment taken by the Parties to the Convention on Biological Diversity under the same provision of the Convention referred to above to consider the need for, and modalities of a protocol in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity,

Determined to control through the use of established procedures of assessment, management and notification of risks associated with living modified organisms and through rules of liability and compensation for damage or loss arising from these organisms and products thereof,

Have agreed on the following:

Option 2

The Parties to the Protocol,

Recalling Article 19, paragraph 3, of the Convention on Biological Diversity,

Recognizing the link between paragraphs 3 and 4 of Article 19 of the Convention,

Recognizing also the link between Article 8 (g) and Article 19, paragraph 3, of the Convention,

Recalling decision II/5 of the Conference of the Parties to the Convention on Biological Diversity to develop a protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement,

Recognizing that the framework includes national, regional, multilateral and international activities on risk assessment, risk management, information exchange, regulations, guidelines, capacity-building and international agreement,

Affirming their support for a two-track approach through which the promotion of the application of the UNEP International Technical Guidelines for Safety in Biotechnology can contribute to and complement the implementation of the Protocol,

Noting the United Nations Recommendations on the Transport of Dangerous Goods,

Noting that the provisions of the Protocol should contribute to protection in the field of biosafety, based on scientific risk assessment and the precautionary principle,

Recognizing that the interaction between living modified organisms (LMOs) resulting from modern biotechnology and the environment, in particular in centres of origin and genetic diversity, is of a very complex nature not always fully elucidated by adequate scientific knowledge,

Aware that some applications of modern biotechnology may have adverse effects on the environment, also taking into account human health,

Recognizing that, while properly addressing the risks from living modified organisms resulting from modern biotechnology, the Protocol should avoid causing unnecessary delays to the benefits that biotechnology could bring for health, agriculture and environment,

Recognizing that the Protocol should not create unwarranted administrative requirements for transboundary transfer of LMOs for contained use,

Recognizing that to be effective and workable, the Protocol should be based on science and up-to-date experience, and include mechanisms to ensure adequate flexibility, such as provisions for exemptions and for rapid adaptation to scientific and technical progress,

Recognizing also that the Protocol should not duplicate other comparable existing legal instruments,

Have agreed as follows:

Option 3

Recalling Article 19, paragraph 3, of the Convention on Biological Diversity,

Recognizing the link between paragraphs 3 and 4 of Article 19 of the Convention,

Recognizing also the link between Article 8 (g) and Article 19, paragraph 3, of the Convention,

Considering that, although there exist international agreements of relevance to the impact of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, there are no legal instruments which specifically address the transboundary movements of such LMOs,

Recognizing also that, although considerable knowledge is gained, significant gaps in knowledge have been identified, specifically in the field of interaction between the environment and living modified organisms (LMOs), resulting from modern biotechnology, taking into account the relatively short period of experience with releases of such organisms, the relatively small number of species and traits used, and the lack of experience in the range of environments, specifically those in centres of origin and genetic diversity,

Noting also the advantages that lie in the potential of modern biotechnology to contribute to sustainable development,

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat,

Recognizing that the safe transfer, handling and use of living modified organisms should be based on a step-by-step and case-by-case approach,

Recognizing that the Protocol should not create unwarranted administrative requirements for transboundary transfer of LMOs for contained use provided that appropriate safety measures are applied,

Recognizing that the production and use of living modified organisms should take place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without adverse effects on human health and the environment,

ARTICLE 1 - PRINCIPLES/OBJECTIVES

The Article may take into account the following elements, as appropriate:

(a) The Protocol should contain a separate Article on objectives and it should be a broad objective;

(b) The objective should reflect the language in this field from decision II/5 of the Conference of the Parties;

(c) The objective should be broad and enable the Protocol to cover all the issues required to protect biodiversity, the environment and human [and animal] health [and social well-being].

GOVERNMENT SUBMISSIONS

Option 1

The objective of this Protocol, to be pursued together with the relevant objectives and provisions of the Convention, is to safeguard human and animal health, the environment, biological diversity and the socio-economic welfare of societies from the potential risks of biotechnology, particularly modern biotechnology involving the development, handling, transfer, use and release of living modified organisms and products thereof.

Option 2

The objective of this Protocol is to promote the safe transboundary movement of living modified organisms resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, including through exchange of information and a scientifically-based and transparent system of advance informed agreement.

Option 3

The objective of this Protocol is to promote the safe transboundary movement of all living modified organisms, and products thereof, resulting from modern biotechnology which may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

Option 4

The objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of biosafety, specifically focusing on transboundary movement, of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Option 5

The objective of this Protocol is to ensure the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effect on the environment, in particular, the conservation and sustainable use of biological diversity, socio-economic imperatives, and the risks to agriculture and human health.

Option 6

The objective of the Protocol is to ensure safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity taking into account the risks to human health. The objective is also to ensure that these activities take place in accordance with the principle of sustainable development and in an ethically and socially justifiable way.

Option 7

The objective of the Protocol is to ensure the safe transfer, handling and use of living modified organisms (LMOs) which result from modem biotechnology and which may have adverse effects on the conservation and sustainable use of biological diversity. Risks to human and animal health should be duly taken into account, and it should further be ensured that these activities take place in accordance with the principle of sustainable development, and in a socially and economically justifiable way.

Option 8

The objective of this Protocol is to promote shared responsibility and cooperative efforts among the Parties to achieve an appropriate level of safety for the transboundary movement of living modified organisms that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, by promoting and facilitating information exchange and providing for appropriate procedures.

ARTICLE 1 bis - GENERAL OBLIGATIONS

The Article may take into account the following elements, as appropriate:

(a) Parties should be obligated to ensure adequate provisions for emergency plans in case of accidental or unintended transboundary movement;

(b) Parties should be obligated to take appropriate national legal, administrative and other measures [exchange of information and non-discrimination] to implement and enforce the provisions of this Protocol;

(c) Parties should ensure the AIA procedure be implemented in a transparent manner based on scientific methods;

(d) There should be no disguised restrictions on international trade;

(e) Parties should recommend relevant bodies to take appropriate action;

(f) Parties should employ a precautionary principle when dealing with the transboundary movement of LMOs;

(g) Parties should be obligated as to ensure that the Protocol is employed on a case-by-case basis.

GOVERNMENT SUBMISSIONS

Option 1

1. The Parties to the present Protocol undertake to implement the provisions of the Protocol and the Annexes hereto which shall constitute an integral part of the present Protocol.

2. Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms or products thereof are undertaken in a manner that prevents or reduces to acceptable levels of risks to human and animal health, biological diversity, the environment and socio-economic welfare of societies.

3. Parties shall prohibit the export of living modified organisms or products thereof unless they obtain an advance informed agreement in writing from the State of import for the specific import.

4. Parties shall prohibit the export of any living modified organisms or products thereof to the Parties which have prohibited the import of such organisms or products. Parties exercising their right to prohibit the import of living modified organisms or products thereof shall inform the Secretariat and the Biosafety Clearing-House of their decision.

5. No Party shall export or import living modified organisms or products thereof to or from non-Parties.

6. Parties shall cooperate among themselves in order to achieve an environmentally sound system of management of the potential risks of living modified organisms and products thereof.

7. Each Party shall take the appropriate measures to:

(a) Ensure safety in biotechnology, especially in the transboundary transfer and release of living modified organisms resulting from modern biotechnology;

(b) Ensure that persons involved in the development, handling, transfer, use or release of living modified organisms and products thereof take such steps as are necessary to avoid unacceptable risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies;

(c) Require that information about a proposed transboundary transfer of any living modified organisms or products thereof be provided to the States concerned according to the appropriate procedures of notification set out in Article 7 of this Protocol;

(d) Prohibit the export of any living modified organisms or products thereof to a State or group of States belonging to a regional economic integration organization that includes Parties which have prohibited imports by their legislation, or if it has reason to believe that the organisms or products in question will not be managed in an environmentally sound manner, according to criteria to be decided on by the Parties at their first meeting;

(e) Cooperate with other Parties and may involve interested organizations as appropriate, directly and through the Secretariat and the Biosafety Clearing-House, with respect to the necessary measures for safety in biotechnology, including the dissemination of information on living modified organisms or products thereof, in order to ensure the environmentally sound management of such organisms and products and to achieve the prevention of illegal traffic and unintended releases;

8. Furthermore, each Party shall:

(a) Prohibit all persons under its national jurisdiction from developing, transferring, using or releasing living modified organisms or products thereof unless such persons are authorized to perform such types of activities or deal with such types of products;

(b) Require that living modified organisms or products thereof that are to be the subject of transfer or a transboundary transfer be packaged, labelled, and transported in conformity with the rules and requirements to be set out by the Secretariat and the competent authorities of the States concerned;

(c) Require that living modified organisms and products thereof be accompanied by a transfer document from the point at which a transfer and transboundary transfer commences to the point of use or release.

9. The Parties agree that failure to provide all the necessary information available about the living modified organisms or products thereof and any illegal traffic are criminal.

10. Each Party shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Protocol, including measures to prevent and punish conduct in contravention of the Protocol.

11. The obligation under this Protocol of States in which the living modified organisms or products thereof have been developed and in which they have originated is to require that those organisms or products are managed in an environmentally sound manner and may not under any circumstances be transferred to the States of import.

12. Nothing in this Protocol shall prevent a Party or group of Parties from imposing additional requirements that are consistent with the objective and provisions of this Protocol and are in accordance with the rules of

international law, in order to better protect human and animal health, biological diversity, the environment and the socio-economic welfare of societies.

Option 2

1. Parties shall take all necessary measures to comply with the provisions set out in this Protocol for the safe transboundary movement of living modified organisms resulting from modern biotechnology.

2. Parties shall introduce, as necessary, implement and enforce national provisions in order to ensure compliance with the advance informed agreement procedures set out in Articles 6-11 of this Protocol.

3. Parties shall ensure that advance informed agreement measures for the import of a living modified organism:

(a) Are implemented in a transparent manner, based on scientific principles and supported by the best available scientific evidence;

(b) Are not more restrictive than measures applied to the same living modified organism produced domestically or imported from other Parties; and

(c) Are applied in a manner which does not constitute a disguised restriction on international trade.

4, Parties may impose additional requirements for the safe transboundary movement of living modified organisms resulting from modern biotechnology, provided that they are consistent with the provisions of this Protocol and accord with other relevant international agreements.

Option 3

1. Each Party shall, in accordance with its particular conditions and capabilities:

(a) Develop an institutional framework for the execution of the provisions set out in this Protocol;

(b) Develop national strategies, plans or programmes for the provisions set out in this Protocol or adapt, for this purpose, existing strategies, plans or programmes;

(c) Integrate, as far as possible and as appropriate, the provisions set out in this Protocol into relevant national strategies, plans or programmes.

2. Importing Parties may impose additional requirements, for the safe transboundary movement of living modified organisms, and products thereof, provided that they are:

(a) Based on scientific principles and supported by the best available scientific evidence;

(b) Detailed in national laws and regulations of the importing Party; and

(c) Consistent with the provisions of this Protocol and in accord with other relevant international agreements.

Option 4

1. Each Party shall apply the AIA procedure provided under Article (AIA) with regard to the transboundary movement of any LMO.

2. Each Party shall ensure that any LMO leaving its territory shall be furnished with due authorization of the designated national authority of the receiving Party.

3. Parties which receive information and notifications of transboundary movements under the present Protocol shall ensure the confidentiality of the information of that nature which they have received.

Option 5

1. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

2. Each Party shall ensure that the measures taken by it to implement this Protocol do not create unnecessary obstacles to and do not constitute a means of arbitrary or unjustifiable discrimination or disguised restrictions on international trade.

3. The Parties shall, in accordance with this Protocol, exchange information relating to transboundary movement of LMOs.

4. Without prejudice to compliance with relevant international requirements for transport operations, the Parties shall, where appropriate, ensure that LMOs within the scope of this Protocol and subject to intentional transboundary movement are accompanied by relevant information on LMOs, as specified in Annex II, and that the exporter shall be able to prove that the movement is in conformity with the requirements of the Protocol.

5. Transport of LMOs shall be carried out under safe conditions in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Option 6

1. Parties exercising their right to prohibit the import of LMOs resulting from modern biotechnology shall inform other Parties thereof.

2. Parties shall prohibit or shall not permit the export of LMOs resulting from modern biotechnology to Parties which have prohibited the import of such LMOs.

3. Parties shall ensure adequate provisions for emergency plans in case of accidental or unintended transboundary movements.

4. Parties shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Protocol, including measures to prevent and punish conduct in contravention of the Protocol.

Option 7

1. The Parties to the Protocol undertake to implement the provisions of the Protocol and its Annexes, which constitute an integral part thereof.

2. Parties shall ensure that the development, handling, transport, use, transfer and release of any LMOs are undertaken in a manner that prevents, or reduces to acceptable levels, risks to biological diversity, the environment and human and animal health.

3. Subject to the provisions in Article 7, paragraph 1, Parties shall not approve or allow the export of LMOs until such time as an advance informed agreement (AIA), with explicit consent, has been obtained in writing, from the State of import for that specific import.

4. Parties shall not approve or allow the export of any LMOs to those Parties which have prohibited the import of such organisms. Parties exercising their right to prohibit the import of LMOs shall inform the Secretariat and the Clearing-house of their decision. [For the purpose of this Protocol, the Secretariat and Clearing-house of the Convention on Biological Diversity will also fulfil those functions for the Protocol.]

5. Parties shall cooperate among themselves in order to develop an environmentally sound risk management system for LMOs.

6. Each Party shall take appropriate legal, administrative and other measures to:

(a) Ensure safety in biotechnology, especially in the handling, use, release and transboundary transfer of LMOs resulting from modern biotechnology;

(b) Ensure that persons involved in the development, handling, transfer, use or release of LMOs take the necessary steps to avoid unacceptable risks to biological diversity, the environment and human and animal health;

(c) Require that information on intended transboundary transfers of any LMO be provided to the States concerned according to the procedures of notification set out in Article 6 of this Protocol;

(d) Prohibit the export of any LMOs to a State, or group of States belonging to a regional economic integration organization that includes Parties, which have prohibited the import of such LMOs through legislation;

(e) Cooperate with other Parties and involve appropriate organizations, directly or through the Secretariat and the Clearing-house, in taking measures aimed at ensuring safety in biotechnology, including the dissemination of information on living modified organisms;

(f) Ensure that appropriate national authorisation is required for all activities, including experimental, involving development, handling,, use, transfer and release of LMOs;

(g) Require that living modified organisms which are to be transferred, either internally or across boundaries, be packaged, labelled, and transported in conformity with the rules and requirements laid down by the Parties and the competent authorities of the States concerned;

(h) Require that living, modified organisms be accompanied by a transfer document front the point at which a transfer and transboundary transfer commences to the point of use or release.

7. Nothing in this Protocol shall prevent a Party or group of Parties from imposing additional requirements that are consistent, with the objectives and provisions of this Protocol, other agreements legally binding on those Parties and in accordance with the principles of international law.

Option 8

1. Each Contracting Party shall take appropriate legislative and/or administrative measures in order to achieve the objectives of this Protocol.

2. The Contracting Parties shall, in accordance with this Protocol, exchange information on living modified organisms in order to contribute to the environmentally sound management of biotechnology.

3. The Contracting Parties shall ensure that measures taken for the oversight of transboundary movement of living modified organisms do not create unnecessary obstacles to, and/or constitute a means of arbitrary or unjustifiable discrimination or disguised restrictions on international trade.

ARTICLE 2 - USE OF TERMS

Accidental release

Accidental release is any incident involving an [significant and] unintended release of a LMO in the course of its [contained use] [contained handling, transfer of use] [natural setting] which [could] [may or may not] [adversely affect] [present an immediate or delayed hazard to] the conservation and sustainable use of biological diversity, taking also into account [risk to] [adverse effects on] human health.

Competent authority

Competent authority means any national [or intergovernmental] [authority] [agency] [possessing sufficient relevant scientific capacity] designated by a Party to be responsible for

Option 1

the implementation of the Protocol.

Option 2

the handling [,issuing and receiving] of [notifications] [AIA] of transboundary movement [or release] of LMOs and any information related to it] [and executing the functions of issuing and withdrawing of approval for handling and use of LMOs].

Option 3

regulating [biotechnology and] [biosafety], [intellectual property rights] [and other relevant aspects].

Contained use

Contained use means any [limited, experimental, non-commercial] activity in which LMOs are cultured, stored, transported, destroyed, disposed of or used in any other way whereby the contact with [or their impacts on] the environment [including humans] is [prevented] [limited] by [specific containment measures] [physical barriers or a combination of physical, chemical and/or biological barriers] [operational requirements].

Deliberate release

Deliberate release means

Option 1

any intentional introduction into the environment of LMOs [which is not contained use] [without specific containment measures] [without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to [limit] [prevent] their contact with the general population and the environment]. [This may take the form of a field trial or a general release].

Option 2

any production and use [or activity or incident] of LMOs that is not [a] [approved as] contained use.

Export and import

Export and import mean, in their respective connotations, the movement from one Party [or State] to another Party [or State], but exclude mere transit operations.

Exporter

Exporter means any legal or natural person under the jurisdiction of the exporting Party [or State] who arranges for LMOs to be exported.

Field trial

Field trial means the [deliberate] introduction [release] of an LMO into the environment [for the purpose of testing] with provisions for limiting the potential for [and monitoring for the] uncontrolled dissemination or persistence of the LMO [or its genetic material] in the environment, [under conditions where the degree of dissemination of the LMOs is limited by physical and/or chemical and/or biological barriers which prevent the survival of such organisms in the environment].

Focal point

Focal point means any [national] body [institutional component] designated by a Party [competent authority] [to be responsible for providing and collecting information on the implementation of the protocol at the national level and communication between the Parties about the implementation of the Protocol] to receive and supply [relevant] information [and assist communication] related to transboundary movements of LMOs, [and other information concerning biosafety].

Illegal traffic

Illegal traffic means any transboundary movement or transfer without notification to, or advance informed agreement of, all Parties concerned; pursuant to the provisions of this Protocol; or with advance informed agreement obtained from Parties concerned through falsification, misrepresentation or fraud; or with advance informed agreement which does not conform in a material way with the documents submitted or which results in the deliberate release of living modified organisms in contravention of this Protocol and of general principles of international law.

Importer

Importer means any legal or natural person under the jurisdiction of the Party [or State] of import [receiving Party] who arranges for LMOs to be imported.

Liability

Liability shall mean the quality or state of being legally obligated or responsible.

Living modified organism (LMO)

LMO means

Option 1

any organism or part thereof which is capable of regenerating itself on its own or in the body or cell of another organism and whose genetic material has been modified by modern biotechnology in a way which does not occur naturally by mating or recombination, [or any living organism or part thereof which had been a fossil but has been resuscitated through modern biotechnology].

Option 2

any organism that has been deliberately modified to exhibit one or more traits, that do not exist in/are novel to the species in the receiving country, not excluding when the LMO is a modified form of an organism that is a new species (exotic) to the receiving country.

Option 3

any organism in which the genetic material [including both DNA and RNA] has been altered in a way that does not occur naturally by mating and/or natural recombination.

Option 4

any organism produced through genetic modification and whose genetic make-up is unlikely to occur in nature, including any genetic material intended for use to produce LMOS, and products derived therefrom. These include subcellular particles such as plasmids, DNA fragments and vectors.

Option 5

any organism whose genome [has been altered by the insertion of] [contains] foreign DNA (or RNA). The DNA (or RNA) insert is gene construction created through chemical manipulations with certain DNA fragments isolated from different sources (organisms, taxa) or synthesized artificially. [In the context of the Protocol the term "LMO" also covers products thereof (food, feed and pharmaceutical ones)].

Notification

Notification means

Option 1

the presentation of documents containing the requisite information to the competent authority(ies)/focal point.

Option 2

the express written notification by the country/person to the [Party of import or] affected country prior to any proposed/intended transboundary movement/release/activity into/within the [Party of import or] affected country which may affect/have an impact on the potentially [Party of import or] affected country. [It may also entail notification to third parties, as appropriate.] [Notification will be necessary whether or not the intended/proposed transfer represents a threat to the [Party of import or] affected country.]

Novel traits

Novel traits are characteristics in an organism that have been created or introduced through a specific genetic change [using modern biotechnology or techniques specified in the definition of LMOs] [or by mating with initial LMOs] and that make the LMO different from the unmodified organism.

Organism

An organism is [the active, infective, or dormant stage or life form of] any biological [acellular, unicellular or multi-cellular] entity capable of [replication] [reproducing itself] or of transferring genetic material. [This definition covers plants, animals, fungi, mycoplasmas, [mycoplasma-like organisms,] micro-organisms, viruses and viroids, including cell and tissue cultures, germinal cells, seeds, pollen and spores)] [other than human or human embryo].

Party of export

Party of export means a Party from which a transboundary movement is planned to be initiated or is initiated.

Party of import

Party of import means a Party to which a transboundary movement is planned to take place or is made.

Party of transit

Party of transit means any Party, other than Party of export or import, through which a movement is planned or takes place.

Party concerned

Party concerned means any Party of export, import, transit and affected Parties or non-Parties.

Party of origin

Party of origin means the Party or Parties to this Protocol from whose jurisdiction a transboundary [release or transfer] [movement] of LMO has taken place or is envisaged to take place.

Potential receiving environment

Potential receiving environment is an ecosystem or habitat, including humans and animals, which is likely to come in contact with released organism.

Product

Product means anything made by or from, or derived from LMOs or a combination of LMOs, living or dead [, which is placed on the market].

Receiving Party

Receiving Party means the Party or Parties to this Protocol to whose jurisdiction a transboundary [release or transfer] [movement] of an LMO has taken place or is envisaged to take place.

Transboundary movement

Option 1

Transboundary movement means any movement from an area under the national jurisdiction of one Party to or through an area under the national jurisdiction of another Party or to or through an area not under the natural jurisdiction of any Party (meaning any land, marine area or airspace within which a Party exercises administrative and regulatory responsibility in accordance with international law in regard to the protection of human health or the environment), provided at least two Parties are involved in the movement.

Option 2

Transboundary movement means any intended [and/or unintended] movement of LMOs [or genetic material] across [one or more national borders] [across the area under national jurisdiction].

Option 3

Transboundary movement is any intentional and/or unintended physical movement/transport of any LMO or products derived therefrom, across national boundaries, including, without limitation to, organisms that are produced, through genetic modification, and products derived therefrom, within the national boundaries of a Party, by persons (legal or natural). Transboundary movement also entails the behaviour of the LMOs, in particular in the receiving country, i.e. in research and development, in handling, transfer, use and disposal of the LMOs.

Transboundary release

Transboundary release means any unintended release of LMOs from the jurisdiction of one Party [or State] to the other or to areas beyond the limits of a national jurisdiction or control.

Unconfined release

Unconfined release means the use of a LMO that is not subject to [provisions to limit the uncontrolled spread or persistence of that LMO] and physical [or biological] isolation from the natural or agricultural environment, site inspections, post-harvest land use restrictions and/or restricted use of seed and progeny.

Unintended release

Unintended release means any release of living modified organisms or products thereof which is not a deliberate release.

Unintended transboundary movement

Unintended transboundary movement is the [natural or] accidental movement of LMOs [or genetic material] across national borders.

ARTICLE 3 - APPLICATION OF THE AIA PROCEDURE

Element paper

A. All LMOs subject to AIA

Option 1

This Protocol applies to the transboundary movement of living modified organisms resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, including human health.

Option 2

A Party shall permit the export of living modified organisms or products thereof only when it confirms that the agreement of the State of import has been obtained in advance based on the necessary information that the State of import has received in accordance with the provisions of Article (4) and Annex (I).

Option 3

Each Party shall apply the AIA procedure provided under Article (AIA) with regard to the transboundary movement of any LMO.

Option 4

Each Party shall apply the Advance Informed Agreement procedure with respect to all living modified organisms defined in this Protocol. No intending country Party shall transfer, handle or use LMOs to or within a receiving country Party without first obtaining the receiving Party's consent. Any Party exercising jurisdiction over an individual person or entity shall ensure that no such person or entity shall transfer, handle or use LMOs to or within the receiving country Party without first obtaining the receiving Party's consent, through the receiving Party's national competent authority.

Option 5

To effect a transboundary movement, the exporter must submit an application, in the official format used by the importing country, to the competent authority of the importing country and before shipping the product, with all the information required by that competent authority and in accordance with the national law in force in the importing country.

Option 6

No transboundary movement of LMOs or products derived therefrom shall be allowed without the Advance Informed Agreement of the importing country.

Option 7

Each Party shall apply the Advance Informed Agreement to LMOs and products thereof that come under its jurisdiction as defined in this Protocol.

Option 8

There is established an Advance Informed Agreement procedure on living modified organisms subject to international trade which may have adverse effects on human health and the environment. At their first meeting, the Parties will establish the scope, the documents and the mechanisms for the information and previous consent procedure and the criteria to select the living modified organisms that would be included in the Advance Informed Agreement procedure.

Option 9

"Advance informed agreement" means an agreement by the competent authority of the State of import to the transfer of any living modified organisms or products thereof based on the information supplied by the competent authority of the State of export with the understanding that the information is accurate and complete. The scope of AIA procedure will cover all the LMOs and their products and all the first and subsequent transfers of all LMOs and their products subject to the Articles of the Protocol.

Option 10

Advanced Informed Agreement is a means of providing official information on LMOs and products thereof, which are to be introduced into a particular country.

B. All first-time transboundary movements of LMOs

Option 1

All initial transfers of LMOs to another country shall be subject to the AIA procedure. No transboundary transfer of LMOs shall be allowed without the AIA. The State of export shall not allow the export and the State of import shall not allow the import of LMOs until the exporter has received the AIA. Explicit consent should be a requirement for initial shipment of all LMOs. Implicit consent shall apply to subsequent shipments of LMOs. In that case, transboundary transfer of the LMOs shall be carried out according to the common procedure adopted in the State of import for transboundary transfer of organisms that are not LMOs.

Option 2

Explicit Advanced Informed Agreement shall be required for the first import of living modified organisms, and/or products thereof, resulting from modern biotechnology, which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account human health.

Option 3

All initial transboundary movements of LMOs shall be subject to AIA. This article does not apply to LMOs:

(a) Imported into contained/confined facilities (imported for contained/confined use); or

(b) Subject to bilateral, multilateral or regional agreements or arrangements as provided in Article (12).

Option 4

Subject to Article (9, paragraph 1), all initial transfers of LMOs to another country that is party to this Protocol will be subject to the AIA procedure.

Option 5

All first intentional transboundary movements of a specific LMO for specific purposes or uses into a new country, shall be subject to the procedure for Advance Informed Agreement (hereafter referred to as AIA). The State of import may, however, declare that low-risk micro-organisms and other low-risk research organisms intended for contained use shall not be covered by the AIA procedure.

C. All LMOs except those explicitly excluded and exempted

Option 1

1. Without prejudice to paragraphs 2 and 3, (this Protocol) (these procedures) shall apply to transboundary movement of living modified organisms resulting from modern biotechnology (LMOs).

2. (This Protocol) (these procedures) shall not apply to:

(a) The transboundary movement of LMOs not likely to have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as specified in Annex (I);

(b) Requirements for transport operations.

3. (ThisProtocol) (these procedures) shall neither apply to the transboundary movement of LMOs destined for subsequent contained use, nor to the transit of LMOs, except as regards Articles (4) (on general provisions) and (11) (on unintentional transboundary movement).

Option 2

1. LMOs subject to the AIA procedures:

(a) All transboundary transfers of LMOs resulting from modern biotechnology, except those mentioned in paragraphs 2 and 3 below, shall be within the scope of the application of the AIA procedures;

(b) Organic materials that are components of LMOs but are not self-reproducible in the environment, such as DNA or RNA segments, plasmids and peptides, shall, by definition, not be regarded as LMOs and be thus excluded from the application of the AIA procedures;

(c) LMO products that do not contain live cells shall also be excluded from the application of the AIA procedures.

2. Exclusion from the application of the AIA procedures:

(a) LMOs that are subject to any other international agreement related to transboundary transfer of LMOs shall be excluded from the application of the AIA procedures;

(b) The LMOs requested to be imported by the competent authority of the recipient Contracting Party for the purpose of carrying out risk assessment as a process of the AIA procedures stipulated in this Protocol shall be excluded from the application of the AIA procedures.

(c) Those LMOs shall be excluded from the application of the AIA procedures if they are to be used, such as for experimental purposes, exclusively under confined conditions defined in this Protocol and if it is established by the Conference of the Parties to the Protocol that there does not exist any risk to the environment and human health by the use of those LMOs under the conditions so defined.

3. Exemption from the application of the AIA procedures. If it is established that there does not exist any risk by the use and release of certain LMOs on the basis of the best available scientific knowledge and experience, as well as relevant information, a recipient Contracting party by means of unilateral declaration or bilateral, regional or multilateral agreement or arrangement, may exempt such LMOs from the application of the AIA procedures, by which no explicit agreement by the competent authority of the recipient Contracting party is required.

D. Importing State decides whether exporter should apply national regulations or Protocol.

Option 1

All first intentional transboundary movements of a specific LMO for specific purposes or uses into a new country, shall be subject to the procedure for Advance Informed Agreement (hereafter referred to as AIA). The State of import may, however, declare that low-risk micro-organisms and other low-risk research organisms intended for contained use shall not be covered by the AIA procedure.

E. LMOs included based on criteria listed in an annex

Option 1

The LMOs to be included will be based on criteria listed in an annex.

F. LMOs intended for field testing, or first field growth or banned/no regulatory decision

Option 1

1. Scope. An LMO is subject to the AIA where:

(a) The LMO is intended for field testing in the importing country; or

(b) The LMO has not been imported into the importing Party and the LMO is not being produced in the importing Party and the LMO is one:

(i) That is intended for first field growth in the importing Party, including in particular first field growth in a center of origin or genetic diversity for that product;

(ii) That has been banned or refused approval in the exporting Party because of potential adverse effect on the conservation and sustainable use of biodiversity that were identified during the review process;

(iii) For which approval is in the process of being sought in the exporting Party;

(iv) For which approval in the exporting Party would have been required had the LMO been intended for domestic commercialization, field testing, or field growth in the exporting Party;

(v) For which approval in the exporting Party would have been required had the LMO been intended for domestic commercialization or growth in the exporting Party but for which an application or request for approval was withdrawn; or

(c) The LMO has been imported into the importing Party, but subsequent to such import, the exporting Party has banned or refused approval of the LMO because of potential adverse effects on the conservation and sustainable use of biodiversity, and the importing Party has not approved the LMO for import or growth since such exporting Party ban or refusal of approval.

ARTICLES 4, 5, 6 AND 7: ADVANCE INFORMED AGREEMENT PROCEDURE

(Notification procedure for AIA; Response to AIA notification; Decision procedure for AIA; Review of decision under AIA)

A. Notification/application (Article 4)

The State of export (Party of origin)

Option 1

The State of export shall notify, or shall require the exporter to notify by application in writing, through the channel of the competent authority of the State of export, the competent authority of the states concerned of any proposed transboundary transfer of living modified organisms or products thereof. Such application shall contain the declarations and information specified in Annex I, written in a language acceptable to the State of import. One application or notification shall be sent to each of the States concerned and to the Biosafety Clearing House.

Option 1b

The State of export shall require the exporter to supply either through the channel of, or by providing a copy to the competent authority of the State of export the information included in Annex I to the State of import, prior to the first intentional transboundary movement of LMOs.

The exporter as required by the State of export or the State of import (receiving Party)

Option 2

For the intentional transboundary movement of LMOs, the exporter shall notify in advance the party of import in writing of that movement and shall only proceed with such movement in compliance with Articles 5 and 6 (these articles address Acknowledgment of Receipt, Procedures and AIA). Information to be provided in the notification is specified in Annex I.

The State of export or the exporter as required by the State of export or import

Option 3

The AIA procedure shall be triggered by the exporter. The application shall be submitted to the competent authority/focal point in the State of Import. The Exporter has to supply all the information about the LMO necessary for implementation of adequate risk assessment.

The importer

Option 4

Each Party of import shall require notification to be given, by the importer, to the Party of import of the first proposed transboundary movement of a living modified organism (LMO) subject to AIA before it is imported.

The state of export or the exporter

Option 5

Each exporting Party shall notify, or require a natural or legal person under its jurisdiction to notify, in writing, the importing Party through the importing Party's national focal point prior tot he first export to the importing party of an LMO that is subject to the AIA (those LMOs which may present risks to the conservation and sustainable use of biodiversity). The notification need be sent to only one focal point in the importing Party concerned. The notification shall include the information contained in the annex to this Protocol.

The exporter through its own competent authority

Option 6

The exporter must notify in writing the competent national authority of the importing country regarding his intention to export, through his own competent national authority.

In writing

Option 7

The exporting Party shall notify, or shall require that notification be given to, in writing, the Focal Point of the importing Party, intent to export a LMO (for the first time)(that is subject to AIA).

Option 7b

The exporting Party shall notify, or shall require that notification be given to, in writing, the Focal Point of the importing Party, intent to export a living modified organism for the first time into an importing Party. The information to be provided with the notification is set out in Annex I to this Protocol.

(Party of origin)

Option 8

The PIC procedure shall be triggered by notification of a request for transboundary movement of any LMO by the designated national authority of the Party of origin addressed to the designated national authority of the receiving Party and, where applicable, to the designated national authority of the Party of transit.

(Receiving Party)

Option 9

Any Party who intends to transfer, handle or use any LMO to or within any receiving country Party shall give prior notice to, through its national competent authority, the national competent authority of the receiving country Party, by application in writing of its intention to do so. Each Party shall ensure that any individual person or entity under its jurisdiction who intends to undertake any transfer, handling or use of LMOs to or within any receiving country Party shall give prior notice to the national competent authority of the receiving country Party by application in writing, of its intention to do so.

Option 10

Explicit Advanced Informed Agreement shall be required for the first import of living modified organisms, and/or products thereof, resulting from modern biotechnology, which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account human health.

B. Information requirements for the notifications/application

Annex I including or excluding risk assessment

Option 1

(The exporting Party) (Importer/exporter) (intending Party) shall submit (declaration and) the information identified in Annex I, in writing, to (the importing Party) (receiving Party).

List of information required as adopted and reviewed by COP

Option 2

The information to be provided to the competent authorities of the recipient Contracting Party for the implementation of the AIA procedures shall be specified and enumerated in a list by the Conference of the Parties to the Protocol. The list shall be reviewed, by the Conference of the Parties to the Protocol, periodically in the light of the most recent and best available scientific knowledge and experience, as well as other relevant information. The Conference of the Parties to the Protocol may establish a technical advisory body with the task of providing the Contracting Parties with scientific backgrounds for reviewing the list.

No specific requirements

Option 3

The AIA procedure shall be triggered by the exporter. The application shall be submitted to the competent authority/focal point in the State of

import. The exporter has to supply all the information about the LMO necessary for implementation of adequate risk assessment.

Under national requirements of the importing Party

Option 4

The competent authority/focal point in the State of import shall provide information to the exporter concerning its laws, regulations, guidelines, legal and administrative procedures and other requirements related to the biosafety.

C. Responsibility for the accuracy of the information

Any new information

Option 1

The national competent authority of the intending country Party shall attest to the accuracy of the information stated above.

Responsibility for the accuracy of the information

Option 2

The State of export shall, through its competent authority, examine the conformity to the notification under paragraphs 1 and 2 above with the requirements of this Protocol and the State of import, and shall stand surety for the accuracy and completeness of the information supplied by the exporter, on the basis of which the advance informed agreement is made.

Option 2b

Parties shall introduce, as necessary, implement and enforce national provisions in order to ensure the compliance with the AIA procedures, including the provision of accurate information.

Option 2c

Each Party shall make its (exporter) responsible for the accuracy of the information provided in a notification and for any new information provided.

Option 3

No provision on responsibility for the accuracy of the information is necessary.

D. Acknowledgment of receipt (Article 5)

No acknowledgment

Option 1

No acknowledgment is required.

Acknowledgment

Option 2

The designated national authority of the receiving Party shall review the content of the request and, if found in order, shall within X days following notification, communicate such finding in writing to the designated national authority of the Party of origin.

In the event that the request is found not to be in order, the designated national authority of the receiving Party may request within the period specified above, the missing information , in which event the deadlines specified for these purposes shall be suspended until the requested information is provided.

Acknowledgment in writing within X (10/30) days or a reasonable period of time

Option 3

Each Party of import shall acknowledge (in writing) to the importer, (not later than X days) (in a reasonable time) on after receiving the notification under this Article, (that the notification contains *prima facie* the information described under Annex I) (the date of the receipt of the notification) (or with a request for further information). Such acknowledgment does not limit the possibility to require further scientific information under Article 13.

Option 3b

The receiving country shall acknowledge in writing to the intending country within X days after receipt of the application by the national competent authority of the receiving country.

E. Information to notifier

Option 1

The Party of import shall within the period referred to in Article 6 (Acknowledgment of receipt) (30 days of the date of receipt of the notification) inform the notifier to proceed according to:

(a) Either its regulatory framework implementing Article 8(g) of the CBD, provided the framework includes a control mechanism for transboundary movement consistent with the protocol; or

(b) The procedure provided for in Article 4 (AIA).

F. Time Frames

In due time

Option 1

The importing Party will communicate its decision to the exporting Party in due time.

Within a reasonable period of time

Option 2

The importing Party shall acknowledge the notification, in writing, within a reasonable period of time. This acknowledgment shall include:

(a) Advice that a risk assessment has been or is to be carried out; and

(b) A request, as necessary, for any further information which remains to be provided in accordance with this Article.

Within x (30/90/120/150/180) days

Option 3

The Party of import shall within the period referred to in Article 6 (30 days of the date of receipt of the notification) communicate to the exporter:

(a) That, unless it has not, with justification, asked for additional information, imposed conditions or refused permission for the notified movement within 150 days after the date of receipt of the notification, the movement may proceed; or

(b) That the movement may proceed only after the Party of import has given its written consent, with or without conditions. The Party of import shall decide within 150 days after the date of receipt of the notification.

Option 3b

The competent authority in the State of import (shall be obliged to respond to the State of export) (shall take appropriate legislative and/or administrative measures to ensure response to the exporter and the Secretariat) within X days after the date of acknowledging the receipt of notification.

Option 3c

An importing Party shall respond to notification of an intention to export to the importing Party an LMO that is subject to the AIA as soon as possible, but not later than 180 days after transmission of such notification.

Extension of time frame

Option 4

The period of response should be extended by the period of time awaiting requested information; the period of time for conducting field trials; or by a request for additional time no longer than 60 days.

Option 4b

The Party of import may inform the notifier with justification that this period (150 days) is extended by a defined period no longer than 60 days. When calculating the period referred to in paragraph 1, the number of days for which the Party of import is waiting for additional information which it has requested from the notifier shall not be taken into account.

Option 4c

The number of days for which the importing Party is waiting for additional information which it has requested from the notifier, shall not be taken into account.

As long as necessary

Option 5

Notwithstanding paragraph 1 above, the receiving country Party shall be allowed as much time as is necessary to assess the information it has received from the intending country Party so as to enable it to reach an informed decision on the application and make its own risk assessment decisions on the transfer, handling or use of the LMO.

Agreed

Option 6

Decisions regarding import should be made within a time frame agreed between the importing and exporting Parties.

G. Interim response

No provision for interim response

Option 1

Interim decision pending final decision

Option 2

The response of the designated national authority of the receiving Party to a request for transboundary movement can take the following form:

An interim response which:

(i) States the need to conduct a risk assessment;

(ii) Requests additional information;

(iii) Requests for extended period of time to respond.

H. Decision by the importing State (Article 6)

Yes, yes with conditions, or no

Option 1

The State of import shall respond to the notifier in writing:

(a) Consenting to the intended movement with or without conditions; or

(b) Denying permission for the movement.

Basis for the decision: whether the decision applies to other imports; and subsequent imports

Option 2

The importing Party shall provide full details to the exporting Party or exporter, in writing, and the Clearing-house on:

(a) The basis for the decisions (to deny imports) including full details of risk assessments; (or)

(b) Whether the decision applies, either in whole or in part, to other potential imports of the same living modified organism; (and) (or)

(c) Whether notification is required for subsequent imports of the same living modified organism, in accordance with (Article 10) (Notification for Subsequent Imports).

The importing Party shall make all import decisions. Decisions shall be based on scientific principles and supported by the best available scientific evidence. Decisions shall consist of:

(a) Approval to import, without conditions; or

(b) Approval to import, with specified conditions; or

(c) Prohibition of import.

Option 2b

All decisions by the Party of import shall be based on scientific risk assessment of the adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Option 2c

The State of import shall communicate in its response to the State of export whether an AIA procedure with explicit consent or implicit consent is required for subsequent imports of the same LMO or whether a simplified notification in accordance with Article XX shall be applied.

Option 2d

The (importing Parties) (receiving country) shall make all decisions on the basis of, inter alia, risk assessment, socio-economic imperatives, and social and ethical considerations.

Option 2e

A final decision shall be accompanied by information describing the legislative and/or administrative measures on which the decision is based. The same conditions, if any, shall apply to the imported and domestic produced living modified organisms.

Option 2f

The importing State shall make decisions based on scientific, social, economic and cultural criteria.

Option 2g

In cases where the State of import considers that the documentation provided by the State of export is not sufficient in order to determine the potential adverse effects of an LMO, the State of import has the right to prohibit import of the LMO in question.

Option 2h

Decisions under the Protocol shall be based on scientific grounds and experience.

Competent authority decision: yes, with conditions, or no

Option 1

On or before the expiration of the period in Article 6 and based on the result of the science-based risk assessment conducted under Article 13, the competent authority of the Party of import shall:

(a) Allow the import; or

(b) Decide to:

(i) Allow the import, subject to conditions;

(ii) Prohibit the import; or

(iii) Request from the importer further scientific information which the competent authority reasonably requires before allowing or prohibiting the import.

Explicit consent, or request for further information

Option 1

Upon receipt of the application by the national competent authority of the receiving country Party, the receiving country Party can indicate to the National Competent Authority of the intending country Party can indicate either:

(a) The request for additional information if the receiving Party feels that the information provided by the intending Party is incomplete; or

(b) Upon satisfactory completion of the assessment of the information supplied to it by the intending Party, the consent to the transfer, handling or use of the LMO with or without conditions;

(c) Reject the application absolutely or provisionally.

I. Consequences of failure to respond (in a given time frame)

Implicit/explicit

Option 1

If the importing Contracting Party fails to transmit a final decision or an interim response within the period of (120 days) of receiving the application, the living modified organism concerned shall not be exported without the explicit consent of the importing Contracting Party.

Option 1b

Should competent authorities of the recipient Contracting Party fail to reply to the exporter within the period mentioned in (X) above, the competent authorities are deemed to have given to the exporter an implicit agreement to the import of the LMOs concerned.

Option 1c

The Parties shall cooperate with a view to deciding, as soon as possible, to what extent in relation to the procedures, and in which cases, to be specified in Annex (es), the intentional transboundary movement cannot proceed without an explicit consent.

Implicit refusal

Option 2

If the receiving Party does not provide any response in 60 days, it shall be deemed to be a rejection of the application.

No response

Option 3

If the importing Party fails to submit a final decision within 180 days, the transboundary movement is no longer governed by the terms of this Protocol and the exporting Party shall have no further obligations under this Protocol with respect to such transboundary movement.

J. Responsibility of Contracting Parties

Option 1

1. The State of export shall, through its competent authority, examine the conformity to the notifications under paragraphs 1 and 2 above with the requirements of this Protocol and the State of import, and shall stand surety for the accuracy and completeness of the information supplied by the exporter, on the basis of which the advance informed agreement is made.

2. No transboundary transfer of living modified organisms or products thereof shall be allowed without the advance informed agreement of the State of import. The State of export shall not allow the exporter to commence the transboundary transfer until it has received written confirmation that the applicant has received the advance informed agreement of the State of import.

3. Any transboundary transfer shall be covered by insurance, bond or other guarantee as may be required by the States Concerned and/or recommended by the Biosafety Clearing-house.

4. The Parties shall, whenever it comes to their knowledge, ensure in the case of any unintended or deliberate release or any accident occurring during or subsequent to the transboundary transfer of living modified organisms, which are likely to present risks to human and animal health, biological diversity, the environment or the socio-economic welfare of societies in other States, that those States are immediately informed.

K. Review of decisions under AIA (Article 7)

New information available

Option 1

If, at any time before, during or after the transboundary transfer, the Competent Authorities or the exporter become aware of relevant new information on the LMO, which may have significant consequences for the associated risks, the competent authorities of the States concerned and the Secretariat and Clearing-house will be informed within 30 days of such information becoming available.

Option 1b

If, subsequent to the intentional transboundary movement, the exporting Party has gained new experience or has become aware of relevant new information that causes the exporting Party to ban or refuse approval of the

LMO because of the potential adverse effects on the conservation and sustainable use of biodiversity, and the importing Party has not approved the LMO for import or growth since such exporting Party ban or refusal of approval, the LMO will again be subject to the AIA, and the exporter will provide notice prior to export. New scientific information concerning the LMOs potential adverse impact on the conservation and sustainable use of biodiversity shall be submitted to the Clearing-house within a reasonable time.

Exporter/exporting State may request importing Party to review its decision

Option 2

Exporters/Exporting Party may request importing Parties to review import decisions in cases where exporting Parties consider that:

(a) A change in circumstances has occurred which may influence the outcome of the risk assessment; or

(b) Additional relevant scientific or technical information has become available.

Competent authority of the importing State shall be informed by the exporting State/exporter on new information within X days

Option 3

If at any time before, during or after the transboundary movement, the Party of export/import becomes aware of relevant new information on the LMOs in question, which could have significant consequences on the accompanying risks, the competent authorities of the Parties concerned shall be informed immediately and the terms of the Advance Informed Agreement be changed accordingly.

Exporter/exporting State shall be informed by the importer/importing State on new information within X days

Option 4

If at any time before, during or after the intentional transboundary movement the State of export or import has gained new experience or becomes aware of relevant new information related to the LMO in question, which could have consequences for the risks, the States concerned shall be informed within 30 days and the AIA decision may be changed accordingly.

Response to request to review decision

Option 5

Exporting Parties may request importing Parties to review import decisions, in cases where exporting Parties consider that:

(a) A change in circumstances has occurred which may influence the outcome of the risk assessment; or

(b) There is reasonable evidence that the decision has not been based on scientific principles and supported by the best available scientific evidence; or

(c) Additional relevant scientific or technical information has become available.

Exporting Parties may provide any additional information which they consider relevant to a review of the import decision.

Importing Parties shall respond to such requests, in writing, within a reasonable period of time, and provide full details on the basis for their decision.

Option 5b

The Party of origin shall only be able through its designated national authority, to request the receiving Party to conduct a risk assessment with a view to reviewing its decision. In this case, the receiving Party shall be able to call for payment of all of the costs of the assessment.

Lack of response implies implicit refusal

Option 6

Importers lack of response to a request to review a decision from exporter, will substantiate an implicit refusal.

New information may cause review by importing Party

Option 7

A receiving country Party may at any time in light of new information or evidence, unilaterally review its decisions on any transfer, handling or use of LMOs into its country and employ any review mechanism established through its national legislation or any other national procedures.

Exporting State may apply to importing State to review decision

Option 8

In light of new scientific evidence and information made available to the receiving country Party, a new application may be submitted in respect of a previously rejected application.

New information available

Option 9

Each Party of import shall require importers to immediately, and in no case later than 30 days, after learning of such information, notify the Party of import of:

(a) Any new available information regarding potential adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, including within the Party of import, and

(b) New information on change in use, containment or conditions of release.

New information

Option 10

Each Party of export shall require the exporters to immediately notify and no later than 15 days in any case, of any new information about the adverse impacts of the LMO and/or products thereof on the environment, biological diversity, human and animal health and agriculture, or of any new use of the LMO or product thereof. The Party of export will be responsible for the accuracy and adequacy of the information.

L. Safeguard clause

Option 1

If at any time a Party has reason to believe, taking into account available scientific information, that LMOs for which an intentional transboundary movement may proceed on the basis of the Articles 5 to 9 are likely to cause adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, that Party may then prohibit such and any such subsequent movements to its territory, or specify conditions under which all such subsequent movements have to take place. In such a case, that Party must promptly inform notifiers who have previously notified movements of such LMOs in accordance with this Protocol with the reason of its decision.

Option 2

No provision regarding a safeguard clause is necessary.

ARTICLE 8 - NOTIFICATION OF TRANSIT

Requirements

Option 1

Parties may require notification, in writing, through their Focal Points, of other Parties' intent to transit a living modified organism through their territory. Where such notification is required, Parties (shall) (should) provide information to the Clearing-house on:

(a) Details of the categories of living modified organisms for which notification is required; and

(b) Information to be provided with the notification, based on that set out in Annex I.

Option 2

1. Parties may require notification, in writing, of other Parties' intent to transit a living modified organism or product through their territory.

2. Parties that require notification of intent to transit living modified organisms, or products thereof, through their territory shall stipulate to the Clearing-house:

(a) Details of the categories of living modified organisms, and products thereof, for which notification is required; and

(b) Information to be provided with the notification.

Option 3

The Party effecting the export must obtain the necessary permits from Party and non-party countries through which the LMOs will be in transit, as well as assuming responsibility for any cases of accidental release in those countries.

Option 4

1. Any LMO or products derived from it may be located in transit between the country of export and country of import, provided that this status is accepted in writing.

2. All the requirements in labelling, packaging and transportation shall be met.

Option 5

Provided prior notification, consent and labelling is given, and subject to the national laws, regulations and procedures, each Party undertakes to facilitate the transit of LMOs through its territory. For the purposes of this Article, transit shall mean the temporary stop-over of an LMO which is on a continuous journey to another destination. For the avoidance of doubt, transit shall not mean the transfer to another Party of LMOs used for field testing, which is bound for another destination after the field testing.

Option 6

1. The State of export shall require the exporter to notify either through the channel of the competent authority in the State of export, or by providing a copy to this authority, the State of transit of the first intended transit movement of a specific LMO for a specified use or purpose. In these cases, the State of export shall supply the information included in (Annex III) to the State of transit. The State of transit shall promptly acknowledge the receipt of the notification to the notifier. It may subsequently respond to the notifier in writing, within 30 days:

(a) Consenting to the transit movement with or without conditions;

(b) Denying permission for the movement; or

(c) Provide an interim response, that may contain a statement to import with or without specified conditions or prohibiting import during the interim period. This may include a statement that a final decision is under consideration and/or a request for further information and/or extended period of time to respond.

2. The State of transit may declare in writing whether a notification is required for subsequent transit movements of the same LMO or whether this is not the case and it shall inform the Secretariat and previous notifiers of such decisions. The handling and transport requirements for LMOs referred to in (Article 18) shall be followed in all transit movements.

Acknowledgment/Response

Option 1

Upon receipt of this information, the Party whose territory is to be transited shall inform the exporting Party, within a reasonable period of time, of any provisions that may be required.

Option 2

On receipt of such notification, the Party (shall)(should) advise, within a reasonable period of time, the exporting Party or the exporter, and the Clearing-house, of any transport, handling, packaging and labeling provisions for transit of the living modified organisms or other requirements in addition to those contained in (Article 18).

Option 3

The Party of transit shall be able with due substantiation, to object to or to place conditions on the passage of the LMO through its territory.

Treatment of goods in Transit

Option 1

The documentation provided for the transport of LMOs must specify the care needed during their transit.

No specific provisions under this Article

Option 1

The Protocol shall neither apply to the transboundary movement of LMOs destined for subsequent contained use, nor to the transit of LMOs, except as regards (Articles 4) (on general provisions) and (11) (on unintentional transboundary movement).

ARTICLE 9 - SIMPLIFIED PROCEDURE

Option 1

No provisions for simplified procedure.

Option 2

The State of export may, subject to the written agreement of the States concerned, use or allow the exporter to use a general notification where living modified organisms or the products thereof having the same characteristics as transferred regularly to the same user via the same customs office of the exit of the State of export, via the same customs office of entry of the State of import.

Option 3

1. Without prejudice to (Article on Procedures), a Party of import can with justification specify, in advance, to other Parties cases:

(a) For which the intentional transboundary movement of LMOs to that Party may proceed according to its regulatory framework implementing Article 8(g) of the Convention on Biological Diversity, provided the framework includes a control mechanism for transboundary movement consistent with the protocol;

(b) For which the intentional transboundary movement can take place at the same time that movement is notified to the relevant instance in the Party of import. Such notifications may apply to subsequent similar movement to the same Party.

2. Information to be provided in the notification is specified in (Annex I).

Option 4

The State of export may, subject to the written agreement of the States concerned, use or allow the exporter to use a general notification where living modified organism or the products thereof having the same characteristics as transferred regularly to the same user.

Option 5

Notification of intent to export LMOs in terms of (para. 2), will contain the following information:

(a) Name and address of exporting company/institution;

(b) Name and address of receiving company/institution;

(c) Origin, name and taxonomic status of donor and recipient organisms;

(d) Information on previous exports of the same LMO to the recipient State.

(e) Date of intended transfer, which will not be less than 30 days from the date of notification.

Option 6

1. If it is established that there does not exist any risk by the use and release of certain LMOs on the basis of the best available scientific knowledge and experience, as well as relevant information, a recipient Contracting Party by means of unilateral declaration or bilateral, regional or multilateral agreement or arrangement, may exempt such LMOs from the application of the AIA procedures, by which no explicit agreement by the competent authority of the recipient Contracting party is required.

2. Moreover, in the case of repeated transboundary transfers of LMOs, a recipient Contracting Party may decide that the application of the AIA procedures be exempted or replaced by simple notification procedures provided for in paragraph 1 above.

3. If a recipient Contracting Party decides to exempt certain LMOs from the application of the AIA procedures or to apply simple notification procedures to certain LMOs, it shall inform the Secretariat of the Protocol accordingly. The Secretariat shall forthwith inform all Contracting Parties of such decisions.

Option 7

The State of import shall communicate in its response to the State of export whether an AIA procedure with explicit consent or implicit consent is required for subsequent imports of the same LMO or whether a simple notification in accordance with (Article 9) shall be applied.

Option 8

1. If it is established by the State of import, on the basis of the best available scientific knowledge and experience, as well as all relevant information, that there is no significant risk associated with the use and release of certain LMOs, a Contracting Party which is a State of import may substitute the AIA procedure regarding such LMOs with a notification procedure in which case no AIA will be required by the recipient State.

2. The competent authority of the State of export may, subject to the provisions (general provisions and notification), substitute or allow the exporter to substitute, an AIA with notification of intent to export LMOs to the recipient State of import.

Option 9:

If the competent authority of the State of export is not notified by the competent authority of the State of import of any objection or reservations to the intended transfer within 30 days of the date of notification of intent to transfer, subject to the provisions of (Article 3),

the State of import will be deemed to have given consent for the intended transfer.

Option 10

If, at any time before, during or after the transboundary transfer, the exporter becomes aware of relevant new information on the LMO, which may have significant consequences for the associated risks, the competent authorities of the States concerned and the Secretariat and Clearing-house will be informed within 30 days of such information becoming available.

ARTICLE 10 - SUBSEQUENT IMPORTS

Notification

Option 1

1. Notification of subsequent imports of the same living modified organism into the same importing party shall not be required unless specifically requested, in writing, by the importing Party, in cases where there may be:

(a) A change in the intended use of the living modified organism; or

(b) Variation in the receiving environment; or

(c) Other factors likely to affect the risk assessment or risk management.

2. Where notification for subsequent imports is specifically requested by the importing Party, full details regarding the information required (shall) (should) be provided, in writing, to exporting Parties or exporters and to the Clearing-house. The information required (shall) (should) be based on that identified in (Annex I) (Information required for notification of import of a living modified organism).

3. The importing Party (shall) (should) acknowledge the notification, in writing, within a reasonable period of time. This acknowledgment shall include:

(a) Advice that a risk assessment has been or is to be carried out, in accordance with Article 13 (Risk assessment); and

(b) A request for any further information which remains to be provided in accordance with this Article.

Option 2

1. Notification in writing is required for all subsequent imports of the same living modified organism into the same importing Party.

2. The importing Party will acknowledge receipt of notification as quickly as possible and will inform the exporting Party that:

(a) Importation can proceed; or

(b) A new risk assessment procedure will be undertaken.

Option 3

A single notification as well as a consent given in response to a notification may cover several similar, including subsequent, transboundary movements to the same Party of import.

Option 4

1. A State of import may at any time declare that subsequent imports of a specific LMO into its territory for specified uses or purposes, are exempted from the requirement of AIA in (Article 4). Such an exemption may specify a procedure for simple notification indicating that the intentional transboundary movement can take place at the same time that specific movement is notified to the State of import.

2. The Parties shall inform the Secretariat and previous notifiers of such declarations followed by a verification that a risk assessment has been carried out earlier, and of any requirements concerning movements, handling and use applicable to such LMOs. Such a declaration may be withdrawn at any time by the State of import and the Secretariat and notifiers who have been previously notified movements of such LMOs to it in accordance with this Protocol shall be informed no later than 30 days prior to the withdrawal.

3. The Secretariat shall inform all Parties of the information it has received pursuant to paragraph 1 and 2. The Secretariat shall be responsible for transmitting this information for inclusion in the database established under (Article 20).

Option 5

1. Thirty days prior to subsequent transboundary movements of a living modified organisms falling into the scope of this Protocol, the exporter shall notify the national focal point of the importing Contracting Party. If no response is received within this 30-day period, the exporter may proceed with the transboundary movement.

2. When the conditions described in (Annex X) are fulfilled, subsequent transboundary movements may proceed without notifying the national focal point of the importing Contracting Party. In this case, the exporter must ensure that appropriate relevant information is provided to the importer and/or the final user.

Option 6

Where the competent authority of the Party of import requires that subsequent imports of an LMO be notified, it shall establish for this purpose:

(a) Notification procedure;

(b) Information requirements to be contained in the notification; and

(c) Procedures for risk assessment and decision-making alternative to those established for first import.

Application

Option 1

1. The exporter must submit a new application for subsequent imports even though the competent authority may have given a positive clearance for the importation of a specific LMO.

Option 2

1. No application or any corresponding study shall be in any way influenced by the existence of a prior acceptance of the same LMOs or products derived from them in the importing country or any other country Party.
2. The importation of an LMO or any of its products is permitted for a specific use; if the use changes, a fresh application must be made to the ompetent national authority for a new clearance for the new use.

Regulation

Option 1

The regulations applied to imports shall be identical to those applied to LMOs produced in the country.

ARTICLE 11 - BILATERAL AND REGIONAL AGREEMENTS

A. No bilateral and regional agreement provision

Option 1

No provision for such article.

B. Type of agreements or arrangements

Bilateral, regional and/or multilateral

Option 1

Contracting Parties may enter into bilateral, multilateral, or regional agreements or arrangements regarding transboundary movement of living modified organisms falling within the scope of this Protocol provided that such arrangements do not derogate from the environmentally sound management of living modified organisms as required by this Protocol. These agreements or arrangements shall stipulate provisions which are not less environmentally sound than those provided for by this Protocol in particular taking into account the interests of developing countries.

Option 1b

These agreements or arrangements shall (stipulate provisions which are not less environmentally sound than those provided for by this) (comply to the minimum requirements of the) Protocol.

Multilateral

Option 2

Parties may enter into multilateral agreements or arrangements regarding procedures and information exchange relating to transboundary movement of LMOs provided that such agreements or arrangements do not result in a lower level of protection than the one provided for by the Protocol.

Bilateral or multilateral

Option 3

Parties to this Protocol may enter into bilateral or multilateral agreements or arrangements regarding requirements relating to the import and/or export of LMOs between or among them, in lieu of the advance informed agreement requirements.

To implement the obligations of the Parties under the Protocol

Option 4

The Parties may enter into bilateral or multilateral agreements or other arrangements in order to implement their obligations under this Protocol.

Transboundary movement of LMOs with Parties

Option 5

Parties may enter into bilateral, regional or multilateral agreements or arrangements regarding transboundary movements of living modified organisms with Parties or Non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of living modified organism resulting from modern biotechnology, in accordance with the objectives of this Protocol. The provisions of this Protocol shall not affect transboundary movements that take place pursuant to such agreements and arrangements as between the Parties to that agreement or arrangement.

Option 5b

If it is established that there does not exist any risk by the use and release of certain LMOs on the basis of the best available scientific knowledge and experience, as well as relevant information, a recipient Contracting party by means of unilateral declaration or bilateral, regional or multilateral agreement or arrangement, may exempt such LMOs from the application of the AIA procedures, by which no explicit agreement by the competent authority of the recipient Contracting Party is required.

C. Notification of agreements or arrangements

Prior to or after entry into force of the Protocol

Option 1

Parties shall notify the Secretariat of any such bilateral, regional and multilateral agreements or arrangements entered into:

(a) Prior to entry into force of this Protocol and which will continue to operate after entry into force of the Protocol; or

(b) After entry into force of the Protocol.

Option 2

Parties shall notify the Secretariat of any multilateral agreements or arrangements referred to in paragraph 1 and those which they have entered prior to the entry into force of the Protocol, for the purpose of controlling tranboundary movements of LMOs which take place entirely among the Parties to such agreements. The provisions of the Protocol shall not affect transboundary movements which take place pursuant to such agreements.

D. International cooperation

Parties shall cooperate in exchanging information, developing technical guidelines

Option 1

The Parties shall cooperate among themselves in exchanging information, developing appropriate technical guidelines and/or codes of practice, and monitoring the effects of risks posed by living modified organisms and products thereof on human and animal health, biological diversity, the environment and socio-economic welfare of societies with a view to promoting the safe management of these organisms and products.

Cooperation in the implementation of the Protocol

Option 2

The Parties shall employ appropriate means to cooperate in order to assist developing countries in the implementation of this Protocol. They shall take due account of the needs of developing countries with respect to capacity-building in order to promote the development and transfer of safe biotechnology and knowledge.

E. Regional economic integration organizations

Option 1

A regional economic integration organization, which itself is a Contracting Party to the Protocol and has a specific legal framework for

biosafety, may declare that the Protocol shall not apply to movements within its territory.

ARTICLE 12 - RISK ASSESSMENT

Aim of risk assessment

Option 1

No provision in the Protocol is necessary.

Option 2

The objective of a risk assessment is to enable evaluation of the risks of possible adverse impacts of LMO's and products thereof in the receiving country party and its environment in particular to the conservation and sustainable use of biodiversity, agriculture, human and animal health, ecological stability and socio-economic imperatives.

Option 3

Adequate risk assessment of possible adverse effects of LMOs on the conservation and sustainable use of biological diversity and adverse impacts on human health in the State of Import is the basis for AIA and also is a necessary requirement for decision on handling, use and release of any LMO in that country.

Option 4

The (importing Party) (receiving country) shall make all decisions on the basis of, inter alia, risk assessment, socio-economic imperatives, and social and ethical considerations.

Option 5

Decisions by importing Parties regarding risk assessment in regard to potential adverse effects on the conservation and sustainable use of biological diversity should make use, as appropriate, of existing guidelines relevant to biosafety. Decisions shall be based on scientific principles and should take into account relevant technical experience. Parties are encouraged to assist importing Parties with importing Parties' risk-assessment decisions through the sharing of information and expertise. No other provisions are necessary.

Option 6

Risk assessment should be undertaken to identify and evaluate possible adverse effects of the living modified organisms to the conservation and sustainable use of biological diversity taking also into account risks to human health.

When does risk assessment have to be carried out?

Option 1

On receipt of a notification for first import of a living modified organism, the importing Party shall undertake, or have undertaken, an assessment of the risk of the living modified organism having an adverse effect on the conservation and sustainable use of biological diversity in the importing Party.

Option 2

A risk assessment shall be carried out prior to decisions under the Protocol, in regard to adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Option 3

(As a basis for AIA, and national regulations,) risk assessment will be undertaken:

(a) Prior to the use, (transboundary movement) (transfer) or handling or LMOs, as the case may be to or within the receiving country Party;

(b) Prior to undertaking a transfer, handling or use of LMOs to or within the receiving Party;

(c) Prior to a first import;

(d) On a case-by-case approach.

Option 4

Each Party shall carry out/shall require any natural or legal person under it jurisdiction who intends to undertake a transfer, handling and use of LMOs to conduct a risk assessment in accordance with Annex II and to submit an application to the competent authority for approval before undertaking a release into the environment.

Option 5

The risk assessment shall be undertaken by the importing Party whenever it deems it to be appropriate.

Basic parameters

Option 1

Each country shall determine for itself, in accordance with its own legislation, the institutional arrangements for the conduct of risk assessments and for the preparation of technical findings with regard to requests for transboundary movement.

Option 2

The State of import shall in its assessment particularly take into account the characteristics of the receiving environment.

Option 3

Risk assessment should not only be based solely on scientific data that would take into account the characteristics of the LMO and its possible adverse effect on the environment, but also other data to address its possible impacts on the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health. The receiving country Party shall take into account other factors including without limitation, social, socio-economic and ethical considerations, in making decisions regarding such transfer, handling or use.

Option 4

Risk assessments shall be carried out at the discretion of the importing Party, in a scientifically sound and transparent manner tailored to the environment of the specific receiving country, and should also take into account other issues, including agricultural production, human and animal health, the population balance of the related organisms, social, economic, and ethical considerations, taking into account information submitted by the country of import.

Option 5

Risk assessments shall be carried out at the discretion of the importing party, in a scientifically sound and transparent manner.

Option 6:

Further parameters for risk assessment can be adopted at the discretion of the importing Party.

Option 7

The competent authorities of the recipient Contracting Party may request the exporter to provide additional relevant information if necessary.

Option 8

Risk assessments should, inter alia, take into account:

(a) All relevant scientific evidence and experience;

(b) The general characteristics of both the living modified organism and the parent organism, the vector used, the genetic modification and the novel trait;

(c) The intended use of the living modified organism and the nature of the receiving environment;

(d) Impact on centres of origin and areas with high genetic diversity relevant to the living modified organism;

(e) Risk assessment techniques developed by relevant international organisations.

(f) Information submitted by the country of origin;

(g) The actual and/or potential effects on human health, the environment and agricultural production, including the population balance of the related organisms;

(h) Ensure that the risk assessment and management processes of micro-organisms of all kinds are conducted in contained conditions;

(i) Socio-economic imperatives and ethical considerations.

Further specifications concerning parameters for risk assessment

Option 1

Evaluation of risk should be conducted, where applicable, at each step of development from the research laboratory to small-scale and large-scale ~~release~~ for production and testing, including commercial use. A multidisciplinary approach is necessary. Risk assessment should be applied for safety in biotechnology including a step-wise and case-by-case approach.

Option 2

Each Party shall ensure that appropriate decisions are taken based on the outcome of the risk assessment and on a case-by-case basis.

Option 3

Decisions under the Protocol, in regard to adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health shall be based on scientific grounds and experience and take account of:

(a) The characteristics of the organisms involved, including any introduced sequences or modified traits;

(b) The characteristics of the intended application;

(c) The characteristcs of the potential receiving environment;
(d) And the interaction between these.

Option 4

Special considerations should be incorporated into risk assessment in the transfer, handling or use of LMOs into centres of origin and genetic diversity.

Option 5

The Conference of the Parties to the Protocol shall establish a minimum standard of risk assessment of LMOs. The minimum standard shall be reviewed periodically by the Conference of the Parties in the light of the most recent and best available scientific knowledge and experience, as well as other relevant information. The Conference of the Parties to the Protocol may establish a technical advisory body for providing the Contracting Parties with scientific backgrounds for reviewing the standard.

Option 6

The risk assessment shall, as appropriate, be based on the information and principles set out in Annex (II).

Option 7

Details should be covered in an Annex.

Option 8

No further specifications should be included.

Option 9

No Annex to be developed.

Subsequent risk assessments

Option 1

No provisions for subsequent transfers.

Option 2

Risk assessment for subsequent imports of the same living modified organisms into the same Party, at the discretion of the receiving Party shall not be required, but should be undertaken in cases where there may be:

(a) A change in the intended use of the living modified organism;

(b) A variation in the receiving environment; or

(c) Other factors likely to affect the risk assessment or risk management.

Option 3

Risk assessment for subsequent imports should be carried out at the discretion of the importing Party.

Option 4

If the assessment shows that risks cannot be avoided or reduced to an acceptable level, the States concerned shall/may refuse authorization to the import or transfer of that particular living modified organism.

Option 5

Where the competent Authority of the Party of import' requires that subsequent imports be notified, it shall establish procedures for risk assessment and decision-making alternative to those established for the first import.

Information to be provided

Option 1

No annex provision.

Option 2

The State of export shall provide or shall require the exporter to provide the State of import with information on the risk assessment as required by Annex II, and other relevant information, in order for the State of import to conduct its own risk assessment.

Option 3

Item to be dealt with under information requirements for AIA.

Option 4

The risk-assessment documentation/report to be submitted to the competent authorities of the states concerned shall, as appropriate, be based on the information and principles set out in Annex (II), to be an integral part of the Protocol.

Option 5

The information set out in Annex (II) is considered as the comprehensive list. Any country who wants more information than contained in Annex (II), has to prove it is an essential part of risk assessment in that specific case.

Option 6

The State of export shall provide or shall require the exporter to provide the competent authority/focal point in the State of import with information related to the risk assessment carried out by it, as required by Annex (II), and other relevant information, in order for the State of import to conduct its own risk assessment on the basis of this information. The exporter is responsible for the reliability of the information provided.

Option 7:

The exporting Party/exporter/importer shall provide information for notification.

Option 8

The information requirements contained in the notification for risk assessment should be covered in an annex and/or in the main text.

Additional information

Option 1

The competent authorities of the receiving Contracting Party may request the exporter to provide additional relevant information if necessary.

Responsibility for risk assessment

Option 1

No provisions necessary.

Option 2

The intending country Party shall also be reponsible over the risk assessment prepared by the individual person or entity under its jurisdiction.

Option 3:

Responsibility of risk assessment (after the risk-assessment decision) shall lie in the competent authorities of the recipient Contracting Party.

Option 4

Each receiving country shall undertake risk assessment to make a decision.

Option 5

The concept of responsibility does not apply to risk assessment.

Option 6

Risk assessment shall be undertaken by, or on behalf of, the importing Party.

Financial responsibility

Option 1

No provisions necessary.

Option 2

The financial responsibility for such risk assessment shall rest with the intending country Party.

Financial and technical assistance

Option 1:

If the receiving country Party lacks the financial and technical capacity to do so, the intending country Party shall technically and financially assist and collaborate with the receiving country Party in the risk-assessment evaluation.

Option 2

The competent authorities of the recipient Contracting Party may request assistance from the exporter or the competent authorities of the exporting Contracting Party, who should respond to the request to the extent possible, especially in cases where the competent authorities of the recipient Contracting Party do not have sufficient experienceof the LMOs in question.

Option 3

The Contracting Parties shall, taking into account in particular the needs of the developing countries and the countries with economies in transition, cooperate in order to promote international harmonization in risk-assessment and risk-management procedures.

ARTICLE 13 - RISK MANAGEMENT

Option 1

No Article containing provisions concerning risk management.

Option 2

In accordance with Article 8(g) of the Convention, Parties intending to undertake any transfer, handling or use of LMOs to or within the receiving country shall establish and maintain appropriate risk-management measures and strategies that may be implemented in the receiving country Party for the management of risks and harm associated with the transfer, handling and use of the LMO and the protection and mitigation of potential harm to the receiving country party, and incorporate such measures and strategies with the risk assessment under Article (12) (Risk assessment) above.

Option 3

Parties to undertake any transfer, handling or use of LMOs to or within the receiving country shall formulate appropriate risk-management measures and strategies that may be implemented in the receiving country Party for the management of risks and harm associated with the transfer, handling and use

of the LMO and the protection and mitigation of potential harm to the receiving country Party, and incorporate such measures and strategies with the risk assessment under Article (12) (Risk assessment) above.

Option 4

Parties shall establish or maintain national means to regulate, manage or control risks associated with the safe use, handling and transboundary movement of living modified organisms, in accordance with Article 8(g) of the Convention. Importing Parties and exporting Parties are encouraged, where appropriate, to cooperate in the development of risk management procedures

Option 5

The type of risk management to be employed shall depend on the LMOs and the activity in question and such risk management strategies and measures shall be commensurate with the risk assessment. In any event, the type of risk management and the practices thereto set out in Annex (III) shall be employed as a minimum.

Option 6

Where applicable, obligatory risk-management measures shall be implemented by the intending country Party or person or entity undertaking such transfer, handling or use.

Option 7

Risk-management strategies shall:

(a) Correspond to the results of the assessment referred to in Article 12 (Risk assessment);

(b) Be established both for confined and contained uses and releases;

(c) Contain a description of the type and class of containment and confinement of the organisms under consideration.

Option 8

The risk-management strategies and measures shall consist of such measures and strategies applicable at any/all stages of transfer, handling, release and/or use of the LMO to or within the receiving country and shall address the ways and means to manage the risks associated with the transfer, handling, or use of the LMO to or within the receiving country.

Option 9

The intending Party shall ensure that the risk-management strategies and measures proposed to be implemented by the receiving country Party under Article 7 shall incorporate strategies and measures that will minimize, prevent or mitigate the potential socio-economic effects and impacts within the receiving country Party, in particular where the introduction of LMOs in the environment of the receiving country Party may entail a displacement of a

particular agricultural or resource use system or the culture and livelihood of the local people.

Option 10

Parties shall require the producers to phase out all antibiotic resistance marker genes in LMOs by the year 2002.

Option 11

If management can not minimize risks to an acceptable level, the competant authority of the importing State shall not allow the transfer, use and release of that LMO.

Option 12

The type of risk management and the practices thereto set out in Annex (X) shall be employed as a minimum.

Option 13

Import-restrictive measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the LMO on the conservation and sustainable use of biological diversity within the territory of the importing Party.

Option 14

Each Party shall ensure that it has appropriate domestic laws in place to manage the risks identified under the risk assessment provisions of the Protocol.

Option 15

If the receiving country Party lacks the financial and technical capacity to do so, the intending country Party shall technically and financially assist and collaborate with the receiving country Party in the risk management.

ARTICLE 14- MINIMUM NATIONAL STANDARDS

Option 1

No provisions necessary.

Option 2

[1. Each Party shall ensure that appropriate legal, institutional and administrative frameworks with regard to the safe [research, manufacture, development,] transfer, handling and use of LMOs are in place upon the date of the entry into force of this Protocol for it. Such regulations shall contain adequate measures for both contained and deliberate release. With regard to contained use each Party shall apply measures referred to in Annex [ ] (to be developed).

2. The national regulations shall as a minimum fulfil the requirements set out in this Protocol with regard to the safe transfer, handling and use of LMOs, including risk-assessment procedures under Article 12 and enforcement of conditions or prohibitions under Article 13.]

Option 3

[1. Each Party shall:

(a) Establish at the national level, or cooperate in establishing at the multinational and/or regional level, procedures to assess the risks of living modified organisms under Article 12;

(b) Ensure that it has appropriate domestic laws in place to manage the risks identified under its risk-assessment procedures under Article 12; and

(c) Ensure that it has appropriate domestic laws in place to enforce any conditions or prohibitions decided under Article 13.]

[2. Parties may impose more stringent or comprehensive requirements, based on scientific consideration.]

ARTICLE 15 - UNINTENTIONAL TRANSBOUNDARY MOVEMENTS

Option 1

No provisions necessary.

Option 2

[1. The Parties shall take all possible precautions to prevent accidental and unintentional release and to reduce natural movements of intentionally released living modified organisms which may result in unintentional transboundary movements.]

[2. The Parties shall, whenever it comes to their knowledge, ensure that, in the case of an accident which may have transboundary effects on human health and/or the environment in other States, these States are immediately informed, and inform affected States about any planned activities associated with LMOs within their territories that are likely to have transboundary effects. The affected State(s) may ask for consultations between the concerned States.]

[3. The information supplied shall include, inter alia, the identity, relevant characteristics and numbers/volumes of the LMOs involved and any available information necessary to assess the effects of the accident and emergency measures taken or needed to be taken, including measures identified under Article 14 (1) of the Convention.]

[4. Parties shall immediately notify affected Parties, potentially affected Parties and the Clearing-house, in case of known unintentional transboundary movements of living modified organisms, or of known domestic releases of

living modified organisms which may result in unintentional transboundary movements. Such notification shall include, inter alia:

(a) The circumstances of the unintentional movement;
(b) The identity and quantities released;

(c) An assessment of the risks to the conservation and sustainable use of biological diversity and/or human health;

(d) Emergency measures taken or needed to be taken;

(e) Any available information regarding the handling of the organisms and related risk-management measures to be applied;

(f) The information specified in Annex I.]

[5. The Party which is the origin of the unintentional transboundary movement [which is likely to present a threat] shall take immediate action, in consultation with the affected Party, [to minimize negative impacts on the environment and] to prevent further release or transboundary movement of the living modified organism.]

[6. A Party which suspects that an unintentional transboundary movement has occurred into its territory shall inform the Party from which the unintentional movement is suspected to have originated. The Party from which the unintentional movement is suspected to have originated, shall immediately investigate this possibility and, if confirmed, trigger the mechanisms described paragraphs 2 and 3 of this Article.]

[7. Each Party shall avoid any activity that may lead to accidental or unintended releases of aquatic living modified organisms to freshwater and marine ecosystems.]

[8. If necessary, the affected Party(ies) may request the Party from which the unintentional tranboundary movement originates, to assist in emergency measures with the aim of minimising adverse effects on conservation and sustainable use of biological diversity and human health.]

[9. In the event of an unintentional release occurring during the international transport of a living modified organism subject to the article on Advance Informed Agreement [where such unintentional release is likely to present risks to the conservation and sustainable use of biodiversity], each Party shall, whenever it comes to its knowledge, ensure that the national focal point of each suspected affected Party is immediately informed and provided with all available relevant information [, subject to the domestic legal requirements for the protection of confidential information and intellectual property rights in the Party providing such information]. For purposes of this Article, international transport refers to that portion of movement that occurs after the LMO has left the area under the national jurisdiction of the exporting Party and before it has entered the area under the national jurisdiction of the importing Party.]

Option 3

[1. In the case that an unintentional transboundary movement of LMOs is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, the Party from which the unintentional movement originates shall ensure that any affected Party(ies) and non-Party(ies) receives, as soon as possible, all relevant information concerning the unintentional transboundary movement and risks to the conservation and sustainable use of biological diversity, taking also into account risks to human health, and their management.

2. Information to be provided is specified in Annex I.]

ARTICLE 16 - EMERGENCY MEASURES

Option 1

No provisions necessary.

Option 2

[1. Each Party shall endeavour to establish appropriate national measures and procedures, including national contingency plans, related to accidental transfers of LMOs which may have potential risks to its environment, in particular, the conservation and sustainable use of biological diversity, and the risks to human health and the emergency measures that need to be taken in regard therewith.

2. Parties shall take the necessary measures to ensure that, in the event of an accident, the user shall be required to inform immediately the competent authorities of the State(s) concerned. The information shall include, inter alia:

(a) The circumstances of the accident;

(b) Other facts necessary to assess the effects of the accident on human and animal health, the environment, and the biological diversity;

(c) The emergency measures taken or needed to be taken together with any available information regarding the handling of the organisms; and

(d) Any other information considered relevant.

3. The States concerned shall, where information is provided under paragraph 2 above, ensure that in any emergency, the medium and long-term measures necessary are taken, including the immediate alerting of any other State which could be affected by the accident.

4. The Parties shall ensure that appropriate risk management strategies and measures, including emergency plans, are incorporated in the risk management strategies and measures under Article 13 above to prevent,

mitigate or rectify any potential risks to the relevant Parties in case of any accidental or emergency release of LMOs.]

ARTICLE 17 - HANDLING, TRANSPORT, PACKAGING AND LABELLING

Option 1 1/

[1. In order to maintain adequate safety levels during transport, each exporting Contracting Party shall [establish appropriate,] [promote, as appropriate,] measures for handling, transportation [,] [and] packaging [and transit] of LMOs [subject to the article on AIA] for transboundary transfer.

2. The receiving Party shall have the right to impose such terms and conditions on the packaging, labelling and transportation of the LMO to or within the receiving country, for the protection of its environment [, in particular the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health and taking into account also such social and ethical matters it deems fit for national-interest purposes].

3. The Parties shall take into account international conventions, agreements and recommendations on classification, bottling, labelling and documentation established by appropriate international organizations related to transport, particularly the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO), the Regulations concerning the International Transport of Dangerous Goods by Rail (RID), the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) and the International Air Transport Association (IATA).

4. Exporting Parties shall ensure that shipments containing living modified organisms:

(a) Are clearly identified as containing living modified organisms;

(b) Are handled and packaged in such a way as to prevent accidental release into the environment;

(c) Include names and contact details of Focal Points for exporting, importing and transit Parties, for use in the case of accidental release of living modified organisms, consistent with Article 15 (Unintentional transboundary movements);

(d) [That LMOs exported from their territories are subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export;]

(e) Require that living modified organisms be accompanied by a movement document from the point at which the transfer commences to the point of use.

1/ [Variations within option 1 are: (i) paragraphs 1 to 6 in their entirety; (ii) only paragraph 1; and (iii) only paragraph 4, with subparagraph (d) deleted.]

5. The Parties shall ensure that LMOs which have not been approved for use shall be handled and packaged in such a way as to ensure their complete isolation.

6. The Parties shall aim at developing standards with regard to packaging and transport practices under the Protocol.]

Option 2

[1. Transport of living modified organisms shall be carried out under safe conditions in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.]

Option 3

[1. Each Party shall require that living modified organisms that are to be subject to a transboundary movement and are subject to AIA be packaged, labelled, and transported in conformity with generally accepted and recognized international rules and standards in the field of packaging, labelling and transport, and that due account is taken of relevant internationally recognized practices.]

Option 4

[1. Each exporting Contracting Party shall establish appropriate measures for handling, transportation, packaging and transit of LMOs for transboundary transfer according to the standards to be elaborated by the Conference of the Parties to the Protocol.]

Option 5

[1. Each Party shall:

(a) Ensure that LMOs exported from their territories are subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export;

(b) Require that living modified organisms be accompanied by a movement document from the point at which the transfer commences to the point of use;

(c) Ensure that all LMOs to be exported are clearly labelled as such. The labelling shall inform that the movement contains a living modified organism. The labelling shall also inform about the type of living modified organism and the names and addresses of the exporter and importer;

(d) Ensure that LMOs to be exported are packaged and transported in accordance with international rules and standards in the field of packaging and transport, particularly in accordance with the United Nations Recommendations on the Transport of Dangerous Goods.

2. The Parties shall aim at developing standards with regard to packaging and transport practices under the Protocol.]

ARTICLE 18 - COMPETENT AUTHORITY/FOCAL POINT

Option 1

[1. To facilitate the implementation of this Protocol, each Party shall designate or establish a national focal point and one or more competent authority(ies), which shall receive applications and notifications and communicate decisions on living modified organisms in accordance with the Advance Informed Agreement procedure set out in Article 3, 4 and 5 and Annex I and II. Where a Party designates more than one competent authority, it shall specify the areas of responsibility for each.

2. Each Party shall inform the Secretariat no later than the date of entry into force of the Protocol for that Party in question, which agencies have been designated as its focal point/competent authority(ies).

3. The Secretariat shall forthwith inform the Parties of notifications received under paragraph 2. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1, and 2 above for inclusion in the database provided for in Article 19, on information-sharing.

4. Parties shall inform the Secretariat and the Biosafety Clearing-house within [ ] days of the date of decision, of any changes regarding the designation made by it under paragraphs 1 and 2 above.

5. The competent authority of each Party shall be the authoritative/decision-making body regarding any intended transfer, handling or use LMOs to or within the receiving country. The competent authority shall be provided with adequate [and timely] financial and technical assistance to establish and develop its infrastructure and human resources to carry out the responsibility assigned to it including as a minimum the responsibilities listed in Annex IV.

6. The competent authority of the receiving country Party may impose [on the exporting country] such conditions and/or national procedures it deems fit regarding the transfer, handling or use of the LMO by the intending Party in order to protect its environment, in particular the conservation and sustainable use of biological diversity, and the [prevention of] risks to human health.]

Option 2

[1. Parties shall:

(a) Designate a focal point; 2/

(b) Designate one or more competent authorities; 2/

2/ These terms will be defined in Article [ ] of the Protocol (Definition of terms).

(c) Inform the Clearing-house, within three months of the date of entry into force of the Protocol for them, which agencies have been designated as the focal point and the competent authority; and

(d) Inform the Clearing-house, within one month of the date of decision, of any changes regarding the above designations.]

Option 3

[1. Each Party shall designate or establish competent authority/ies and/or focal points/s that shall be responsible for the administrative functions required by this Protocol and shall notify this to the Secretariat no later than the date of entry into force of this Protocol for it.

2. Each Party shall also notify relevant data concerning its designated competent authority/ies and/or focal point/s to the Secretariat for inclusion in the Database provided for in Article 19 [on information-sharing]. Each Party shall also immediately notify the Secretariat of any subsequent changes.

3. Each Party shall ensure that its national focal point has sufficient resources to perform its task efficiently.]

Option 4

[1. Contracting Parties shall designate or establish one national focal point and one or more competent authorities for the implementation of the Protocol.

2. The national focal point shall perform the following tasks:

(a) To provide other Contracting Parties, through the Secretariat of the Protocol, with general information on the implementation of the Protocol at the national level including, in particular, information on competent authorities responsible for the AIA procedures and/or for LMOs;

(b) To collect information on the implementation of the Protocol at its national level; and

(c) To assist communication between foreign, regional or international institutions established for the implementation of the Protocol on the one hand and the national competent authorities on the other.

3. The competent authorities shall perform the following tasks:

(a) To establish national guidelines and/or regulations for the implementation of the AIA procedures including detailed criteria for risk assessment within their competence;

(b) To receive from exporters applications for the AIA procedures;

(c) To conduct risk assessment;

(d) To take a decision on result of the risk assessment;

(e) To inform the exporter with the result of the risk assessment; and

(f) To conduct, if necessary, additional trials, including field trials.]

Option 5

[1. Each Party shall designate one or more national authorities that shall serve as its focal point(s) and be authorized to act on its behalf with respect to the functions required by this protocol.

2. Each Party shall, concurrently with the deposit of its instruments of ratification, provide the name and address of its designated national focal point(s) to the Convention on Biological Diversity (CBD) Secretariat. Each Party shall also immediately notify the Secretariat of any subsequent changes. Where a Party designates more than one national authority, it shall specify the areas of responsibility for each.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2.]

ARTICLE 19 - INFORMATION-SHARING/BIOSAFETY CLEARING-HOUSE

Option 1

[1. Subject to the national laws, regulations and procedures of each Party, and without prejudice to the obligation to provide information under the AIA procedure under Article 4 the Parties shall facilitate through a clearing-house mechanism and/or national focal points of each Party, the exchange of information relevant to [safety in biotechnology and the transfer, handling or use of LMOs and its impacts thereof, taking into account the special needs of developing countries] [the implementation of the Protocol]. Such information shall be transmitted to the Secretariat [, the Biosafety Clearing-house] and other relevant bodies and Parties as the case may be.

2. Parties shall endeavour to cooperate with existing international agencies, organizations, mechanisms and regional networks for the dissemination of biosafety-related information[and standards applicable in other countries].

3. A database for international information exchange shall be established and administered by the Secretariat. [The Biosafety Clearing-house should be established no later than the date of entry into force of this Protocol on the basis of existing international biosafety exchange mechanisms.]

[4. The Biosafety Clearing-house shall serve as a body for information exchange, monitoring of implementation, and scientific and technical cooperation among Parties. It shall report regularly to the meeting of the Parties on all aspects of its work and to the Secretariat regarding the implementation of procedures on notification and Advance Informed Agreement.

The modalities of establishment of the Biosafety Clearing-house shall be considered and decided upon by the Parties at their first meeting.]

[5. Each Party shall inform its public about the contents of, and mode of public accessibility to, the clearing-house mechanism.]

6. The Secretariat shall keep this database up-to-date and accurate; submit as soon as possible to the Conference of the Parties a proposal for the format to be used for the inclusion of information in the Database.

7. Without prejudice to Article 20, the database shall contain and provide public access to information relevant to the implementation of the Protocol as follows:

(a) [The information identified in Annex V;]

(b) Information on risk assessments or environmental reviews generated by the regulatory process;

(c) [Information on decisions regarding the importation, field testing, or commercial use of any LMO;]

(d) Information concerning the development, use and transfer of LMOs;

(e) Available results relating to risk assessment and management;

(f) National procedures for regulation, assessment and risk management;

(g) [Scientific references necessary to risk assessment and risk management;]

(h) Information on transboundary movement [of LMOs resulting from modern biotechnology which may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health];

(i) Information on unintentional movements according to Article 15;]

(j) [General description of products consisting of or containing LMOs having received consent by a Party or Parties for placing on the market;

(k) [A summary of any methods and plans for monitoring LMOs;

(l) Point a) of Annex V;

(m) The text of any decision on a notification of an intentional transboundary movement and the summary of the risk assessment;

(n) Information concerning its biosafety regulatory framework on LMOs;

(o) A summary of any notified unintentional transboundary movements which are likely to have significant adverse effects in another Party or non-

Party on the conservation and sustainable use of biological diversity, taking also into account risks to human health;

(p) The text of decisions taken pursuant to Article 10 [safeguard clause as referred to in BSWG 3/3/Add 1.]

Option 2

[1. The Parties shall facilitate the exchange of publicly available information on, and experience with, living modified organisms (LMOs) to enable Parties to make informed decisions related to biosafety.

2. Each Party shall make available to a [centralized database/]clearing-house its domestic laws, regulations, and guidelines applicable to the production, use, and handling of LMOs.

3. Each Party shall make available to a [centralized database/]clearing-house publicly available information on risk assessments or environmental reviews generated by the regulatory process.

4. Each Party shall make available publicly available information on its decisions regarding the importation, field testing, or commercial use of any LMO.]

[5. Each Party shall provide transparent procedures for validation and verification of data which it makes available to the public and to the clearing-house.]

Option 3

[1. The mechanism for the exchange of information and cooperation under the Protocol shall be that established by the Convention on Biological Diversity in its Article 18, paragraph 3.

2. This mechanism shall include, inter alia, the following information:

(a) Information on measures adopted by the national legislation of the countries;

(b) Information on decisions adopted by the countries with regard to transboundary movement of LMOs;

(c) Information on accidental or unintended movements of LMOs, including contingency or mitigation plans to be used in such event;

(d) Information relating to the appropriate assessment and management of risks;

(e) Information on the implementation of the AIA procedure, including simplified procedures and bilateral, multilateral and regional agreements;

(f) Updated information on the designated national authorities for the purposes of this Protocol.]

Option 4

[1. Each Contracting Party shall facilitate the collection and exchange of all publicly available scientific, technical, environmental and legal information relevant to the implementation of this Protocol taking into account the special needs of developing country and the countries with economies in transition through a [Biosafety Clearing-house] [International Safety Database] [Database for International Information Exchange]. 3/

2. Without prejudice to Article 20 [which addresses confidentiality], each Contracting Party shall ensure that the following information is provided to the Secretariat for inclusion in the [Biosafety Clearing-house] [International Safety Database] [Database for International Information Exchange]:

(a) Information on intentional movement having been subject to Advance Informed Agreement according to Article 4 and related decision(s);

(b) Information on unintentional movements according to Article 15.

3. A [Biosafety Clearing-house] [International Safety Database] [Database for International Information Exchange] should be established no later than the date of entry into force of this Protocol on the basis of existing international biosafety-exchange Mechanisms.]

Option 5

[Information to be submitted to the Secretariat of the Protocol

1. The Contracting Parties shall provide the Secretariat of the Protocol with the following information:

(a) National regulatory framework for the implementation of the Protocol, including:

(i) Names, addresses and telecommunication numbers of the national focal point and the competent authorities;

(ii) National guidelines and/or regulations for the implementation of the Protocol, including information required for the AIA procedures and for risk assessment;

(iii) If any bilateral, regional and multinational agreements or arrangements as well as unilateral declarations on the exemption and/or the simplification of the AIA procedures;

(b) A periodical report on the implementation of the AIA procedures, including statistics.

2. The Secretariat of the Protocol shall circulate the information received pursuant toparagraph 1 above to all Contracting Parties.

3/ On Biosafety Clearing-house, reference should be made to the African Group submission.

Information to be made available

The Contracting are encouraged to make available to all interested parties, including other Contracting Parties, regional and international institutions as well as individuals information on the implementation of the Protocol, not included in that submitted under paragraph 1 above.]

Option 6

[1. Each Party of import shall make available to the clearing-house mechanism 4/ established under Article 18.3 of the Convention subject to appropriate protection of confidential business information identified:

(a) Information to assist other Parties in decision-making under the Protocol with respect to national laws, regulations, guidelines, codes of practice and administrative procedures for the safe transfer, handling and use of living modified organisms;

(b) Any other information regarding living modified organisms that the Party considers would be of benefit to other Parties and to the public, including information with respect to risk assessment and management, and other scientific information; and

(c) A list of living modified organisms subject to advance informed agreement that have been assessed or import into or use in its territory at the time of coming into force of this Protocol for that party and a description of any conditions attached to imports of such living modified organisms.

Option 7

[1. The clearing-house mechanism under the Convention on Biological Diversity shall function as the clearing-house mechanism to provide the Parties and, as appropriate the Secretariat, with timely advice and information relating to the implementation of this Protocol.

2. Each Party shall ensure that timely information pertaining to biosafety is provided to the Clearing-house.

3. The Parties shall facilitate and encourage the collection and exchange of scientific, technical, environmental, socio-economic, commercial and legal information relevant to the implementation of this Protocol. Such information shall be transmitted to the Secretariat, the Clearing-house and other relevant bodies and Parties as the case may be.]

4/ A two-part clearing-house is envisaged: one used primarily for information on decisions made after notification and assessment; another would provide for more general information on LMOs, regulatory requirements, etc.

ARTICLE 20 - CONFIDENTIAL INFORMATION

Option 1

[1. [Parties receiving notifications [5/] shall respect the need to protect intellectual proprietary rights and confidential information relevant to living modified organisms. [The information specified in Annex I shall not be regarded as confidential information, with respect to the Protocol.]]

2. The notifier should indicate any information submitted under the procedures of this Protocol that it considers to be confidential and/or subject to intellectual property protection. [Confidentiality and proprietary provisions shall not be excessive or broad so as to hinder information-sharing among Parties which would undermine the ability of the national competent authority to take informed decisions.] Any Party receiving such information shall establish appropriate internal procedures for the protection of information so received.

3. The competent authority shall decide, after consultation with the notifier, which information is confidential and shall inform the notifier of its decisions. If, for whatever reasons, including in case[s where] the competent authority and notifier disagree, a notifier withdraws a notification, the confidentiality of all the information supplied [and indicated as confidential and/or subject to intellectual property protection] must be respected by the competent authorities and focal points, [subject to national legislation].

4. [Competent authorities, focal points] [Parties [,including their competent authorities and focal points]] [and the Secretariat] shall not divulge any confidential information received under the Protocol and [have the obligation to] [shall] protect intellectual property and proprietary rights relating to the data received.]

[5. Cependant la confidentialité ne pourra être retenu si l'information sur le retrait de la notification concerne des aspects de risques pour un éventuel demandeur ultérieur.]

Option 2

[1. [Competent authorities, focal points] [Parties] and the Secretariat shall not divulge any confidential information received under the Protocol [without the prior written consent of the notifier and shall comply with such conditions regarding release that the notifier may prescribe] and [have the obligation to] [shall] protect intellectual property [and proprietary] rights relating to the [data] [information] received. [Any Party receiving such information shall establish appropriate internal procedures for the protection of information so received, and the confidentiality of information about imported LMOs should be treated in a way no less favourable than for domestic LMOs.]

5/ This provision should be re-examined in the context of what is agreed regarding contents of the notice in the AIA provisions.

[2. However, all information requested by the importing Party for the purpose of decision making must be provided by the exporting Party.]

3. The notifier may indicate [the] [any] information submitted under the procedures of this Protocol that should be treated as confidential [and/or subject to intellectual property protection]. [Verifiable] justification must be given in such cases [upon request].

4. [The competent authority or focal points shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions.] or [Should the Party decide, after consultation with the notifier, not to treat information as confidential that the notifier has indicated is confidential, the Party shall inform the notifier of its decisions.]

[5. Without prejudice to Article 11(6) [in no case may the following information be kept confidential] [the following information should not generally be considered confidential:

(a) The general description of the LMO or LMOs, name and address of the notifier, [purpose of the movement];

(b) A summary of the risk assessment of effects on the conservation and sustainable use of biological diversity, taking also into account human health;

(c) Any methods and plans for emergency response.]

[6. If, for whatever reasons including in case the [competent authority] [Party] and notifier disagree, a notifier withdraws a notification, the confidentiality of all the information supplied [and indicated as confidential] must be respected by the competent authorities and focal points.]

ARTICLE 21 - CAPACITY-BUILDING

Option 1

No provisions necessary.

Option 2 6/

[1. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety including where necessary, through the appropriate international and national institutions. They shall take due account of the needs of developing countries with respect to capacity-building in order to promote the development and transfer of safe biotechnology and knowledge.

6/ [Variations under options 2 are: (i) paragraphs 1 to 9 in their entirety; (ii) only paragraphs 4 and 5 (with amendments shown); and (iii) only paragraphs 4, 5 and 6.]

2. The Secretariat, in collaboration with the Biosafety Clearing-house, shall develop and implement regional and global capacity building programmes based on the identified needs of the concerned Parties. The Secretariat and the Biosafety Clearing-house shall, in particular, assist developing countries in their efforts to identify and plan their capacity-building requirements and secure funds for the implementation of their capacity-building programmes.

3. The Parties agree that, according to the specific needs of different regions and subregions, regional or subregional activities/centres for training and capacity-building regarding the safe management of living modified organisms shall be established. with financial assistance provided through the financial mechanisms under the Convention on Biological Diversity (CBD).

4. The Parties shall promote [technical and scientific cooperation] [capacity-building], including the promotion of cooperation in the training of personnel and the exchange of experts, informational exchange and institutional capacity building in order to strengthen the ability of importing States to perform risk assessments and to develop and implement [decision-making and] risk-management procedures.

5. Capacity-building programmes should maximize the use of existing multilateral, regional and bilateral mechanisms [where possible, including those addressed under the Convention]. Technical assistance from the private sector should also be facilitated and encouraged.]

6. Such capacity-building shall aim to ensure:

(a) That Parties develop and strengthen their capacities to implement this Protocol;

(b) That national legislation, frameworks and guidelines related to biosafety are developed;

(c) That States involved in the transfer, handling and use of LMOs and or products thereof are aware of any associated risks and have the means to assess and manage the risks;

(d) That States are able to achieve safety through proper risk assessment and management when certain LMOs and or products thereof are transferred into and/or to be used in their territories and act adequately in cases of accidental release of LMOs;

(e) The development of procedures for risk assessment and risk management of LMOs.

7. Any Party to this Protocol or any of its signatories will be able to make scientific-technical cooperation requests to the Secretariat for the purpose of applying the Protocol or participating in it, in particular:

(a) Preparing or evaluating risk-assessment reports or impact statements;

(b) Developing or evaluating risk-management schemes and appropriate monitoring programmes, procedures and standards;

(c) Preparing emergency plans and other safety measures;

(d) Transmitting requests for assistance and relevant information in the event of accidents;

(e) Providing information that may be relevant to the settlement of disputes.

8. The developed country Parties shall establish effective measures for strengthening and/or development of human resources and institutional capacities in biotechnology and biosafety in developing country Parties, encompassing technical, financial and institutional provisions.

9. The developed country Parties shall establish such measures to enhance the capacity of developing country Parties to acquire and/or develop relevant biotechnology, and its proper and safe management, and the building up of their local, technological and institutional competence, thereby contributing to the distribution of benefits from the potentials of biotechnology. through training in science related to safety in biotechnology and in the use of risk assessment and risk management techniques and the transfer of relevant knowledge, in biotechnology and biosafety on fair and most favourable terms including on concessional and preferential terms.]

Option 3

[1. The Parties agree that measures for capacity building in the form of information exchange, training, education and institutional capacities, are essential for the effective functioning of the Protocol.

2. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and Biosafety including where necessary, through the appropriate international and national institutions. They shall take due account of the needs of developing countries with respect to capacity building in order to promote the development and transfer of safe biotechnology and knowledge. (NB: Same as option 2, para 1)

3. Such capacity-building shall aim to ensure:

(a) That Parties develop and strengthen their capacities to implement this Protocol;

(b) That national legislation, frameworks and guidelines related to Biosafety are developed;

(c) That States involved in the transfer, handling and use of LMOs and or products thereof are aware of any associated risks and have the means to assess and manage the risks;

(d) That States are able to achieve safety through proper risk assessment and management when certain LMOs and or products thereof are transferred into and/or to be used in their territories and act adequately in cases of accidental release of LMOs;

(e) The development of procedures for risk assessment and risk management of LMOs.] (NB: same as option 2, para 6, above)

Option 4

[1. Each Party shall strengthen and/or develop human resources and institutional capacities in order to facilitate effective implementation of the Protocol. Such capacity-building shall aim to ensure:

(a) That national legislation related to Biosafety is developed;

(b) That Parties involved in the transfer, handling and use of living modified organisms and/or products thereof, are aware of associated risks and have the means to assess and manage such risks; and

(c) That Parties are able to conduct proper risk assessment and management when living modified organisms and/or products thereof are transferred into and/or used in their national territories.

2. Parties shall cooperate to build capacity for risk assessment, decision-making and risk management. Capacity-building may include technical assistance, information exchange, training, education and institutional strengthening.

3. Capacity building programmes should maximize the use of existing mechanisms where possible, including those addressed under the Convention, and should be particularly aimed at developing countries.

4. Technical assistance from the private sector should be facilitated and encouraged.]

Option 5

[1. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety, including where necessary, through the appropriate international and national institutions. They shall take due account of the needs of developing countries with respect to capacity-building in order to promote the development and transfer of safe biotechnology and knowledge. (NB: same as Option 2, para 1, above)

2. The Parties agree that, according to the specific needs of different regions and subregions, regional or subregional activities/centres for training and capacity-building regarding the safe management of living modified organisms shall be established, with financial assistance provided through the financial mechanisms under the Convention on Biological Diversity (CBD). (NB: same as Option 2, para. 3, above)

3. Implementation of [these measures] is properly addressed in the general framework of the Convention and through programmes and activities under international organizations such as the United Nations Environment Programme and the United Nations Industrial Development Organization.]

ARTICLE 22 - PUBLIC AWARENESS/PUBLIC PARTICIPATION

Option 1

No provisions necessary.

Option 2

[Include these matters in the Preamble]

Option 3 7/

[1. The Parties shall ensure that adequate information on the safe transfer, handling and use of LMOs is provided to the public in accordance with Article 13 and Article 14, paragraph 1, of the Convention with regard to public participation Parties are encouraged to facilitate public participation in risk assessment decisions.

2. The Parties shall promote and facilitate, at the national, subregional and regional levels, as appropriate, and in accordance with national laws and regulations, and within their respective capacities, the development and implementation of educational, both formal and informal, and public awareness programmes on safety in biotechnology.

3. Each Party shall, in accordance with its national laws and regulations, provide the public which is likely to be affected by any activity or product involving living modified organisms, an opportunity for public hearings in the process of approving the release, transfer or use, contained or otherwise, of such living modified organisms.

4. While respecting the need to protect commercial-in-confidence information, Parties shall:

(a) Promote and encourage understanding of the safe use, handling and management of living modified organisms in relation to the transboundary movements and the conservation and sustainable use of biological diversity, including human health;

(b) Make available to the public risk-assessment results and decisions concerning the transboundary movement of living modified organisms;

5. The Parties shall stipulate public participation by allowing access to information on which decisions are based and shall cooperate to favour public

---

7/ [Variations to option 3 are: (i) paragraphs 1 to 7 in their entirety; (ii) only paragraphs 4 and 6, with amendments; (iii) only paragraphs 3, 4 and 6; and (iv) paragraphs 1 to 7 in their entirety, with the amendments to paragraphs 1 and 2 proposed by Mali (awaiting text).]

awareness on any possible effects for the environment and health in general that living-modified-organisms release may produce.

6. The Parties shall cooperate as appropriate, with other States and international organizations in developing educational and public awareness programmes [with respect to any risks and benefits associated to] [on safety in] modern biotechnology.

7. Subject to relevant national legislation, Parties shall endeavour to disclose or make available information on biotechnology, safety in biotechnology and the results and impacts of any releases or use of any LMO thereof to the public.]

Option 4

[1. The Contracting Parties shall take appropriate measures to enhance public awareness of and/or public participation in the implementation of the Protocol.]

Option 5

[1. Each Contracting Party shall take appropriate measures to ensure to the extent practicable, that the public has appropriate access to information related to the implementation of this Protocol, whilst respecting confidential commercial information.

2. Each Contracting Party shall promote and facilitate, as appropriate and in accordance with national laws and regulations, and within their respective capacities, the development of educational public-awareness programmes on safety in biotechnology.]

ARTICLE 23 - NON-PARTIES

Element paper

Element I. Non-Parties

1. The issue of non-Parties should not be addressed in the Protocol at this stage.

2. The issue of non-Parties should be addressed in the Protocol:

(a) They may have an important role/influence (in accordance or against) the provisions of the Protocol and in the transfer of LMOs;

(b) Due to increasing globalization and transboundary movement, commercialization by non-Parties will become an increasingly important issue;

(c) However it is not just a trade issue, but should be dealt with in the context of whether the transfer, handling or use of LMOs with non-Parties should be allowed.

3. The biosafety protocol once established should be ratified by as many countries as possible in order that it will provide a real international standardized procedure for the transboundary transfer of LMOs.

4. Parties and non-Parties may enter into bilateral or regional agreements provided that such agreements are compatible with the biosafety protocol. Such agreements should be made available to Parties through the clearing-house mechanism and through the Secretariat of the Protocol.

5. The Protocol should contain a provision related to the traffic of Parties and non-Parties considering the movement and transit of LMOs:

(a) From Parties to the Convention on Biological Diversity to non-Parties;

(b) From non-Parties to Parties to the Convention on Biological Diversity. The provision should address export and imports of LMOs from non-Parties only under certain conditions.

6. The provisions on non-Parties in the Basel Convention is not relevant to the Protocol as the objectives and the nature of that Convention are different from those of the biosafety protocol.

Element II. Trade with non-Parties

7. Trade with non-Parties should be permitted if adequate measures are taken to ensure safe movement. This could be included in the article on bilateral agreements.

8. The Protocol should not impose restrictions more stringent than those of the World Trade Organization in regard to LMOs and trade with non-Parties.

9. The question of whether trade with non-Parties should be allowed should not be relevant if no LMOs are involved.

10. Non-Parties should be permitted to transfer LMOs to Parties, because non-Parties to the Convention may possess technology and LMOs which Parties may wish to access. Importers may need to access technology and LMOs on a bilateral basis.

11. Trade with non-Parties who are in compliance with the Protocol should be permitted and non-Parties should fulfil safety provisions in regard to trade of LMOs.

12. In the event that the Protocol contains non-Parties provisions, trade could be permitted but must be flexible and not overly restrictive.

13. The provisions are needed so as to assure the compliance with the terms established within this Protocol, either on a bilateral or regional basis.

14. Non-Parties should commit themselves to being subjected to the arbitration mechanism provided for in the Protocol (by becoming a party to such Protocol).

15. Measures taken to implement the Protocol should not create unnecessary obstacles to and should not constitute a means of arbitrary or unjustifiable discrimination or disguised restriction on international trade.

GOVERNMENT SUBMISSIONS

Option 1

No Party shall export or import living modified organisms or products thereof to or from non-Parties.

Option 2

Parties may enter into bilateral, regional or multilateral agreements or arrangements regarding transboundary movements of living modified organisms with Parties or Non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of living modified organisms resulting from modern biotechnology, in accordance with the objectives of this Protocol. The provisions of this Protocol shall not affect transboundary movements that take place pursuant to such agreements and arrangements as between the Parties to that agreement or arrangement.

Option 3

Parties shall not be restricted from trade in living modified organisms with Non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of living modified organisms resulting from modern biotechnology, in accordance with the objectives of this Protocol.

Option 4

Any transboundary movement of LMOs, their parts, products, subproducts and derivatives resulting from biotechnology, originating from the jurisdiction of non-party States, shall be regulated in accordance with the national law of each Contracting Party.

ARTICLE 24 - NON-DISCRIMINATION

Option 1

No provisions necessary.

Option 2

The Protocol should contain such an Article, which may take into account the following elements, as appropriate:

1. The concept of national treatment should be applied in the course of the AIA procedure in the sense that any LMO of foreign origin should be treated in the same way as LMOs of domestic origin;

2. The decision of risk assessment should not be biased by the mere fact that the LMO in question is of foreign origin.;

3. The parameters and information used for risk assessment should not be interpreted in a manner that LMOs of foreign origin are unnecessarily discriminated;

4. The Protocol should be consistent with trade-related international treaties, especially those under the World Trade Organization;

5. Further work is required to determine what non-discrimination would mean in the context of the biosafety protocol.

6. Parties may [not] restrict trade of certain LMOs while permitting others;

7. LMOs should be equally evaluated and equally considered;

8. Parties are best placed to judge their environment and as such should be allowed to discriminate as to what to allow into their country/environment;

9. Parties may discriminate only on the basis/context of AIA;

10. Parties shall ensure that Advance Informed Agreement measures for the import of a living modified organism are not more restrictive than measures applied to the same living modified organism produced domestically or imported from other Parties;

11. Parties shall ensure that advance informed agreement measures for the import of a living modified organism are applied in a manner which does not constitute a disguised restriction on international trade;

12. Non-discrimination issue is subject to sovereign right and prerogative of national authority in receiving country;

13. Non-discrimination could cover a number of issues such as non-discrimination between Parties, between Parties and non-Parties, between LMOs, between uses of LMOs or any number of issues, including in a trade context.

ARTICLE 25 - ILLEGAL TRAFFIC

Option 1

No provisions necessary.

Option 2

The Protocol should contain such an Article, which may take into account the following elements, as appropriate:

1. Illegal traffic must be understood to mean movement of LMOs not in accordance with national legislation implementing the Protocol;

2. Parties should introduce appropriate measures/national legislation to prevent illegal traffic;

3. In case of a transboundary movement of LMOs or living products thereof deemed to be illegal traffic, the State of import/receiving country shall exercise the right of sovereignty to destroy or dispose the organisms or products in question. Each Party shall adopt appropriate domestic legislation that prevents and punishes illegal traffic. The Parties shall cooperate in this respect with a view to achieving the objective of this Protocol;

4. The Protocol should contain a provision related to the traffic of Parties and non-Parties;

5. Data concerning known cases of illegal traffic could be included in the information exchange mechanism;

6. Illegal traffic could be addressed in the Protocol by a general provision referring to the relevant World Trade Organization provisions;

7. Parties should transmit to all affected Parties, as quickly and as effectively as possible, all the relevant available information concerning the illegal traffic movement and any related risks.

GOVERNMENT SUBMISSIONS

Option 3

1. Any transboundary transfer of living modified organisms or products thereof without notification to, or Advance Informed Agreement of, all States concerned, pursuant to the provisions of this Protocol; or with Advance Informed Agreement obtained from States concerned through falsification, misrepresentation or fraud; or with Advance Informed Agreement which does not conform in a material way with the documents submitted or which results in the deliberate release of living modified organisms in contravention of this Protocol and of general principles of international law, shall be deemed to be illegal traffic.

2. In case of a transboundary transfer of living modified organisms or products thereof deemed to be illegal traffic, the State of import shall have the right to destroy or dispose of the organisms or products in question.

3. Each Party shall adopt appropriate domestic legislation that prevents and punishes illegal traffic. The Parties shall cooperate in this respect with a view to achieving the objective of this Protocol.

Option 4

1. For the purpose of this Protocol, any transboundary movement of living modified organisms shall be deemed to be illegal traffic if it:

(a) Occurs without compliance with the Advance Informed Agreement provisions outlined in this Protocol, including notification and approval, except as provided under Article 11 for bilateral, regional and multilateral agreements; or

(b) Occurs with approval obtained through falsification, misrepresentation or fraud; or

(c) Does not conform in a material way with the documentation provided pursuant to this Protocol.

2. Parties shall introduce appropriate national legislation to prevent and punish illegal traffic. In cases where illegal traffic has occurred, the importing Party may:

(a) Impound the living modified organisms; or

(b) Require and direct the disposal or re-export of the living modified organisms.

3. Parties may impose additional penalties for illegal traffic, as appropriate.

Option 5

1. For the purposes of this Protocol, any transfer, handling or use of any LMO to or within the receiving country Party by the intending Party or person or entity under the jurisdiction of the intending Party:

(a) Without notification pursuant to the provisions of this Protocol to Parties under this Protocol; or

(b) Without the Advance Informed Agreement pursuant to the provisions of this Protocol of any Party concerned; or

(c) With Advance Informed Agreement obtained from Parties concerned through falsification, misrepresentation or fraud; or

(d) That does not conform in any material way with the information given under the AIA procedure; or

(e) That results in deliberate transfer, release, handling or use of LMOs in contravention of this protocol and of general principles of international law, shall be deemed to be illegal traffic/unauthorized transfers.

2. In the case of a transfer, handling or use of LMOs deemed to be illegal traffic/unauthorized transfers, the receiving country Party has the right ot destroy or dispose the LMO in question or where possible require the person responsible for the illegal traffic to remove the LMO from the environment of the receiving country Party at his own expense.

3. Each Party shall develop appropriate national/domestic legislation to prevent or punish illegal traffic.

Option 6

1. Any transboundary transfer of LMOs without appropriate notification to, or Advance Informed Agreement of, all States concerned, pursuant to and in accordance with the provisions of this Protocol, shall be deemed to be illegal traffic.

2. [In the case of a transboundary transfer of LMOs thereof deemed to be illegal traffic, the State of import shall have the right to destroy or dispose of the organisms or products in question.]

3. Each Party shall adopt appropriate legislative measures to prevent illegal traffic. Parties shall cooperate in this respect, with a view to achieving the objective of this Protocol.

ARTICLE 26 - SOCIO-ECONOMIC CONSIDERATIONS

Option 1

Socio-economic considerations should not be dealt with in the Protocol.

Option 2

1. Parties shall ensure that the socio-economic impacts of the introduction of living modified organisms and products thereof are appropriately considered during the assessment and management of risks. In particular, the user shall take due account of the long observation period that these socio-economic impacts may require to manifest such adverse consequences as genetic erosion and associated loss of income and dislocation of traditional farmers and farm products.

2. A Party that intends to produce, using a living modified organism, a hitherto imported commodity, shall notify the other Party or Parties whose export is to be affected long enough, and in no case less than seven years in advance so as to enable them to diversify their production and to implement measures concerning the biodiversity that would be reduced following the disruption of production of the commodity in question. The Party substituting its import in such unnatural way shall, when the affected Party is a

developing country, provide financial and technical assistance to the affected Party.

Option 3

1. The Parties hereby agree that socio-economic imperatives must be taken into account at all levels, during the transfer, handling or use of LMOs. To this end, the intending country Party shall ensure that the risk assessment prepared by it or person or entity under its jurisdiction under Article 12 shall incorporate specific assessments on the socio-economic effects and impacts of the transfer, handling or use of the LMO to or within the receiving country and its environment, in particular to the conservation and sustainable use of biological diversity, taking into account its human health, agriculture and welfare.

2. The risk assessment shall in particular include an assessment of whether introduction of LMOs in the environment of the receiving country may entail a displacement of a particular agricultural and resource use system or the culture and livelihood of the local people.

3. The intending Party shall ensure that the risk-management strategies and measures proposed to be implemented by the receiving country Party under Article 13 shall incorporate strategies and measures that will minimize, prevent or mitigate the potential socio-economic effects and impacts within the receiving country Party, in particular where the introduction of LMOs in the environment of the receiving country Party may entail a displacement of a particular agricultural or resource use system or the culture and livelihood of the local people.

Option 4

1. The Parties shall ensure that the socio-economic impacts specific and unique to the use of living modified organisms that may manifest adverse consequences are appropriately considered during the assessment and management of risks taking into account the fact that socio-economic considerations will vary considerable from Party to Party.

2. Parties shall encourage research on socio-economic considerations relating to the use, handling and transfer of living modified organisms and the exchange of the results of such research.

ARTICLE 27 - LIABILITY AND COMPENSATION

Option 1

Liability and compensation should not be dealt with in the Protocol.

Option 2

Liability and compensation should only be dealt with by reference to paragraph 2 of the Article 14 of the Convention.

Option 3

1. If harm, including transboundary harm, arises as a consequence of living modified organisms or activities or products involving such organisms, the State or States of origin shall be bound to negotiate with the affected State or States to determine the legal consequences of the harm, and the State or States of origin shall be strictly liable and the harm must be fully compensated.

2. If the harm, including the transboundary harm, proves detrimental to human or animal health, biological diversity, the environment or the socio-economic welfare of the affected State:

(a) The State of origin shall bear the costs of any operation to restore, as far as possible, the conditions that existed prior to the occurrence of the harm. If it is impossible to restore these conditions fully, agreement may be reached on compensation, monetary or otherwise, between the State of origin and the affected State for the deterioration suffered;

(b) If, as a consequence of the harm referred to in the preceding subparagraph, there is also harm to persons or damage to property in the affected States, payments by the State of origin shall also include compensation for such harm.

3. In the cases referred to in paragraph 2, if there is more than one State of origin, they shall be jointly and severally liable for the resulting harm, without prejudice to any claims which they may bring among themselves for their proportionate share of liability.

4. There shall be no liability on the part of the State of origin if the harm was directly due to a natural catastrophe of an exceptional, inevitable and irresistible character.

5. Proceedings in respect of liability under this Article shall lapse after a period of five years from the date on which the affected Party learned, or could reasonably be expected to have learned, of the harm and of the identity of the state of origin or the user, as the case may be. In no event shall proceedings be instituted once 150 years have elapsed in the case of trees, and 30 years in all other cases since the date of the occurrence of events or the accident that caused the harm. If the cause of the harm consisted of a series of occurrences, the 150 or the 30 years duration shall start from the date of the last occurrence.

6. The preceding paragraphs shall not prevent:

(a) The Parties from adopting and elaborating further the rules of liability and enforcement of judgements;

(b) Any Party from submitting its claim to the World Biosafety Court, or to arbitration, or to the International Court of Justice, or to conciliation;

(c) A Party, or any individual or legal entity represented by a Party, that considers it has been injured as a consequence of an activity or product involving living modified organisms, from submitting a claim to the courts of the State of origin or, where access to courts is permitted by domestic law, to

the courts of the affected State. In that case, however, the affected State may not use the diplomatic channel to claim for the same harm for which such claim has been made.

Option 4

1. While importing Parties remain responsible for the use of living modified organisms, and products thereof, within their national territories, exporting Parties shall be liable for any negative or harmful effects of living modified organisms, or products thereof, which could not have reasonably been foreseen on the basis of the information provided at the time of the first import.

2. Exporting Parties shall also be liable for any negative or harmful effects produced as a result of any breach of the obligations under this Protocol.

3. Exporting Parties shall also be liable for all forms of unauthorized, uninformed or otherwise illegal transboundary movements of living modified organisms and products thereof, including, inter alia:

(a) Unsafe packaging;

(b) Fraud, falsification of approval; or

(c) Material exported that does not conform with information provided by exporting Party.

4. The Parties from which unintentional transboundary movements of living modified organisms originate shall pay any costs incurred as a result of the unintentional movements and shall be liable for any resulting negative or harmful effects.

5. All cases of proven liability shall result in the payment of fair and adequate compensation by the exporting Parties to Parties affected.

6. If necessary, the importing Parties may impound, destroy or re-export unauthorized living modified organisms, or products thereof, at the cost of the exporting Party.

Option 5

1. The exporter shall be liable for and shall fully compensate any damage deriving from the transboundary movement of LMOs, in accordance with the provisions of the present Protocol.

Option 6

1. The Parties shall cooperate with a view to adopting in accordance with Article 14, paragraph 2, of the Convention, appropriate rules and procedures in the field of liability and redress, including restoration and compensation for damage to the conservation and sustainable use of biological diversity.

Option 7

1. Parties are responsible for the fulfilment of their international obligations concerning the conservation and sustainable use of biological diversity and preservation of the environment. They shall be liable in accordance with international law.

2. Parties shall ensure that recourse is available in accordance with their legal systems for prompt and adequate compensation or other relief in respect of damage caused by the use, handling and transfer of living modified organisms by natural or juridical persons under their jurisdiction.

3. With the objective of assuring prompt and adequate compensation in respect of all damage cause by the use, handling and transfer of living modified organisms, Parties shall cooperate in the implementation of existing international law and the further development of international law relating to responsibility and liability for the assessment and compensation of damage and the settlement of related disputes, as well as, where appropriate, development of criteria and procedures for payment of adequate compensation, such as compulsory insurance and compensation funds.

ARTICLE 28 - FINANCIAL MECHANISM AND RESOURCES

Option 1

1. The financial mechanism defined in Article 21 of the Convention, as well as the institutional structure carrying out its operation, shall serve as the financial mechanism and institutional structure for the purposes of this Protocol.

2. Additional funding for the purposes of implementing the provisions of this Protocol shall be provided to the financial mechanism by developed country Parties in a predictable and timely manner.

3. On matters related to activities under the provisions of this Protocol, the financial mechanism, as well as the institutional structure carrying out its operation, shall function under the authority and guidance of, and be accountable to, the Conference of the Parties.

4. The developed country Parties may also provide, and developing country Parties avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Option 2

The developed country Parties may provide, and developing country Parties avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

ARTICLE 29 - CONFERENCE OF THE PARTIES

1. The Conference of the Parties to the Convention shall serve as the supreme body of this Protocol and shall be able to exercise all of its functions in this capacity.

2. In accordance with Article 32, paragraph 2, of the Convention, when the Conference of the Parties exercises its functions in relation to this Protocol, decisions shall be taken only by those of its members that are, at the same time, Parties to this Protocol.

3. When the Conference of the Parties exercises its functions in relation to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at the same time, not a Party to this Protocol, shall be substituted by an additional member to be elected by and from the Parties to this Protocol.

Option 1

4. The Conference of the Parties, acting in relation to this Protocol, shall, at its first meeting after the entry into force of this Protocol, decide upon modalities for the conduct of business on matters relating to this Protocol.

Option 2

4. The members of the Conference of the Parties whose members are, at the same time, Parties to the Protocol, shall, at the first meeting of the Conference of the Parties after the entry into force of this Protocol, decide upon modalities for the conduct of business on matters relating to this Protocol.

5. Without prejudice to paragraphs 1 to 4 above, the Parties to this Protocol may also meet at any such times as may be deemed necessary by the Parties to this Protocol.

ARTICLE 30 - SUBSIDIARY BODIES AND MECHANISMS

1. Subject to Article [financial mechanism and resources], the subsidiary bodies and mechanisms of the Convention shall, where appropriate, serve as subsidiary bodies and mechanisms for this Protocol.

Option 1

When a subsidiary body exercises its functions with regard to matters concerning this Protocol, decisions shall be taken only by the Parties to the Protocol.

Option 2

Delete Article 30, paragraph 2.

ARTICLE 31 - SECRETARIAT

1. The Secretariat established by Article 24, paragraph 1, of the Convention shall serve as the Secretariat to this Protocol.

Option 1

To the extent that these are distinct, the costs of Secretariat services for this Protocol shall be met by the Parties hereto. A Trust Fund is hereby established for this purpose.

Option 2

To the extent that these are distinct, the costs of Secretariat services for this Protocol shall be met by the Parties hereto on a voluntary basis. A Trust Fund is hereby established for this purpose.

ARTICLE 32 - JURISDICTIONAL SCOPE

Article 4 of the Convention shall apply to this Protocol.

ARTICLE 33 - RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol. 8/

ARTICLE 34 - RELATIONSHIP WITH OTHER INTERNATIONAL CONVENTIONS

Option 1

The provisions of this Protocol shall not affect the rights and obligations of any Party to this Protocol deriving from any existing international agreement to which it is also a Party at the time that this Protocol enters into force for that Party.

Option 2

The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.

8/ This provision potentially allows for the provisions of the Convention on, for example, settlement of disputes; amendment; adoption and amendment of annexes; and right to vote to apply to the Protocol.

ARTICLE 35 - MONITORING AND COMPLIANCE

Option 1

The Parties to this Protocol shall, at their first meeting, determine how to establish procedures and institutional mechanisms for determining non-compliance with the provisions of this Protocol and for the treatment of Parties found in non-compliance.

Option 2

The Parties to this Protocol shall determine whether to establish procedures and institutional mechanisms for determining non-compliance with the provisions of this Protocol and for the treatment of Parties found in non-compliance.

Option 3

1. Parties shall introduce, as necessary, implement and enforce national compliance and monitoring systems, taking into account, as appropriate, recognized international standards and guidelines.

2. Parties shall provide information on national monitoring and compliance systems to the Clearing-house.

3. Parties should provide information on any significant incidents of illegal traffic to the Clearing-house.

Option 4

1. Each Party shall report annually to the Secretariat and the Clearing-house on the steps taken to implement this Protocol. Reports shall, in particular, include information on the status of living modified organisms released deliberately or accidentally, and on the operation of the advance informed agreement system.

2. Each Party shall ensure that monitoring of activities and products involving living modified organisms is undertaken at regular intervals by the user and the same is reported to the competent authority.

ARTICLE 36 - ASSESSMENT AND REVIEW OF PROCEDURES/ANNEXES

Beginning in [ ], and at least every five years thereafter, the Parties shall assess the procedures and annexes provided in this Protocol on the basis of available scientific, environmental and technical information. At least one year before each assessment, the Parties shall convene appropriate panel of experts and determine its composition and terms of reference. Within one year of being convened, the panels will report their conclusions, through the Secretariat, to the Parties.

ARTICLE 37 - SIGNATURE

This Protocol shall be open for signature at [ ] by all States and any regional economic integration organization from [ ] until [ ] , and at the United Nations Headquarters in New York from [ ] to [ ].

ARTICLE 38 - RATIFICATION, ACCEPTANCE, OR APPROVAL

1. In accordance with Article 34 of the Convention, this Protocol shall be subject to ratification, acceptance or approval by States and by regional economic integration organizations. Instruments of ratification, acceptance or approval shall be deposited with the Depositary.

2. Any organization referred to in paragraph 1 above which becomes a Party to this Protocol without any of its member States being a Party hereto shall be bound by all the obligations under the Protocol. In the case of such organizations, one or more of whose member States is a Party to this Protocol, the organization and its member States shall decide on their respective responsibilities for the performance of their obligations under the Protocol. In such cases, the organization and the member States shall not be entitled to exercise rights under the Protocol concurrently.

3. In their instruments of ratification, acceptance or approval, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

ARTICLE 39 - ACCESSION

1. In accordance with Article 35 of the Convention, this Protocol shall be open for accession by States and by regional economic integration organizations from the date on which the Protocol is closed for signature. The instruments of accession shall be deposited with the Depositary.

2. In their instruments of accession, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

3. The provisions of Article [Ratification,] paragraph (2), shall apply to regional economic integration organizations which accede to this Protocol.

ARTICLE 40 - ENTRY INTO FORCE

1. In accordance with Article 36, paragraph 2, of the Convention, this Protocol shall enter into force on the ninetieth day after the date of deposit of the [ ] instrument of ratification, acceptance, approval or accession.

2. This Protocol shall enter into force for a Party that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph (1) above, on the ninetieth day after the date on which that Party deposits its instrument of ratification, acceptance, approval or accession, or on the date on which this Protocol enters into force for that Party, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

ARTICLE 41 - RESERVATIONS

Option 1

No reservations may be made to this Protocol.

Option 2

Delete Article 41.

ARTICLE 42 - WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notifications to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

3. Any Party which withdraws from the Convention shall be considered as also having withdrawn from this Protocol.

ARTICLE 43 - AUTHENTIC TEXT

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

Appendix

ANNEXES TO THE PROTOCOL

Note by the Co-Chairs

The contact group adopted the consolidated text from the Chairman'sdraft content of text items (UNEP/CBD/BSWG/3/Inf.4), amended only by removal of the chapeau in Annex I, as consolidated draft text to be negotiated later. This decision was taken by the contact group with the explicit understanding that these draft annexes may or may not form part of the protocol, that annexes and proposed annexes contained in all government and regional economic integration organization submissions would be considered for future inclusion and that the list of annexes and proposed annexes to be considered for the protocol would remain open for any future additions. In particular, the following proposed annexes would remain on the agenda for future consideration:

* Requirements/guidelines for the use of LMOs in contained facilities;

* Information requirements for unintentional release/transboundary movement;

* Information requirements for notifications;

* Lists of and criteria for LMOs, genes/traits and activities with LMOs to which the Protocol shall not apply;

* Relevant information on LMOs [in relation to EU submission Article 4(4)];

* Cases of explicit consent [in relation to EU submission Article 7(2)];

* Information requirements for simplified procedures.

Annex I

INFORMATION REQUIRED IN ORDER TO OBTAIN ADVANCE INFORMED AGREEMENT

(a) Name and address of exporting company/institution.

(b) Name and address of receiving company/institution.

(c) Origin, common name and taxonomic status of recipient organism.

(d) Description of all traits introduced or modified and characteristics of the organism.

(e) Purpose and methodology of the genetic modification (and stability of introduced genetic material.

(f) A complete risk assessment report on the living modified organism in accordance with the risk assessment parameters stated in Annex II of

the protocol including as far as possible the conditions in the State of import. Taking particularly into account releases in centers of origin for the LMO, the State of export shall also evaluate whether the LMOs in question may establish viable populations or may hybridize with local species in the receiving environment.

(g) Quantity of organisms to be transferred or volume or culture and physical state.

(h) Any relevant requirements to ensure safe handling, storage, subsequent transport and use.

(i) Intended dates of transfer/movement/release/activity.

(j) Intended means of transport.

(k) Intended use of the organism.

(l) Methods for safe disposal and contingency plans in case of accidents/unintended movements.

(m) Information on experiences with previous releases and the impacts on conservation and sustainable use of biological diversity human health of such releases.

(n) Intended labelling of the LMO.

(o) Any differences between the environment of the exporting country and the environment into which the organism is to be released.

(p) Centre of origin of the organism that has been modified and areas with high genetic diversity relevant to the living modified organism).

(q) The applicable laws, procedures and guidelines of the State of export and the stage reached in the testing and observation of the living modified organism or the product thereof according to the legal and administrative requirements of the State of export.

(r) Any requirements to manage risks and to ensure safe handling (storage, transport) and use, and methods for safe disposal and appropriate emergency procedures in case of accidents.

(s) Information relating to insurance (liability and compensation).

(t) Declaration by the exporter (competent authority or the accredited agency of the Party of export) that the information is correct.

(u) Specific instructions or recommendations for storage and handling.

(v) Name of person(s) responsible for planning and carrying out the release including those responsible for supervision, monitoring and

safety, in particular, name and qualifications of the responsible scientist.

(w) Information on training and qualifications of personnel involved in carrying out the release.

Annex II to the Protocol

RISK-ASSESSMENT PARAMETERS

1. Prior to the use and release of living modified organisms an assessment as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies shall be performed. This assessment shall take the following parameters into consideration, including any other parameter deemed to be relevant:

A. General principles:

Risk assessment should, inter alia, take into account:

(a) All relevant scientific evidence and experience;

(b) The general characteristics of both the living modified organism and the parent organism, the vector used, the genetic modification and the novel trait;

(c) The intended use of the living modified organism and the nature of the receiving environment;

(d) Potential impact of the living modified organism on the environment , particularly on centers of origin and areas with high genetic diversity relevant to the living modified organism;

(e) Possible effects of the living modified organism on human health;

(f) Risk-assessment techniques developed by relevant international organizations; and details of risk assessments completed elsewhere, as appropriate.

B. Specific information requirements:

1. Characteristics of donor and recipient organisms or parental organisms:

(a) Strain, cultivar or other name;

(b) Species it is related to and degree of relatedness;

(c) The degree of relatedness between the donor and recipient organisms, or between parental organisms; pathogenicity, toxicity and allergenicity (in the case of micro-organisms, it should be noted that there are internationally accepted classification lists for human pathogens. Similar lists exist at national level for plant and animal pathogens in some countries);

(d) The natural habitat and the geographic origin of the organism, its distribution and its role in the environment;

(e) All sites from where the donor and recipient organisms or parental organisms were collected, if known;

(f) Information on the type of reproduction (sexual/asexual) and the length of reproductive cycle or generation time, as appropriate, as well as the formation of resting and survival stages;

(g) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;

(h) Phenotypic and genetic markers of interest;

(i) Ability of the organisms to survive and colonize the environment to which release, is intended or otherwise;

(j) Genetic stability of the organisms, and factors affecting the stability;

(k) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;

(l) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;

(m) Pathogenicity to humans or animals, if any;

(n) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;

(o) Known allogenicity and/or toxicity of biochemical and metabolic products;

(p) Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

2. Characteristic of the vector(s):

(a) Nature and source of the vector(s);

(b) Genetic map of the vector(s), position of the gene(s) inserted for the transfer, other coding and non-coding sequences affecting the expression of introduced gene(s), and maker gene(s);

(c) Ability of the vector(s) to mobilize and transfer genes by integration and methods for determining the presence of the vector(s);

(d) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;

(e) Potential for pathogenicity and virulence;

(f) Natural and host range of vectors;

(g) Natural habitat and geographic distribution of natural and potential hosts;

(h) Potential impacts on human and animal health and the environment;

(i) Measures for counteracting adverse impacts;

(j) Potential to survive and multiply in the environment, or to form genetic recombinants;

(k) Genetic stability of vector(s), such as hypermutability.

3. Characteristics of living modified organisms The LMO should be compared with the organism from which it is derived, examining, where relevant the following points:

(a) The description of the modifications made using gene technology;

(b) The function of the genetic modifications and/or the new insert, including any marker gene(s);

(c) Purpose of the modification and intended use in relation to need or benefit;

(d) Method of modification, and in case of transgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism;

(e) Whether introduced gene(s) integrated or extra-chromosomal;

(f) Number of insert(s) and its/their structure(s), for example, the copy number whether in tandem or other types of repeats;

(g) Products of the transferred gene(s), levels of expression and methods for measuring expression;

(h) Stability of the introduced gene(s) in terms of expression and integration;

(i) Biochemical and metabolic differences of living modified organism compared with the unmodified organism;

(j) Probability of vertical or horizontal gene transfer to other species;

(k) Activity of the expressed protein(s);

(l) Description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

(m) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(n) Health considerations;

(o) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;

(p) Allogencities, toxicities, pathogenicities and unintended effects;

(q) Autoecology of the living modified organism compared with that of the unmodified organism;

(r) Susceptibility of the living modified organism to diseases and pests compared with the unmodified organism;

(s) Detailed information on past uses including results on all experiments leading to previous releases.

(t) History of previous genetic modifications

(u) Natural and potential range of geographical distribution of the LMO and its parental organisms including information on their natural habitats, predators, prey, parasites, competitors, symbionts, commensals and hosts;

(v) Biochemical and metabolic differences of the LMO compared with those of the unmodified organisms;

(w) Probability of inserts or transferred genes to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;

(x) Description of genetic traits which may prevent or minimize dispersal of genetic material.

4. Safety considerations for human and animal health: information on the living modified organism and when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

(a) Capacity for colonization;

(b) If the living modified organism is pathogenic to humans or animals the following information is required:

(i) Diseases caused and mechanism of pathogenicity, including invasiveness and virulence, and property of virulence;

(ii) Communicability;

(iii) Infective dose;

(iv) Host range and possibilities of alteration;

(v) Ability to survive outside of the human or animal host;

(vi) The existence of vectors or other means of transmission;

(vii) Biological stability;

(viii) Allergenicity;

(ix) Availability of appropriate therapies;

(x) Comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(xi) Antibiotic-resistance patterns;

(xii) Generation time in natural ecosystems, sexual and asexual reproductive cycle;

(xiii) Information on ability to form survival structure e.g.: seeds, spores or sclerotia;

(xiv) Possible activation of latent viruses (parvoviruses);

(xv) Ability to colonize other organisms;

(xvi) Involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.;

(xvii) Classification of hazard according to existing rules concerning the protection of human health and/or the environment;

5. Environmental considerations: Information on the living modified organism and when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

(a) Factors affecting the survival, reproduction and spread of the living modified organism in the environment;

(b) Available techniques for detection, identification and monitoring of the living modified organism;

(c) Available techniques for detecting transmission of genes from the living modified organism to other organisms;

(d) Known and predicted habitats of the living modified organism;

(e) Description of the ecosystems which could be affected by accidental release of the living modified organism;

(f) Possible interactions between the living modified organism and other organisms in the ecosystem which might be affected by accidental release;

(g) Known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, being a vector of pathogens, allergenicity, and colonization;

(h) Possible involvement in biogeochemical processes;

(i) Availability of methods for decontamination of the area in case of accidental releases;

(j) Effects on agricultural practices with possible undesirable impacts on the environment.

(k) purpose and scale of the release;

(l) Geographical description and location of the release;

(m) Proximity to residences and human activities;

(n) Method and frequency of release;

(o) Training and supervision of personnel carrying out the work;

(p) Expected environmental conditions during the release

(q) Subsequent treatment of the site and plans for waste management.

6. Release of GMOs for biological control: Apart from compliance with the general principles, other specific factors that should be taken into consideration can include:

(a) Effect on species targeted for biological control, parent organism and probable effect on ecosystem;

(b) Host range specifiicities as to whether there will be possibilities of GMOs affecting non-target species;

(c) Secondary effect on predators and parasite of the target species;

(d) Effect of secondary metabolities produced by GMOs on other organisms in the food chain.

7. Release experiment of GMO for bioremediation: Apart from compliance with the general principles, other specific factors that should be taken into consideration can include:

(a) Effect of the parent organism on its target substrate;

(b) Effect of GMOs on target substrate;

(c) Effect of secondary metabolities produced by a GMO on other organisms in the community/site of release;

(d) Effect of GMO on water, air or soil quality;

(e) Possible toxicity effect to other organisms that ingest the GMO;

(f) Possible dispersal of GMO from site of application and its consequences;

(g) The geographical location of the site, the identity and any special features of the receiving environments that expose them to damage;

(h) The proximity of the site to humans and to significant biota;

(i) Any flora, fauna and ecosystems that could be affected by the release, including keystone, rare, endangered or endemic species, potential competitive species and non-target organisms;

(j) The potential of any organism in the potential receiving environment to receive genes from the released organism.

8. Socio-economic considerations:

(a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the living modified organism or product thereof;

(b) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;

(c) Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones;

(d) Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities likely to be affected by the introduction of the living modified organisms;

(e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;

(f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the living modified organism or product thereof.

ANNEX III to the Protocol

RISK-MANAGEMENT SCHEMES

1. The user shall employ the following risk-management schemes and procedures from the development, through all stages of testing of the living modified organism or the product thereof, to its intended use or commercialization.

A. General precautions:

(a) Appropriate information and training is provided for those involved in handling the organisms;

(b) Monitoring procedures are applied in such a way that appropriate measures can be taken in case of unexpected effects during or after the release;

(c) The dissemination of the released organisms and/or gene flow from the released organisms are controlled;

(d) Controlling access to the release site;

(e) All trials, experiments or observations shall be subjected to the procedures of approval by the institutional and national level bodies;

(f) All experiments outside of strict laboratory isolation and initial experiments involving imported living modified organism shall be subject to approval;

(g) Once approval from the appropriate national authority is obtained at the completion of the final stage of the trials, experiments or observations, the living modified organisms in question can be employed for its intended use. The appropriate national authority shall notify its decision in writing to the competent authority;

(h) Whenever there is a need to dispose of the living modified organism upon the completion of every trial or experiment, it shall be made through complete incineration or other approved means of complete destruction;

(i) The release of living modified organism shall be monitored appropriately and emergency plans to prevent escape and accident shall always be in place.

B. For plants:

Applying reproductive isolation, by:

(a) Spatial separation;

(b) Temporal separation: use of plants that will flower either earlier or later than plants of nearby reproductively compatible species;

(c) Biological prevention of flowering (e.g. by omitting vernalisation);

(d) Removal of the male or female reproductive structures;

(e) Bagging of flowers;

(f) Making use of sterility;

(g) Controlling the persistence or reproductive structures such as propagates or seeds;

(h) Destroying volunteer plants after harvest; control of volunteers nay be necessary during longer periods, depending on the species. The reports from releases in areas other then the State of import shall be thoroughly evaluated by the designated authority. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;

(i) If it is decided that the previous release mechanisms have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but otherwise kept at the same soil community, moisture, air temperature and plant and animal community conditions as the intended area of release;

(j) The observations will include the health of the living modified organism, the health of the organism within the area of limited release, the biological diversity and the ecology of the area;

(k) Nationally approved limited filed releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

C. For animals:

(a) Confining by appropriate means such as fences, filters, islands, ponds;

(b) Applying reproductive isolation by using sterile animals;

(c) Isolation from feral animals of the same species;

(d) Controlling the persistence or dispersal of reproductive structures such as larvae or eggs. The reports from releases in areas other than the State of import shall be thoroughly evaluated by the designated authority. Particular emphasis shall be given to whether the applicable controls in the previous release have been adequate to ensure safety;

(e) If the controls used in the previous release have been rigorous enough, then observations will be made in complete containment in the expected ambient climatic, nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers;

(f) When the results have met the stated requirements, then a trial release may be authorized with adequate emergency plans put in place to deal with cases of escape.

D. For micro-organisms:

(a) Using organisms with impaired ability to grow or persist in the environment;

(b) Minimizing gene transfer by:

(i) Using organisms that do not contain known self-transmissible mobilizable or transposable genetic elements;

(ii) Ensuring that introduced traits are stably located on the chromosome.

These measures will often not be applicable once an LMO, such as a modified crop plant, as a result of testing during research and development, it has been shown that the risks are acceptable low.

ANNEX IV to the Protocol

FUNCTION OF FOCAL POINTS/COMPETENT AUTHORITIES

1. The competent authority/ies shall be responsible for procedures related to Advance Informed Agreement (AIA), notification and information exchange.

2. The competent authority in the State of import shall also be responsible for procedures related to risk assessment and risk management.

3. The competent authority shall fulfil the following responsibilities:

(a) To establish national guidelines and/or regulations for the implementation of the AIA procedures including detailed criteria for risk assessment within their competence;

(b) To receive from exporters applications for the AIA procedures;

(c) To conduct/evaluate risk assessment;

(d) To take a decision on result of the risk assessment;

(e) To transmit decisions on AIA to the notifier and other relevant agencies;

(f) Making decisions on the transfer, handling or use of the LMO to or within the receiving country;

(g) To establish and impose such conditions as it deems appropriate regarding the movement of LMOs in order to protect its environment and human health;

(h) To establish appropriate procedures of control or mitigation, to finish release and eliminate wastes;

(i) To establish mechanisms for information exchange between countries and to develop national databases;

(j) To keep a registry of all activities related to living modified organisms;

(k) The rest as established by this Protocol;

(l) Any other assigned by their corresponding Governments.

4. The focal point, which preferably shall be identical to the competent authority/ies, shall function as the contact point for the Protocol and shall be responsible for receiving and submitting information provided for in Articles 4, 5 & 6.

5. The focal point shall have the following responsibilities:

(a) To provide other Contracting Parties, through the Secretariat of the Protocol, with general information on the implementation of the Protocol

at the national level including, in particular, information on competent authorities responsible for the AIA procedures and/or for LMOs;

(b) To collect information on the implementation of the protocol at its national level;

(c) To assist communication between foreign, regional or international institutions established for the implementation of the Protocol on the one hand and the national competent authorities on the other;

(d) To serve as the focal point for handling inquiries and proposals regarding any intended transfer/transboundary movement/release which affects its country or any activity undertaken on LMOs within its national boundaries;

(e) To be informed immediately in the event of an adverse effect of the transfer of the LMOs which could affect it.

ANNEX V to the Protocol

INFORMATION TO BE PROVIDED TO THE SECRETARIAT UNDER INFORMATION-SHARING/CLEARING-HOUSE

1. The Parties shall facilitate and encourage the collection and exchange of information relevant to the implementation of this Protocol. The Parties shall provide the Secretariat with the following information inter alia:

(a) Designations of competent authorities/focal points and changes in such designations;

(b) The text of any national decisions/reviews about LMOs contained uses, releases, marketing and transboundary transfers under AIA;

(c) General matters relevant to risk assessment/management associated with LMOs;

(d) Information on accidental/unintentional movements of LMOs;

(e) Other relevant information ;

(f) National risk-management procedures for use and handling of living modified organisms;

(g) National institutional framework for monitoring and compliance within their territories;

(h) All living modified organisms which have been subject to bans or restrictions by that Party;

(i) Any unintentional/accidental transboundary movements of living modified organisms and biosafety measures implemented in such cases;

(j) Any releases of living modified organisms which could result in unintentional transboundary movements of living modified organisms; and biosafety measures implemented in such cases;

(k) Any incidents of unauthorized or otherwise illicit transboundary movements of living modified organisms;

(l) A list of living modified organisms subject to advance informed agreement which have been assessed for import into or use in its territory at the time of coming into force of this Protocol for that Party and a description of any conditions attached to imports of such living modified organisms;

(m) General description of products consisting of or containing LMOs having received consent by a Party or Parties for placing on the market;

(n) A summary of any methods and plans for monitoring of LMOs

(o) National guidelines and/or regulations for the implementation of the Protocol, including information required for the AIA procedures and for risk assessment;

(p) Any bilateral, regional and multinational agreements or arrangements as well as unilateral declarations on the exemption and/or the simplification of the AIA procedures;

(q) Periodical report on the implementation of the AIA procedures, including statistics;

(r) Information on LMOs released on the market;

(s) Information on prohibited, approved and newly developed LMOs;

(t) Information on monitoring post-commercial release of LMOs;

(u) Lists of experts, advisory bodies and training workshops/programmes.

Annex II

PROCEDURAL ELEMENTS FOR FUTURE WORK

Chairman's draft

1. Character of the consolidated draft

Three main features:

(a) The draft does not preclude other options than those contained in the current draft;

(b) The draft does not imply that items which are addressed in the draft should be contained in the Protocol;

(c) The consolidated draft should in its entirety be considered to be in square brackets, and the same applies for everything in the draft.

2. Continuation of the present structure

(a) The two Sub-Working Groups and the two Contact Groups should be maintained for the fourth meeting of the Working Group;

(b) The mandates of these groups, with minor revision to reflect changes in work should more or less remain as they stand, but little by little the products will probably change from producing legal text with options to the negotiation of precise language;

(c) Remaining substantive items so far not dealt with by either of the Sub-Working Groups will be assigned to Sub-Working Group II, including the preamble and the title;

(d) Contact Group II might at a later stage be used as a legal review group.

3. Work to be undertaken until the next Meeting of the Working Group

(a) In so far as legal texts are at hand in the consolidated draft, Governments are encouraged to submit further options or comments in the form of amendments to what is already available in the draft;

(b) To the extent that legal texts or options in the form of legal language have not been developed sufficiently during the third meeting, two possibilities are available:

(i) Governments could submit proposals for legal texts;

(ii) The Chairman be asked to provide legal text.

Where Governments provide submissions, the Governments must identify in a very careful manner to what item and to which precise part of that item in the consolidated text the submission refers.

Texts or amendments from Governments, as well as texts prepared by the Chairman, would be contained in one document using the same structure for reference as the consolidated draft itself.

The documents for the fourth meeting of the Working Group will be:

(i) The consolidated draft from the present meeting;

(ii) A document prepared by the Secretariat containing a compilation of legal texts or amendments submitted by Governments or the Chairman as appropriate, building on the same structure as the consolidated draft itself. Statements that are not presented in the format of legal texts will not be included. These two documents will be the basis for the work to be done in either of the four groups.

Irrespectively of the official documents for the next meeting, the Chairman will consider in which manner the process ahead might be facilitated by the means of draft articles produced by the Chairman relying in this respect to the extent possible on advice from the Co-Chairs of the two sub-working groups and of the contact groups.

4. Character of the next meeting

(a) The main task will be to complete the consolidated draft in order for it to fulfil the requirements of Article 28, paragraph 3, and to be put to the Conference of the Parties, which also implies that all substantive items that were not discussed in either of the groups at the third meeting would need to be referred to one of them at the fourth meeting for such treatment;

(b) To the extent possible negotiate legal texts in the consolidated draft.

Annex III

RECOMMENDATIONS BY THE WORKING GROUP TO THE CONFERENCE OF THE PARTIES REGARDING THE MEETINGS OF THE WORKING GROUP IN 1998

1. The Open-ended Ad Hoc Working Group on Biosafety strongly recommends to the Conference of the Parties the need for extended consultations and negotiations to the two already approved meetings in 1998. These additional consultations and negotiations would require extending the first meeting in 1998 by an additional three days and extending the second meeting in 1998 by an additional five days. A further third meeting of the Working Group in 1998 would be required in order for the Working Group to complete its work. In addition, the Working Group recommends to the Conference of the Parties that a special session of the Conference of the Parties be held following the last meeting of the Working Group at which the protocol on biosafety would be considered for adoption.

2. The Open-ended Ad Hoc Working Group recommends that the Conference of the Parties consider the necessary mechanism by which these additional meetings could be supported financially.
