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OPEN-ENDED AD HOC WORKING
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Note from the Secretariat

COMPILATION OF GOVERNMENT SUBMISSIONS ON THE DRAFT TEXT (STRUCTURED BY ARTICLE)

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COMPILATION OF NEW GOVERNMENT SUBMISSIONS OF DRAFT TEXT (STRUCTURED BY ARTICLE)

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1. GENERAL COMMENTS

GENERAL COMMENTS

ECUADOR

1. We consider it important to take into account the adverse effect that living modified organisms (LMOs) may have on the socio-economic and cultural welfare of communities.

2. Clauses should be included on the response to the notification of Advance Informed Agreement (AIA), to avoid arbitrary interpretations by the Party of export.

3. We consider that consent is necessary for subsequent imports of the same LMO.

4. The provisions of the Protocol should be peremptory, not conditional, so as to ensure due respect for the rules.

5. We consider that entering bilateral and multilateral agreements (especially regional agreements) is of great importance, as it facilitates cooperation in research and in the structuring of information systems.

6. We consider it necessary to include provisions in the Protocol on risk assessment and management.

7. The case of non-Party States should be regulated in a separate section with specific clauses.

8. The relationship of the Protocol on Biosafety with agreements on disarmament and declarations on human rights should be reviewed in regard to human genomes.

9. It is a matter of concern that the recombinant deoxyribonucleic acid (rDNA) of LMOs be transferred to wild relative organisms, which could increase risks to unpredictable levels.

10. It is a matter of concern that LMOs may produce toxic metabolites.

11. It is a matter of concern that most biotechnology research (for example, agricultural biotechnology) is not directed towards addressing problems relevant to sustainability but rather towards the area of industrial production.

12. The Protocol should contain an AIA applicable to all cases of transfers of LMOs.

13. It should be recognized that the introduction of new technologies into traditional production systems may have serious consequences for a large number of communities which depend on wild biodiversity for subsistence, particularly in States rich in that biodiversity, such as Ecuador.

14. There should be an option of access to information on carrying out risk assessments on LMOs and products thereof, even when acquired protection exists through intellectual property rights.

15. The implementation of rules on biosafety should not be considered as barriers to trade, consistent with the rules of the World Trade Organization.

16. We are concerned at the strong possibility that LMO cultivation may be carried out or increase in our country, because of certain comparative advantages, such as good soil, cheap land and labour costs, etc.

17. There should be an option for the declaration of a moratorium on any kind of trial with LMOs until the Protocol on Biosafety enters into force.

MEXICO

1. Because some options in articles and the brackets of some paragraphs still contain the concept of LMOs [and their products [or their products]] in their various versions, we consider it necessary to include also a precise definition of products derived from LMOs, to facilitate a better delimitation of scope within the Protocol and of possible consequences in the internal regulations. The spirit of this proposal is the same as that underlying the inclusion of definitions of "Release into the environment", "Contained use" and "Party of transit".

2. We suggest the addition of a new Article numbered "27 bis" under the title "Settlement of disputes" with the following content:

ARTICLE 27 BIS. SETTLEMENT OF DISPUTES.

1. Should a dispute arise between Parties in relation to the interpretation or application of or compliance with the present Protocol, the Parties shall endeavour to resolve it by negotiation or by any other peaceful means of their choice.

2. If the Parties concerned cannot reach agreement through negotiation, they shall be entitled to enlist the good offices of a third party or request its mediation.

3. At the time of ratification, acceptance or approval of this Protocol or accession to it, or at any later time, any Party or regional economic integration organization shall be entitled to declare in writing to the Depositary that, to settle any dispute that may not have been resolved under paragraphs 1 and 2 of the present Article, it accepts as binding one or both of the following means of settling such dispute:

(a) Arbitration in conformity with the procedures that may be approved by the Conference of the Parties at its first ordinary meeting;

(b) Submission of the dispute to the International Court of Justice.

4. If the Parties, by virtue of what is set out in paragraph 3 of the present Article, have not accepted that or any other procedure, the dispute shall be submitted to conciliation in conformity with paragraph 5, unless the Parties otherwise agree.

5. A conciliation commission shall be established at the request of one of the Parties in dispute. Such commission shall be composed of equal numbers

of members designated by each interested Party and a chairman jointly elected by the members designated by the Parties. The commission shall give a definitive recommendatory ruling which the Parties should take into account in good faith.

PANAMA

The Government of Panama is in agreement with:

1. The inclusion of Advance Informed Agreement, with a binding character for the transboundary movement of living modified organisms.

2. The establishment of an information system on safety in biotechnology.

3. The import and export formalities being carried out through the competent authorities designated by the Contracting Parties.

SWITZERLAND

We should like to take the opportunity offered by the present communication to reiterate the principal points of the Swiss position in regard to the content and objectives of the protocol on biosafety:

The Protocol should promote cooperation and the exchange of information between all the private and governmental actors in order to ensure a high level of safety in the use of living modified organisms in the environment. To this end, priority should be given to an instrument that is simple, practical, favours transparency, is based on scientific and environmental criteria, and that takes into account the specific needs of developing countries and countries with economies in transition. Only such a solution will permit the greatest number of States to ratify the Protocol speedily, a condition sine qua non to assure its effectiveness.

The central operating element of the Protocol must be the Advance Informed Agreement (AIA) procedure applied to the transboundary movement of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity. This procedure should ensure the exchange of all the information necessary to assess the impacts of the use of living modified organisms in the environment. States should take the necessary measures so that "researchers and industry" meet the obligations set by AIA.

The Protocol should integrate the basic principles to be applied in regard to risk assessment and management. At a scientific and technical level, the Protocol should support cooperation in technical and institutional capacity-building and promote the harmonization of procedures at an international level.

The Protocol should give priority to issues of safety for the environment and human health. Questions of liability and compensation for damage caused to biological diversity, along with socio-economic implications could be dealt with at a later stage, in the light of studies carried out within the programme of work of the Convention on Biological Diversity.

The compatibility and, if needs be, the complementarity of the Protocol with other existing international instruments, in particular the WTO Agreements, should be ensured.

URUGUAY

ADVANCE INFORMED AGREEMENT PROCEDURES

We believe that there should be a balance of responsibilities between the importers, exporters and their respective Governments in advance informed agreement procedures.

These procedures should comprise:

1. Initial steps:

(a) An application for importation to the Party of import on the part of an importer;

(b) Accompanying information for the corresponding risk assessment.

2. The exporter shall be responsible for the provision of information and shall provide the importer with verifiable technical information on the characteristics and risks associated with the LMO, as required by the Party of import as listed in Annex 1 of the Protocol, and excluding those aspects considered irrelevant to the objectives of the Protocol.

3. The Party of export shall, directly or under its responsibility, vouch for:

(a) The information provided by the exporter, and

(b) Compliance with the requirements for entry, identity and conditions laid down by the Party of import.

4. Risk analysis (identification, assessment, management and notification) shall be the responsibility of the Government of the Party of import. The notification shall be sent to the importer, the exporter and the Party of export and shall indicate complete consent (deregulation), conditional consent, or prohibition. Risk analyses shall be based on scientific evidence and principles and shall be carried out in accordance with those principles.

5. The Government of the Party of import shall, directly or under its responsibility, verify compliance with the requirements for the transfer, handling and use of the LMO.

6. Whenever the risk analysis concludes that the prohibition of entry of the LMO in question is justified, such cases shall be communicated by the Party of import to the Database of the Protocol Secretariat, for inclusion in a list of LMOs subject to obligatory notification prior to each shipment on the part of the Party of export to the Party of import which established the prohibition.

7. Points 1 (a), 3 (b) and 5 shall apply in the case of subsequent transboundary movements in cases of conditional consent. For the reconsideration of cases subject to conditional consent or prohibited, the entire AIA procedure shall be completed.

OTHER ADVANCE INFORMED AGREEMENT PROCEDURES

In the case of LMOs included in the list of prohibited cases of the Database of the Secretariat, the time period to be specified for acknowledgement of the notification shall be a maximum of 30 days after receipt of the notification and that acknowledgement shall state the date of receipt.

Failure to acknowledge receipt shall not be interpreted as tacit consent for transboundary movement.

ILLEGAL TRAFFIC AND SOCIO-ECONOMIC CONSIDERATIONS

Provisions relating to illegal traffic and socio-economic considerations are not necessary.

VANUATU

Funds have to be made available for participation of Pacific Islanders and Small Island States including Vanuatu in the negotiations to ensure that our needs are being accommodated in the formulation of the protocol.

The protocol has to recognize the lack of resources and expertise in the underdeveloped countries such as Vanuatu to implement its provisions. Therefore, a complementary arrangement between the developed and underdeveloped or northern/southern countries to ensure equitable benefits provided for under the protocol.

Finally, Vanuatu wishes to reiterate the importance of a protocol to provide both financial and technical assistance in terms of capacity building both at the national and regional level to implement the protocol. This includes developing appropriate national and regional legal framework to effectively regulate and monitor its provisions.

2. COMMENTS BY ARTICLE

TITLE

NEW ZEALAND

We propose that the title of the Protocol should be: Protocol for the Safe Transboundary Movement of Living Modified Organisms.

PREAMBLE

ECUADOR

We accept option 2, adding "and products thereof" when reference is made to LMOs.

EUROPEAN COMMUNITY

The EC and its Member States propose the inclusion of the following recital:

Recognizing the need to take into account the precautionary principle in the context of the Protocol;"

MEXICO

Add in option 2, second paragraph, the following text in brackets:

Recalling Article 19, paragraphs 3 and 4 [, Article 15, paragraph 7] and Articles 8(g) [, 14, 16] and 17 of the Convention, and recognizing the linkages between them,

Add in option 2, after paragraph 6:

Reaffirming Principles 12, 13, 15 and 26 of the Rio Declaration on Environment and Development,

Add in option 2, after paragraph 8:

Aware that the constant development of biotechnology will enable LMOs to be improved in response to the concern of the general public with respect to their possible adverse effects.

NEW ZEALAND

We favour a modified option 1, including some elements of option 2, as follows.

Modified Option 1

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

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

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the social and economic values of biodiversity and the importance of safeguarding biodiversity through management of the introduction and release of LMOs,

Noting that where there is a risk 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 risk,

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 LMOs,

Have agreed as follows:

PANAMA

We are of the opinion that, in the Preamble, paragraph 2 on page 4 of the English version of the Protocol document contains a contradiction, and we recommend that it be removed.

Also, paragraph 5 on page 4, is similar to paragraph 7 propose that paragraph 5 be removed.

PERU

Option 1

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8(g) and 17 of the Convention,

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

agreement,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

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 (LMOs),

Have agreed as follows:

Option 2

2. [The objective of this Protocol is to ensure that transboundary movements of LMOs take place in conditions that are safe for the conservation and sustainable use of biological diversity and human health; to mitigate the harmful effects of unintentional transboundary movement; as well as to strengthen the capacities of developing countries and countries with economies in transition, inter alia, through adequate financing; to control transboundary movement; and for the environmentally sound management of the organisms subject to this Protocol.]

THAILAND

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8(g) and 17 of the Convention, and recognizing the linkages between them,

Recalling also decision II/5 of the Conference of the Parties to the Convention to develop a protocol on biosafety, specifically focusing on transboundary movement of any living modified organism (LMO) 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,

Reaffirming decision III/20 of the Conference of the Parties to the Convention and, in particular its 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 this Protocol,

Noting the potential contribution of the United Nations Recommendations on the Transport of Dangerous Goods to the implementation of the Protocol,

Recalling the support of the international community for Agenda 21 adopted by the 1992 United Nations Conference on Environment and Development and, in particular Chapter 16, 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,

Recognizing that, while properly addressing the risks from living modified organisms (LMOs) resulting from modern biotechnology the Protocol should avoid causing unnecessary delays, including through the creation of unwarranted administrative requirements for the transboundary transfer of LMOs for contained use,

Aware of 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,

Aware also of the benefit that biotechnology can bring for health agriculture and the environment and mindful that unnecessary negative impacts on biotechnology research and development and on access to and transfer of technology should be avoided.

Concerned that significant gaps in scientific knowledge remain, specifically with regard to the interaction between the environment and living modified organisms (LMOs) resulting from modern biotechnology,

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 (LMOs) resulting from biotechnology,

Recognizing also that, although considerable knowledge has accumulated, significant gaps in knowledge have been identified, specifically in the field of interaction between living modified organisms (LMOs) resulting from modern biotechnology and the environment, 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,

Determined to avoid and minimize the risks associated with the transfer, handling and use of living modified organisms (LMOs) through appropriate risk assessment and management techniques,

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 (LMOs) and products thereof,

Recognizing that the socio-economic impacts of the introduction of LMOs and products thereof should be considered in risk assessment and management, taking particularly into account the needs and concerns of developing countries,

Affirming the need to provide adequate compensation for in the event of any damage caused by or arising from the handling, transfer and use of living modified organisms (LMOs),

Conscious of the need to promote and encourage public awareness of the safe use, handling and transfer of living modified organisms (LMOs) through the development and implementation of educational and public awareness programmes, and through public participation in risk assessment and

management procedures,

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 (LMOs),

Acknowledging the need for appropriate policies and measures to develop and strengthen human resources and institutional capacities in the safe handling, transfer and use of living modified organisms (LMOs), taking due account of the needs of developing countries,

Noting that the provisions of the Protocol should contribute to the field of biosafety, based on scientific risk assessment.

Have agreed as follows:

ARTICLE 1 - OBJECTIVES

ECUADOR

We accept option 3; instead of "risks to human health" substitute "risks to human or animal health, to biodiversity, to the socio-economic and cultural welfare of communities, to agriculture and to the environment".

EUROPEAN COMMUNITY

The EC and its Member States propose the inclusion of the words ", in accordance with the precautionary principle," in the 1 st line of Option 2, paragraph 1, after the word "is". The 1 st line would thus read:

"1. The objective of this Protocol is , in accordance with the Precautionary Principle, to [contribute to ensuring an adequate ..."

NEW ZEALAND

We favour a modified option 2, as follows.

Modified Option 2

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

SLOVENIA

Revised, option 1.

THAILAND

The objectives 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.

URUGUAY

The objective of the Protocol should be confined to aspects related to the conservation of biological diversity in the terms defined by the Convention regulating it. We believe that an appropriate definition of this would be:

"The objective of the Protocol is the establishment of procedures to ensure the safe transfer, handling and use of LMOs resulting from biotechnology that might have adverse effect on the conservation and sustainable use of biological diversity".

VENEZUELA

The objective of the present Protocol is to ensure that the transboundary movement, handling and use of living modified organisms (LMOs) and products thereof, resulting from modern biotechnology, may be carried out in safe conditions so as to mitigate the adverse effects on the environment, the conservation of biological diversity, animal and human health, and the socio-economic welfare of societies.

ARTICLE 1 BIS - GENERAL OBLIGATIONS

ECUADOR

We accept option 1; we suggest leaving out paragraph no. 5 and in no. 9 beginning with the following text: "Each Party shall, in accordance with its own circumstances and capacity,...". The text on AIA of option 2 we suggest be included in option 1.

KENYA

The parties shall take all appropriate legislative and administrative measures to comply with the provisions set in this protocol for the safe transboundary movement of LMOs resulting from modern biotechnology.

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 and shall ensure that advance informed agreements measures for the input of a LMO are implemented in a transparent manner based on scientific principles and supported by the best scientific evidence.

MEXICO

Inside option 2, add a new option 5C under the same heading:

5C. Parties shall ensure that measures taken based on this Protocol do not constitute an obstacle or a disguised restriction on free trade.

Add in option 2, in paragraph 6, the following in brackets at the end: .. relevant international agreements [, and do not create and/or constitute an obstacle or disguised restriction on international trade].

NEW ZEALAND

At this stage we favour none of the current options, pending clarification of the detailed provisions of the Protocol.

PERU

(Revised)

- 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 LMOs or products thereof are undertaken in such a manner that prevents or reduces risks to human and animal health, biological diversity, the environment and socio-economic welfare of societies.

3. Parties shall not approve or allow the export of LMOs until such time as they have obtained advance informed agreement in writing from the State of import for the specific import.

4. Parties shall prohibit the export of any LMOs 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 LMOs [or products thereof] shall inform the Secretariat and the Biosafety Clearing-house of their decision.

5. No Party shall export or import LMOs 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 LMOs and products thereof.

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

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

(b) Ensure that persons involved in the development, handling, transfer, use or release of LMOs 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 LMOs or products thereof be provided to the States concerned according to the appropriate procedures of notification set out in Article [ ] of this Protocol;

(d) Prohibit the export of any LMOs [or products thereof] to a State or group of States belonging to a regional economic integration organization that includes Parties, which has prohibited imports of such LMOs by its legislation;

(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 LMOs 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;

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

(g) Require that LMOs [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;

(h) Require that LMOs [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.

8. The Parties agree that failure to provide all the necessary information available about the LMOs or products thereof and any illegal traffic are criminal.

9. 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.

10. The obligation under this Protocol of States in which the LMOs 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.

11. 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.

SLOVENIA

Revised, option 1, 9, AIA, 5B.

THAILAND

General

1. Parties shall take all [appropriate legislative and/or administrative] measures to comply with the provisions set out in this Protocol for the safe transboundary movement of LMOs resulting from modern biotechnology [, and, in particular, measures to prevent transboundary transfer of LMOs not pursuant to the provisions of the Protocol].

AIA

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, and shall ensure that advance informed agreement measures for the import of a LMO are implemented in a transparent manner, based on scientific principles and supported by the best available scientific evidence.

Information exchange

3. The Parties shall, in accordance with this Protocol, exchange information on LMOs in order to contribute to the environmentally sound management of biotechnology.

Cooperation

4. Each Party shall cooperate with other Parties for the internationally harmonized implementation of the provisions of the Protocol.

Disguised restriction on trade

5A. The Parties shall ensure that measures taken for the oversight of transboundary movement of LMOs do not create unnecessary obstacles to, and/or constitute a means of arbitrary or unjustifiable discrimination or disguised restrictions on international trade.

Additional requirements

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

Transport of LMOs

7. 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 [ ], and that the exporter shall be able to prove that the movement is in conformity with the requirements of the Protocol. 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.

Territorial sea and exclusive economic zone

8. 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.

VENEZUELA

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 LMOs or products thereof are undertaken in such a manner that prevents or reduces risks to human and animal health, biological diversity, the environment and socio-economic welfare of societies.

3. Subject to the provisions of Article 5, paragraph 4, of the present Protocol, Parties shall not approve or allow the export of LMOs until such time as they have obtained advance informed agreement in writing from the State of import, authorizing the transfer of the LMO or products thereof.

4. Parties shall prohibit the export of any LMOs 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 LMOs or products thereof shall inform the Secretariat and the Biosafety Clearing-house of their decision.

5. No Party shall export or import LMOs 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 LMOs and products thereof.

6 bis. Parties shall be entitled to impose stricter or more complete requirements based on the precautionary principle.

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

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

(b) Ensure that persons involved in the development, handling, transfer, use or release of LMOs 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 LMOs or products thereof be provided to the States concerned according to the appropriate procedures of notification set out in Article [ ] of this Protocol;

(d) Prohibit the export of any LMOs [or products thereof] to a State or group of States belonging to a regional economic integration organization that includes Parties, which has prohibited imports of such LMOs by its legislation, 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 LMOs 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;

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

(g) Require that LMOs or products thereof that are to be the subject of transfer or a transboundary transfer be packaged, labelled, and transported in conformity with the established rules and requirements;

(h) Require that LMOs 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.

8. The Parties agree that failure to provide all the necessary information available about the LMOs or products thereof and any illegal traffic are criminal. The Parties shall ensure that those committing for such acts shall take responsibility for them and compensate their victims, without prejudice to the penalties that may be established in the States of import.

9. The obligation under this Protocol of States in which the LMOs 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 such obligation may not under any circumstances be transferred to the States of import.

10. 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.

11. The Parties shall adopt plans for emergency response in the case of accidental or unintentional transboundary movements.

12. The Parties shall cooperate with other Parties for the international harmonization of the provisions of the Protocol.
12 bis. The Parties shall cooperate with developing countries in the

implementation of the present Protocol, taking due account of the needs of those countries with regard to capacity-building for the promotion of development and the transfer of sound knowledge and technology.

13. The Parties shall ensure that measures taken for the oversight of the transboundary movement of LMOs or products thereof and those relating to advance informed agreement (AIA) are not more restrictive than those applied to the same LMO produced domestically or imported from other Parties and are applied in such a manner which does not constitute a disguised restriction on international trade.

ARTICLE 2 - USE OF TERMS

ECUADOR

Ecuador suggests the wording should be: LMO means any biological entity capable of replication or actively transferring its genetic material, including viruses, of which the resulting expected genetic composition is unlikely to occur in nature or confers one or more novel traits.

JAPAN

Transboundary movement

"Transboundary movement" means an intentional movement of an LMO from the territory of a Party or non-Party into the territory of another Party.

Transit

"Transit" means transboundary movement of an LMO through the territory of a Party without having undergone the Party's national quarantine and/or customs inspection procedures.

MEXICO

Add the following definitions:

Release to the environment

The action of deliberately or accidentally introducing an LMO into a specific environment, implying the possible establishment of a population of the organism.

Contained use

The use of an LMO in safe conditions without the intention of releasing it to the environment. In the case of an accidental release of an LMO, measures shall be taken to prevent and address the harm that this might cause to biological diversity and human health.

State of transit

Any State, distinct from the State of export and the State of import, through which it is planned or is effected a movement of an LMO.

Add as an option to the definition of "Transboundary movement":

Transboundary movement

(...)
or
A transboundary movement means any movement proceeding from an area subject to the jurisdiction of one State to an area under the jurisdiction of another State, or through that area or to an area not under the jurisdiction of any State, or through this area provided that the movement affects at least two States.

NEW ZEALAND

We have the following preferences, including some modifications, amongst options given for the following terms: Export/Import, LMO, Organism, Transboundary. We also propose definitions for the following terms: Applicant, Contained Use, Deliberate Release.

Applicant

Applicant means any natural or juridical person under the jurisdiction of the Party of export and/or import who is responsible for making an application to the competent national authority of the Party of import under Article 4 of the Protocol.

Contained Use

Contained use means an operation which restricts an LMO to a particular location or locations so as to prevent escape to, or free movement into, the outside environment.

Deliberate Release

Deliberate release means allowing an LMO to move freely within the jurisdiction of a Party, without imposed restrictions on location.

Export/Import

Export and import mean, in their respective connotations, the movement into the territory of one Party from the territory of another Party.

LMO

LMO means any organism that contains genetic material which has been modified by recombinant nucleic acid technology and of which the resulting genotype is unlikely to occur in nature.

Organism

Organism means any entity capable of replication of its genetic material.

Transboundary movement

Transboundary movement means any movement from the territory of one Party to the territory of another Party.

PANAMA

In regard to the Article 2, Use of Terms, we agree that in the definition of an organism, proteins and nucleic acid sequences, which can multiply inside organisms, should be included.

PERU

LMO means any

[[biological] entity [or part thereof,] capable of [replication of [or [actively] transferring] its genetic material] [multiplication] [metabolic activity][natural propagation][reproduction of its specific genotype or whose genotype can be reproduced][,including viruses,]
[organism]

* that contains genetic material which has been [deliberately] modified
  - [by in vitro [gene] technologies]
  - [in a way that
    = [[does not][is not known to] occur naturally by reproduction or recombination]
    = [overcomes natural physiological reproduction or recombination barriers]]
  [and

* of which the resulting [,expected or unexpected,] [genetic composition][genotype]
  - [contains [foreign][transgenic] genetic material]
  - [is unlikely to occur in nature,]]

[and] [or]

[would confer] [confers]
- [one or more novel traits]
- [traits novel to the species [in the receiving environment]].

Organism[1]

Organism means any [[biological] entity [or part thereof,] capable of [replication of [or [actively] transferring] its genetic material] [multiplication] [metabolic activity][natural propagation][reproduction of its specific genotype or whose genotype can be reproduced][,including viruses].

---

[1] One delegation noted a need to include entities, e.g. nucleic acid and sequences and proteins, which can multiply inside organisms.

Transboundary movement

Transboundary movement [of an LMO [2]] means any movement [of an LMO] from [an area under the jurisdiction][the territory] of one Party[/State] to [an area under the jurisdiction][the territory] of another Party[/State].

Export

Export means the intentional movement [of an LMO] from [an area under the jurisdiction][the territory] of one Party[/State] into [an area under the jurisdiction][the territory] of another Party[/State][,but does not include transit through a third Party[/State]].

Import

Import means the intentional movement [of an LMO] into [an area under the jurisdiction][the territory] of one Party[/State] from [an area under the jurisdiction][the territory] of another Party[/State][,but does not include transit through a third Party[/State]].

Exporter

Exporter means any legal or natural person, under the jurisdiction of the Party[/State] of export, who [arranges][is responsible] for an LMO to be exported.

Importer

Importer means any legal or natural person, under the jurisdiction of the Party[/State] of import, who [arranges][is responsible] for an LMO to be imported.

Party of export

Party of export means a Party[/State] from which a [transboundary movement][export] [of an LMO] [is planned to be initiated or] is initiated.

Party of import

Party of import means a Party[/State] into which a [transboundary movement][import] [of an LMO] [is planned to be initiated or] is initiated.

SLOVENIA

LMO means any biological entity capable of replication its genetic material, including viruses.

THAILAND

LMO

LMO means any
[[biological] entity [or part thereof,] capable of [actively]

[2] At a later stage, Contact Group 2 will check the consistency of the use of the term "of an LMO" throughout the entire document.

transferring] its genetic material

[organism]

* that contains genetic material which has been [deliberately] modified
  - [by in vitro [gene] technologies]
  - [in a way that
  = [is not known to] occur naturally by reproduction or recombination]

[and

* of which the resulting [genetic composition]
  - [contains [transgenic] genetic material]
  - [is unlikely to occur in nature,]]

[or]

[would confer] [confers]
- [one or more novel traits]
- [traits novel to the species.

Organism

Organism means any [biological] entity [or part thereof,] capable of [actively] transferring] its genetic material].

Transboundary movement

Transboundary movement [of an LMO [1/]] means any movement [of an LMO] from [the territory] of one Party[/State] to [the territory] of another Party[/State].

Export

Export means the intentional movement [of an LMO] from [the territory] of one Party into [the territory] of another Party[/State][,but does not include transit through a third Party[/State]].

Import

Import means the intentional movement [of an LMO] into [an area under the jurisdiction][the territory] of one Party[/State] from [an area under the jurisdiction][the territory] of another Party[/State][,but does not include transit through a third Party[/State]].

Exporter

Exporter means any legal or natural person, under the jurisdiction of the Party[/State] of export, who [arranges][is responsible] for an LMO to be exported.

Importer

Importer means any legal or natural person, under the jurisdiction of the Party of import, who [is responsible] for an LMO to be imported.

Party of export

Party of export means a Party from which a [transboundary movement] [of an LMO] is initiated.

Party of import

Party of import means a Party into which a [transboundary movement] [of an LMO] is initiated.

UNITED STATES OF AMERICA

Export - omit "third Party" at the end of the sentence.

Import - omit "third Party" at the end of the sentence.

Party of Export - replace "is initiated" at the end of the sentence with "occurs".

Party of Import - replace "as initiated" at the end of the sentence with "occurs".

Add the following terms:

Field growth means the intentional introduction of LMOs into the environment for growth or propagation (e.g., sees for planting, fish for release, microbes for microremediation) for non-experimental purposes.

Field test means an experiment involving the growth or propagation of LMOs which is conducted in the environment under controlled conditions so that the LMOs will not persist in the environment.

Territory means the land, inland waterways or internal waters of a State, or the territorial sea of a State when the intentional introduction of a LMO is to take place in such territorial sea.

International transport means, for purposes of Article 15, that portion of movement that occurs after the LMO has left the Party of export and before it has entered the Party of import.

LMO - replace "in vitro gene technologies" with "recombinant DNA techniques".

URUGUAY

In the Article corresponding to "Use of terms", the key terms are "organism" and "living modified organism", and we suggest the following definitions:

Organism: Any entity capable of replicating its genetic material.

Living modified organism: An organism that contains genetic material which has been deliberately modified in a way that does not occur naturally by reproduction or recombination and confers one or more novel traits.

We also believe that in the definition of "Transboundary movement", transit should be included and should be considered as one of the transboundary operations subject to Advance Informed Agreement (AIA).

VENEZUELA

LMO

LMO means any organism that contains genetic material which has been deliberately modified by in vitro gene technologies in a way that is not known to occur naturally by reproduction or recombination, overcomes natural physiological reproduction or recombination barriers and of which the resulting, expected or unexpected, genetic composition contains transgenic genetic material and is unlikely to occur in nature.

Organism

Organism means any biological entity capable of replication or actively transferring its genetic material, with metabolic activity and natural propagation.

Transboundary movement

Transboundary movement of an LMO means any movement of an LMO or products thereof, from an area under the jurisdiction of one Party to an area under the jurisdiction of another Party, including the transit space between the two States.

Export

Export means the intentional movement of an LMO and/or products thereof from an area under the jurisdiction of one Party into an area under the jurisdiction of another Party, but does not include transit through a third State.

Import

Import means the intentional movement of an LMO and/or products thereof into an area under the jurisdiction of one Party from an area under the jurisdiction of another Party, but does not include transit through a third State.

Exporter

Exporter means any legal or natural person, under the jurisdiction of the Party of export, who is responsible for an LMO and/or products thereof to be exported.

Importer

Importer means any legal or natural person, under the jurisdiction of the Party of import, who is responsible for an LMO and/or products thereof to be imported.

Party of export

Party of export means a Party from which a transboundary movement of an LMO is initiated.

Party of import

Party of import means a Party into which a transboundary movement of an LMO is initiated.

State of transit

Any State, distinct from the Party of export and the Party of import, through which it is planned or is effected a movement of an LMO and/or products thereof.

ARTICLE 3A - THE SCOPE OF THE PROTOCOL

ECUADOR

Ecuador accepts option 1 which specifies "This Protocol shall apply to the transboundary movement, handling and use of living modified organisms..."

KENYA

This protocol applies to the transboundary movement; handling and use of LMO resulting from modern biotechnology that many have an effect on the conservation and sustainable use of biological diversity, taking into account risks to human health.

NEW ZEALAND

We have no comment at this stage pending clarification of other provisions in the draft Protocol.

PERU

(New)
Option 1

2. This Protocol shall not apply to:

(a) Transboundary movements of LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as specified in Annex X;

(b) Requirements for transport operations;

(c) Transit of LMOs and transboundary movements destined for

subsequent contained use, except as regards Articles 1 bis (General obligations) and 15 (Unintentional transboundary movements).

SLOVENIA

New, 1. This Protocol applies to the transboudary movement, handling and use of LMO resulting from modern biotechnology that may have and adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

THAILAND

1. This Protocol [shall, without prejudice to paragraph 2 below, apply] to the transboundary movement [, handling and use] of living modified organisms resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

[2. This Protocol shall not apply to:

(a) Transboundary movements of LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as specified in Annex X;

(b) Requirements for transport operations;

(c) Transit of LMOs and transboundary movements destined for subsequent contained use, except as regards Articles 1 bis (General obligations) and 15 (Unintentional transboundary movements).]

VENEZUELA

1. This Protocol shall apply to the transboundary movement, handling and use of living modified organisms resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies.

ARTICLE 3B - THE APPLICATION OF THE AIA PROCEDURE

ECUADOR

Ecuador accepts the option beginning: "Each Party shall apply the Advance Informed Agreement procedure..."

KENYA

All initial and subsequent transboundary movements of LMOs resulting from modern biotechnology or products thereof that may have an adverse effect on the conservation and sustainable use of biological diversity taking also into account risks to human health shall be subject to AIA.

NEW ZEALAND

We favour the following formulation.

The AIA procedure shall apply to all first intentional transboundary movements of an LMO intended for:

(a) contained use in the Party of import; or

(b) deliberate release into the environment of the Party of import.

NORWAY

Add at p. 13 under para. 3 B as an additional paragraph under the second Option 1:

«Each Party shall implement and enforce national provisions in order to ensure compliance with the Advance Informed Agreement procedure set out in articles…..».

Add in the second Option 1 in the first para. After of a specific LMO «for specific purposes or uses into a new state»

Add at page 15 in the second para. At the top of the page: …covered by the AIA procedure, provided they are handled in accordance with Annex XX on contained use».

PERU

(Revised)

1. Each Party shall apply the Advance Informed Agreement procedure with respect to [the transboundary movement of] all living modified organisms defined in this Protocol.

SLOVENIA

Revised, 1.

THAILAND

1. Each Party shall apply the Advance Informed Agreement procedure with respect to [the transboundary movements of] all living modified organisms defined in this Protocol.

2. The [Party 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.

URUGUAY

In regard to the application of the AIA procedure, Uruguay considers that it should only be applied to the first deliberate transboundary movement of LMOs intended for propagation, reproduction and/or multiplication, and subsequently to cases that have been subject to conditional consent or prohibition by the Party of import.

The scope of application of the AIA procedure shall not apply to:

- The LMOs whose introduction is subject to bilateral, multilateral or regional agreements exempting LMO from AIA between the Parties of such agreements;

- Organic materials which are components of LMOs but are not self-reproducible in the environment, such as DNA or RNA segments, plastids and peptides;
- Those cases (event-species-destination) which have been subject to total consent (deregulation) by the Party of import;

- LMOs, and products, subproducts or derivatives thereof intended for consumption or processing.

VENEZUELA

1. Each Party shall apply the Advance Informed Agreement (AIA) procedure with respect to the transboundary movements of all living modified organisms and/or products thereof defined in this Protocol.

ARTICLE 4 - NOTIFICATION [PROCEDURE] [FOR AIA]

ECUADOR

The wording could be as follows:

1. The Party of export shall notify, in writing in a language that is acceptable to the importer, the designated national competent authority of the receiving Party and, where applicable, the designated national competent authority of the Party of transit, prior to any intentional transboundary movement to the Party of import of any LMO or products thereof that fall under the scope of Article 3.

2. The notification to the national competent authority of the receiving Party shall contain the information specified in a list to be established by the Meeting of the Parties.

3. Each Party shall make its importer or exporter, as the case may be, responsible for the accuracy of the information provided in the notification and for any new information provided.

NEW ZEALAND

We favour the following modification of option 1.

(1) Each applicant shall apply in writing to the competent national authority of the Party of import prior to the transboundary movement to the Party of import of any LMO that falls under the scope of Article 3B.

(2) The application to the competent national authority of the Party of import shall contain the information specified in Annex I, and any additional information required by the Party of import under Article 5.

PERU

(Revised)

1. The designated national competent authority of the Party of origin shall notify, in writing in a language that is acceptable to the importer, the national authority of the receiving Party and, where applicable, the designated national competent authority of the Party of transit, prior to any intentional transboundary movement to the Party of import of any LMO or products thereof.

2. The notification to the national competent authority of the receiving Party shall contain the information specified in Annex I.

3. The Party of export shall be responsible for the accuracy of the information provided in the notification and any new information provided.

THAILAND

1. [The importer] shall notify in writing [the national authority of the receiving Party and, where applicable, the designated national authority of the Party of transit] of the Party of import prior to [any] [intentional] transboundary movement to the Party of import of [any] LMO [or products thereof] [that fall[s] under the scope of Article 3].

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

OR

3. [Each Party shall make [its importer] responsible for the accuracy of the information provided in the notification and for any new information provided.

UNITED STATES OF AMERICA

Paragraph 1 at the end of the paragraph add: "Only one notification need be sent to the Party of import concerned."

URUGUAY

VENEZUELA

1. The designated national competent authority of the Party of export, at the request of the exporter, shall notify, in writing in a language that is acceptable to the Party of import, the designated national competent authority of the Party of import and, where applicable, the competent authority of the Party of transit, prior to any intentional transboundary movement to the Party of import of any LMO and/or products thereof.

2. The notification shall contain the information specified in Annex I.

3. The Party of export shall ensure that its exporter shall be responsible for the accuracy of the information provided and for any new information provided.

ARTICLE 5 - RESPONSE TO [AIA] NOTIFICATION

ECUADOR

Ecuador accepts option 1, omitting subparagraph (a) of paragraph 6, page 19.

NEW ZEALAND

We favour the following modification of option 1.

Modified Option 1

(1) The competent national authority of the Party of import shall, within X days of receipt of the application, inform the applicant whether the application is complete or whether further information is needed.

(2) If further information is needed, the competent national authority shall, within a period of X days following receipt of the requested further information, notify the applicant that the application is complete.

PERU

(Revised)
Option 1

1. The Party of import shall acknowledge receipt of the notification, in writing, to the competent authority of the Party of export within [X] days.

2. The acknowledgement shall state the date of receipt of the notification.

3. Failure to acknowledge will not imply consent for transboundary movement.

4. The Party of import may, within the period of time referred to in paragraph 1, inform the notifier whether to proceed according to the Party of import's domestic regulatory framework, provided that the framework is consistent with this Protocol, or according to the procedures provided for in Article 6 of this Protocol.

5. The Party of import shall within X days inform the notifier whether the notification contains prima facie the required information or whether further information in accordance with Annex II is needed or whether an extended period of time to respond is needed.

6. The Party of import shall, within the period of time referred to in paragraph 1, inform the notifier whether, at the end of the period specified in Article 6:

(b) The intentional transboundary movement may proceed only after the Party of import has given its written consent.

SLOVENIA

Revised, option 1; 5/6.

THAILAND

Option 1

No acknowledgment of receipt is required.

Option 2

1. The Party of import shall acknowledge receipt of the notification, in writing, to the applicant [within [30] days].

2. The acknowledgment shall state the date of receipt of the notification [and inform the notifier whether the notification is in the correct form and it is accepted for consideration].

3. Failure to acknowledge will not imply consent for transboundary movement.

4. The Party of import [shall], within the period of time referred to in paragraph 1, inform the notifier whether to proceed according to the Party of import's domestic regulatory framework, provided that the [framework is consistent with this Protocol, or according to the procedures provided for in Article 6 of this Protocol].

VENEZUELA

1. The Party of import shall acknowledge receipt of the notification, in writing, to the designated national competent authority of the Party of export within 15 days from the date of receipt of the notification.

2. The acknowledgement shall state the date of receipt of the notification and inform the notifier whether the notification is in the correct form and is accepted for consideration.

3. Failure to acknowledge will not imply consent for transboundary

movement.

4. The intentional transboundary movement may proceed only after the Party of import and the Party of transit have given their written consent.

ARTICLE 6 - DECISION PROCEDURE FOR AIA

ECUADOR

Reference should be made to animal health, the socio-economic and cultural welfare of communities, of agriculture, and of the environment. Subparagraph (a) of paragraph 2, page 20, should be omitted. Paragraph 9 could read as follows: "If, after acknowledgement of receipt and after repeat notification to the Party of import, the Party of import does not respond within the period specified under paragraph [ ], the Party of export shall not allow the exporter to commence with the proposed transfer until the AIA of the Party of import has been received. The competent authority of the Party of import shall be deemed to have prohibited import of the LMO concerned.

KENYA

The international transboundary movement may proceed only after the party of import has given its written consent.

NEW ZEALAND

We favour the following modification.

1. Decisions shall be based on scientific principles and supported by the best available scientific evidence.

2. Within X days of receipt of a complete application, the competent national authority shall respond in writing to the applicant with:

(a) a decision to approve the import of an LMO without conditions;

(b) a decision to approve import into containment with specific conditions;

(c) a decision to prohibit import.

3. The transboundary movement of any LMO should not proceed without the authorisation, or contrary to the decision, of the competent national authority of the Party of import.

PERU

1. Decisions shall be based on scientific information provided by the exporter, including technical experience, taking also into account risks to human health, in accordance with Annex II.

2. The Party of import shall within the period of time referred to in [Article 5] inform the notifier that:

(b) The intentional transboundary movement may proceed only after the Party of import has given its written consent.

3. 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 an annex, a transboundary movement cannot proceed without an explicit consent.

4. The Party of import shall, within [X] days, inform the notifier whether the notification contains prima facie the required information or whether further information is needed or whether an extended period of time to respond is needed.

5. Within [X] days of acknowledgement of receipt of notification in accordance with a time-frame determined by the Party of import, the Party of import shall respond, in writing, to the notifier with:

(a) A decision to approve the import, with or without conditions;

(b) An absolute or provisional decision to prohibit import, based on the best available scientific evidence, including technical experience, scientific risk assessment of adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

6. In cases where the State of import, in applying the precautionary principle, considers that the information provided [by the notifier] is not sufficient in order to determine the potential adverse effects of an LMO, or determines that there are potential adverse effects of an LMO, the State of import has the right to prohibit the import of the LMO in question. Lack of full scientific certainty or of scientific consensus shall not prevent the [State of import] [Party of import] from prohibiting the import of the LMO in question.

7. The transboundary movement of any living modified organisms should not take place without the authorization, or contrary to the decision, of the receiving Party.

8. Should the importing Party impose conditions on the import, deny permission for the import, or request additional information, it shall state its reasons in writing to the notifier, including information on the legislative and/or administrative measures on which its decision is based.

9. The Party of import has the right to address the consequences of its failure to respond following a notification, according to its domestic legislation as it sees appropriate, in accordance with the principles set out in this Protocol.

SLOVENIA

1. Decisions shall be based on scientific risk assessment of the adverse effect on the conservation and sustainable use of biological diversity in accordance with Annex II.

2. (b) The intentional transboudary movement may proceed only after the Party of import has given its written consent.

4. The Party of import shall within X days inform the notifier whether the

notification required is complete or whether further information in accordance to Annex II is needed or whether an extended period of time to respond is needed.

5. Within XXX days of receipt of notification the Party of import shall respond to the notifier with:

(a) A decision to approve imports, with or without specified conditions;

(b) Decision to prohibit import, based on the best available scientific evidence, including technical experience, scientific risk assessment of adverse effects on the conservation and sustainable use of biological diversity in accordance with Annex II;

(c) A request for additional relevant scientific and technical information before allowing or prohibiting the import;

(d) Determining whether and how the decision applies to subsequent imports of the same LMO;

(e) Determining whether notification is required fro subsequent imports of the same LMO, in accordance with Article 10;

(f) Informing the notifier that the period specified in this paragraph is extended by a defined period no longer than XX days.

6. In cases where the Party of import in applying the precautionary principle considers that the information provided by the [notifier] is not sufficient in order to determine the potential adverse effects of an LMO, or determines that there are potential adverse effects of an LMO, the State of import has the right to prohibit import of the LMO in question. Lack of full scientific certainty or of scientific consensus shall not prevent the Party of import from prohibiting the import of the LMO in question.

7. No comment

8. Should the Party of export impose conditions on the import, deny permission for the import, or request of additional information it shall state its reasons in writing to the importer. Party of export for its decision including information describing the legislative and/or administrative measures on which its decision is based.

9. OR, if the Party of import fails to communicate its final decision within X days of the transmission of the notification, the transboudary movement is no longer governed by the terms of this Protocol and the Party of export shall have no further obligations under this Protocol with respect to such transboundary movement.

THAILAND

1. Decisions shall be based on [scientific principles and supported by the best available scientific evidence[, including technical experience]], [taking also into account risks to human health] [in accordance with Annex II].

5. [In accordance with a time-frame determined by the Party of import], the Party of import [shall] respond, [in writing], to the notifier with:

(a) [A decision to approve] imports, with or without [specified] conditions;

(b) [Decision to prohibit] import, [based on the best available scientific evidence, including technical experience, scientific risk assessment of adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;]

(c) [A request for] additional relevant [scientific] [technical] information [before allowing or prohibiting the import]. When calculating the time for the Party of import to communicate its decision to the notifier under paragraph 2, the number of days for which the Party of import is waiting for additional relevant [technical] information which it has requested from the notifier shall not be taken into account;

(d) Whether and how the decision applies to subsequent imports of the same LMO;

(e) Whether notification is required for subsequent imports of the same LMO, in accordance with Article 10;

(f) [The Party of import may inform] the notifier that the period specified in this paragraph is extended by [as much time as is necessary to assess the information it has received from the [notifier] 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.]

6. In cases where the [Party of import] in applying the precautionary principle considers that the information provided by the [notifier] is not sufficient in order to determine the potential adverse effects of an LMO, or determines that there are potential adverse effects of an LMO, the Party of import has the right to prohibit import of the LMO in question. Lack of full scientific certainty or of scientific consensus shall not prevent [Party of import] from prohibiting the import of the LMO in question.

7. The transboundary movement of any living modified organisms should not take place without the authorization, or contrary to the decision, of the receiving Party.

8. Should the importing Party impose conditions on the import, deny permission for the import, [or request additional information] it shall state its reasons [in writing] to the [importer], [for its decision] including information describing the legislative and/or administrative measures on which its decision is based.

9. If the Party of import fails to communicate its final decision within [X] days of the transmission of the notification, the transboundary movement is no longer governed by the terms of this Protocol and the Party of export shall have no further obligations under this Protocol with respect to such transboundary movement.

VENEZUELA

1. Decisions shall be based on scientific information provided by the exporter, scientific principles and supported by technical experience, scientific risk assessment of the adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human and animal health, in accordance with Annex II and social, economic and cultural criteria.

2. The Party of import shall, within [X] days, inform the notifier whether the notification contains prima facie the required information, is complete or whether further information is needed and whether risk assessment or a field trial is to be carried out, or whether an extended period of time to respond is needed. The intentional transboundary movement may proceed only after the Party of import has given its written consent.

3. Within 90 days of acknowledgement of receipt of notification, the Party of import shall respond, in writing, to the notifier with:

(a) A decision to approve the import, with or without specified conditions, or a prohibition of the transboundary movement of the LMO and/or products thereof;

(b) A request for additional relevant scientific or technical information, or additional field trials, before allowing or prohibiting the import. When calculating the time for the Party of import to communicate its decision to the notifier under paragraph 2, the number of days for which the Party of import is waiting for additional relevant information shall not be taken into account;

(c) The Party of import may inform the notifier with justification that the period specified in this paragraph is extended by as much time as is necessary to assess the information it has received, 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 and/or the products thereof.

4. In cases where the State of import, in applying the precautionary principle, considers that the information provided by the notifier is not sufficient in order to determine the potential adverse effects of an LMO and/or products thereof, or determines that there are potential adverse effects of an LMO and/or products thereof, the State of import has the right to prohibit the import of the LMO and/or products thereof in question. Lack of full scientific certainty or of scientific consensus shall not prevent the Party of import from prohibiting the import of an LMO.

5. The transboundary movement of any living modified organisms and/or products thereof should not take place without the authorization, or contrary to the decision of the Party of import.

6. Should the importing Party impose conditions on the import, or deny permission for the import, it shall state the reasons for its decision in writing to the Party of export and the Clearing-house, including information on the legislative, administrative and/or technical measures on which its decision is based.

7. If, after acknowledgement of receipt, the Party of import does not respond within the period specified under paragraph 2, the Party of export shall not allow the exporter to commence with the transfer until the AIA of the Party of import has been received.

ARTICLE 7 - REVIEW OF DECISIONS [UNDER AIA]

ECUADOR

The second paragraph of subparagraph (c) of paragraph 2, page 23, should be modified to read as follows: "In such a case, the receiving Party shall be able to require the Party of origin to cover all the costs of the assessment."

NEW ZEALAND

We favour the following modification.

(1) If at any time an applicant becomes aware of relevant new information which may have significant consequences for the risks associated with an LMO, it shall immediately inform the competent national authority which has made a decision in respect of the transboundary movement of the LMO.

(2) An applicant may request the competent national authority of the Party of import to review a decision to prohibit import when the applicant considers that:

(a) a change in circumstances has occurred which may influence the outcome of the risk assessment upon which the decision was based; or

(b) additional relevant scientific or technical information has become available; or

(c) there is reasonable evidence that the decision has not been based scientific principles and supported by the best available scientific evidence.

3. A competent national authority may at any time in the light of relevant new information that may have significant consequences for the risks associated with an LMO, unilaterally review any decision made under Article 6 and employ any review mechanism established through its national legislation or any other national procedures.

PERU

1. If at any time a Party of import, export, transit or any other person has reason to believe, taking into account available scientific information, or becomes aware of relevant new information, that an LMO and/or products thereof may cause adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, the environment, biological diversity, human and animal health and agriculture, that Party may prohibit such movements or specify the conditions under which all such movements may take place. In such a case, the Party must inform the Parties concerned, the Secretariat and the Clearing-house, giving the reasons for its decision.

2. A Party of export may request a Party of import through its designated

national competent authority to conduct risk assessment in order to review a decision it has made in respect of it under Article 6 where the Party of export considers that:

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

(c) There is reasonable evidence that the decision has not been based on scientific, socio-economic, cultural or the precautionary principle and supported by the best available scientific evidence. In such a case, the receiving Party shall be able to require the Party of origin to cover some or all the costs of the assessment.

3. Exporting Parties shall provide any additional information which they consider is 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. 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.

4. A Party of import 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. In a case of dispute the costs of risk assessment will be borne by the exporter.

SLOVENIA

1. If any time a Party of transit becomes aware of relevant new information that LMO and/or products thereof cause adverse effects on conservation and sustainable use of biological diversity, human and animal health and agriculture, the Party may prohibit such movements or specify the conditions under which all such movements may take place. In such case, the Party must within the 30 days inform to the Parties concerned and the Clearing-house and giving the reasons for its decision.

2. A Party of export may request a Party of import through its national competent authority to conduct risk assessment in order to review a decision it has made in respect of it under Article 6 where the Party of export considers that additional relevant scientific or technical information has become available.

3. Exporting Parties shall provide any additional information which is 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. 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.

4. Party of import may at any time in light of 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. In a case of dispute costs of risk assessment will be borne by the exporter.

THAILAND

1. If at any time a Party of [import][becomes aware of relevant new information] that an LMO [and/or products thereof] [is likely to] cause [significant] adverse effects on [conservation and sustainable use of biological diversity,[the environment, biological diversity, human and animal health and agriculture], that Party may prohibit such movements or specify the conditions under which all such movements may take place. In such a case, the Party must [promptly], [Parties concerned,][the Party of import] [the Secretariat] [and the Clearing-house] and giving the reasons for its decision.

2. A Party of export may request a Party of import [through its designated [national] authority] to review a decision it has made in respect of it under Article 6 where the Party of export considers that:

(a) A change in circumstances has occurred which may influence the outcome of the risk assessment upon which the decision was based; [or]

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

(c) There is reasonable evidence that the decision has not been based on scientific principle[s] and supported by the best available scientific evidence.

In such a case, the receiving Party shall be able to require the Party of origin to cover some or all the costs of the assessment.

3. Exporting Parties [shall] provide any additional information which[is] 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. 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.

4. A [Party of import] may at any time in light of 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.

VENEZUELA

1. If at any time a Party of import, export, and/or transit or any other person has reason to believe, taking into account available scientific and/or technical information, or becomes aware of relevant new information, that an LMO and/or products thereof may cause adverse effects on the environment, biological diversity, human and/or animal health and/or agriculture, that Party may prohibit such movements. In such a case, the Party must promptly inform the Parties concerned, the Secretariat and the Clearing-house, giving the reasons for its decision. The Clearing-house shall as soon as possible transmit the information received to the Parties.

2. A Party of export may request a Party of import to review a decision it has made in respect of it under Article 6 where the Party of export considers that:

(a) A change in circumstances has occurred which may influence the outcome of the risk assessment upon which the decision was based;

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

(c) There is reasonable evidence that the decision has not been based on scientific, socio-economic, cultural or the precautionary principle and supported by the best available scientific evidence.

In such a case, the receiving Party shall be able to require the Party of origin to cover some or all the costs of the assessment.

3. Exporting Parties shall provide any additional information which they consider is 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. In light of new scientific evidence and information made available to the Party of import, a new application may be submitted in respect of a previously rejected application.

4. A Party of import may at any time, in light of new information or evidence, unilaterally review its decisions on any transfer, handling or use of LMOs and/or products thereof into its country and employ any review mechanism established through its national legislation or any other national procedures. In a case of dispute the costs of risk assessment will be borne by the exporter.

ARTICLE 8 - NOTIFICATION OF TRANSIT

ECUADOR

Ecuador accepts option 1.

NEW ZEALAND

Modified Option 1

1. Parties may require notification in writing to the competent national authority of other Parties' intent to transit for the first time an LMO through their territory.

2. The competent national authority of the Party of transit shall acknowledge the receipt of the notification to the notifier. Within X days of receipt of a complete notification, the competent national authority may respond in writing to the notifier:

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

(b) Denying permission for the movement.

3. If the competent national authority of the Party of transit fails to notify the notifier within the specified time frame, implicit consent shall be assumed for the transit of the LMO.

PERU

Option 1

1. The State Party of export must require notification, in writing, through the channel of the competent authority of the State of export or by providing a copy to this authority, of other Parties intent to transit a living modified organism or products thereof through their territory for a specified use or purpose. All the requirements for labelling, packaging and transportation shall be met. Where such notification is required, Parties that require notification of intent to transit living modified organisms or products thereof through their territory, the State of export should provide information to the Clearing-house on:

(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, based on that set out in Annex Y.

2. 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.

3. The State of transit may declare in writing whether or not a notification is required for subsequent transit movements of the same living modified organism or products of an LMO and it shall inform the Secretariat and previous notifiers of such decisions. The handling and transport requirements for living modified organisms referred to in Article 4 shall be followed in all transit movements.

4. The documentation provided for the transport of living modified organisms or products of an LMO must specify the care needed during their transit.

SLOVENIA

Option 1:

1. Party of export must require notification by the exporter ,in writing, through their focal point of other Parties intent to transit a living

modified organisms or products thereof through their territory for specified use and purpose as well as assuming responsibility for any case of accidental release in those State. All the requirements for labelling, packaging and transportation shall be met. Where such notification is required, the State of export shall provide information included in Annex X to the Clearing-house on:

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

2. The State of transit shall acknowledge 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 conditions;

(b) Provide an interim response, that may contain a statement to import with 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 extended period of time to respond.

3. The State of transit may declare in writing whether or not a notification is required for subsequent transit movements of the same living modified organism of the same living modified organism and products of an LMO.

4. The documentation provided for the transport of living modified organisms and products of an LMO must specify the care needed during their transit.

THAILAND

Option 2

1. [Party] of export][must] require notification [by the exporter], in writing, [through the channel of the competent authority of the State of export or by providing a copy to this authority] of other Parties intent to transit a living modified organism [or products thereof] through their territory [for a specified use or purpose] [as well as assuming responsibility for any cases of accidental release in those States]. [All the requirements for labelling, packaging and transportation shall be met]. Where such notification is required, [Parties that require notification of intent to transit living modified organisms [or products thereof], through their territory][shall] [provide information] [included in Annex X] on:

(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, [based on that set out in Annex Y].

2. 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.

3. The State of transit may declare in writing whether or not a notification is required for subsequent transit movements of the same living modified organism [or products of an LMO] and it shall inform the Secretariat and previous notifiers of such decisions. The handling and transport requirements for living modified organisms referred to in Article 4 shall be followed in all transit movements.

4. The documentation provided for the transport of living modified organisms [or products of an LMO] [shall as appropriate] specify the care needed during their transit.

VENEZUELA

1. The Party of export shall, in writing, notify the designated national competent authority of all States of transit, through the channel of its national competent authority, in a language previously agreed upon, of its intent to carry out a transboundary movement of an LMO and/or products thereof.

2. The notification shall contain the information specified in Annex I.

3. 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 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. In no case shall the transboundary movement of an LMO and/or products thereof commence without the consent of the State or States of transit.

3. The Party of export shall be responsible for the accuracy of the information provided and for any new information provided.

4. The documentation provided for the transport of living modified organisms or products of an LMO must specify the care needed during their transit.

ARTICLE 9 - SIMPLIFIED PROCEDURE

ECUADOR

Ecuador accepts option zero.

NEW ZEALAND

Modified Option 1

A Party of import may specify in advance the LMOs to be exempted from the AIA procedures where, on the basis of the best available scientific knowledge and experience, it is satisfied that there is negligible risk from release of the LMO into the environment.

PERU

Option zero
No provision for a simplified procedure in the Protocol.

SLOVENIA

Option 1, OR:

1 Parties of import may introduce simplified procedures for Advance Informed Agreement for subsequent imports of living modified organisms and products of an LMO, (rest the same)

2. If State of import decides, pursuant to this Article, to exempt certain living modified organisms and products of an LMO from the application of the AIA procedures or to apply simple notification procedures to certain living modified organisms and products of an LMO, it shall inform the Biosafety Database in writing accordingly.

THAILAND

Option 2

1. Parties of import may introduce simplified procedures for Advance Informed Agreement for [subsequent] imports of living modified organisms [or products of an LMO], provided that any relevant international standards are applied and 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.

2. If a State of import decides, pursuant to this Article, to exempt certain living modified organisms [or products of an LMO] from the application of the AIA procedures or to apply simple notification procedures to certain living modified organisms [or products of an LMO], it shall inform the [Secretariat of the Protocol] in writing accordingly. [The Secretariat shall forthwith inform all [Contracting Parties] of such decisions.]

VENEZUELA

No provision for a simplified procedure in the Protocol.

ARTICLE 10 - SUBSEQUENT IMPORTS

ECUADOR

Ecuador accepts option 3.

NEW ZEALAND

We favour no provision.

PERU

Option 3

1. Notification in writing is required for all subsequent imports of the same living modified organism [and products thereof] into the same Party of import.

2. The State of import will acknowledge receipt of notification as quickly as possible and will inform the State of export that:

(a) Importation can proceed; or

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

The provisions of this article could be reflected in Articles 6 or 9.

SLOVENIA

Option 2:

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

2. Where notification for subsequent imports is specifically requested by the importing Party, full details regarding the information shall be provided provided, in writing, to exporting Parties or exporters and to the Clearing-house. The information required shall be based on that identified in in Annex

THAILAND

Option 3

1. Notification in writing is required for all subsequent imports of the same living modified organism [and products thereof] into the same Party of import.

2. The State of import will acknowledge receipt of notification as quickly as possible and will inform the State of export that:

(a) Importation can proceed; or
(b) A new risk assessment procedure will be undertaken.

VENEZUELA

No provision for subsequent imports is necessary in the Protocol.

ARTICLE 11 - [INTERNATIONAL COOPERATION] MULTILATERAL, BILATERAL AND REGIONAL AGREEMENTS [OTHER THAN THE PROTOCOL]

AUSTRALIA

Australia wishes to see the following reflected in the text of Option 1 paragraph 1:

1. Parties may enter into bilateral, multilateral, or regional agreements or arrangements with Parties or non-Parties regarding transboundary movement of LMOs provided that adequate measures are taken to ensure the safe transboundary movement of LMOs in accordance with the objectives of this Protocol[4].

ECUADOR

Ecuador accepts option 1, with the wording in paragraph 1 of "with Parties or non-Parties" and "do not result in a lower level of protection than the one provided for by the Protocol". Omit the wording referring to AIA requirements. Omit paragraph 2 and subparagraph (b) of paragraph 3. In paragraph 4, add wording to enable bilateral, multilateral or regional agreements signed before the entry into force of this Protocol to be adapted to the guidelines of the Protocol. Include also a wording in the same terms for agreements signed after the entry into force of this Protocol.

JAPAN

/ Parties may enter into bilateral, multilateral or regional agreements or arrangements with Parties and/or non-Parties so as to:

1. cooperate for the implementation of the Protocol, in particular for cooperation in the course of risk assessment procedures;

2. identify categories of LMOs to which the simplified procedures provided for in article 9 should apply;

3. Eensure that transboundary movement of LMOs from non-Parties will be regulated in a manner compatible with the Protocol as referred to in Article 23.

/ Parties shall notify the Secretariat of such bilateral, multilateral or regional agreements or arrangements concluded with Parties and/or non-Parties.

[4] underlined text is not already reflected in the existing draft

NEW ZEALAND

Modified Option 1

Parties may enter into multilateral, bilateral or regional agreements or arrangements for the transboundary movement of LMOs provided that adequate measures are observed to ensure the safe transboundary movements of LMOs in accordance with the objectives of this Protocol.

PERU

Option 1

1. Contracting Parties may enter into bilateral, multilateral, or regional agreements or arrangements with Parties regarding procedures and information exchange relating to transboundary movement of LMOs or products of an LMO falling within the scope of this Protocol, provided that such agreements or arrangements will not derogate from the provisions of this Protocol.

2. 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.

4. Parties shall notify the Secretariat of any such bilateral, regional and multilateral agreements or arrangements entered into. Any Party may notify the Secretariat at any time that AIA provisions shall not apply with respect to imports to such Party.

5. The Parties should cooperate among themselves in exchanging information and, when appropriate, developing appropriate technical guidelines and/or codes of practice, and monitoring the benefits of modern biotechnology, 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. The Parties shall assist developing countries in the implementation of this Protocol, taking due account of their needs with respect to capacity-building in order to promote the development and transfer of safe biotechnology and knowledge.

6. A regional economic integration organization, which itself is a Contracting Party to the Protocol and has a specific framework for biosafety, may declare that the Protocol shall not apply to movements within its territory.

SLOVENIA

Option 1:

1. Contracting Parties may enter into bilateral multilateral, or regional agreements or arrangements with Parties or non-Parties regarding procedures and information exchange relating to transboundary movement of LMO's and products of an LMO in lieu of the AIA requirements that such agreements or arrangements do not derogate from the environmentally sound management of living modified organisms as required by this Protocol.

2. 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 agreements or arrangement.

3. (a) The identification of categories of LMOs and products of an LMO to which the simplified procedures provided for in Article 9 apply;

(b) A guidance to transboundary movement of LMOs and products of an LMO involving non-Parties.

4. Parties shall notify the Secretariat of any such bilateral, regional and multilateral agreements or arrangements entered into force of this Protocol.

5. The Parties shall co-operate among themselves in exchanging information, developing appropriate technical guidelines and/or codes of practice, and monitoring the benefits of modern biotechnology the effects of risks posed by living modified organisms and products thereof on biological diversity and the environment with a view to promoting the safe management of these organisms and products. The Parties shall assist developing countries in the implementation of this Protocol, taking due account of their needs with respect to capacity-building in order to promote the development and transfer of safe biotechnology and knowledge.

THAILAND

Option 1

1. [Contracting] Parties may enter into bilateral, multilateral, or regional agreements or arrangements [with Parties] [or non-Parties] regarding [procedures and information exchange relating to] transboundary movement of LMOs [or products of an LMO] [falling within the scope of this Protocol] [in lieu of the AIA requirements] [provided] [that] such agreements or arrangements] [will not derogate from the provisions of this Protocol].

[3. Bilateral, multilateral or regional agreements or arrangements give further basis for:

(a) The identification of categories of LMOs [or products of an LMO] to which the simplified procedures provided for in Article 9 apply;

(b) A guidance to transboundary movement of LMOs [or products of an LMO] involving non-Parties.]

4. [Any Party may notify the Secretariat at any time that AIA provisions shall not apply with respect to imports to such Party.]

VENEZUELA

Deleted

ARTICLE 12 - RISK ASSESSMENT

AUSTRALIA

Australia wishes to see the following reflected in the text of Option 1 paragraph 4:

4. Risk assessment for subsequent imports of the LMO into the same Party of import, may only be required if:

(a) there is a change in the intended use of the LMO;

(b) there is a change in import volume and frequency of the LMO, where such a change could increase the risk of adverse impacts on biological diversity through increased exposure in the receiving environment;

(c) there is a variation in the receiving environment;

(d) there is relevant new information or other factors likely to affect the risk assessment or risk management of the LMO;

(e) it is a condition of first import of the LMO under Article 6.

ECUADOR

Ecuador accepts option 1. Paragraph 2 should read: "Each decision based on risk assessment should be undertaken on a case-by-case basis, and be based on scientific grounds, the precautionary principle, socio-economic and cultural concerns and experience and other available scientific evidence..." We accept the first alternative of paragraph 2, with the wording: "Risk assessment as referred to in paragraph 1 above shall be undertaken, by the competent authority or any natural and legal person under its jurisdiction." We accept the second alternative of paragraph 5, with the wording beginning: "The Conference of the Parties shall establish a minimum standard..." but modifying the wording "The Conference of the Parties may establish..." to "The Conference of the Parties should establish..."

We accept the second alternative of paragraph 6, with the wording: "The exporter shall be..." We accept the second alternative of paragraph 7, with the wording "...Party of export", and the second alternative of paragraph 9 and "Elements for consideration...".

JAPAN

/ The competent authority of the Party of import shall have the right to require the exporter to provide information necessary for the implementation of the risk assessment of the LMOs. The Party of export shall take appropriate measure to ensure that such information be provided by the exporter. Should the exporter not provide such information, the competent authority of the Party of import may refuse to conduct the risk assessment procedures.

/ The competent authority of the Party of import may request the exporter or the competent authority of the exporting country for scientific, technical and technological assistance required for the implementation of the risk assessment of the LMOs. The exporter and the competent authority of the exporting country should provide such assistance to the extent possible.

KENYA

Risk assessment should be undertaken on a case by case basis in a scientifically sound, transparent manner and be based on the precautionary principle, social-economic and cultural concerns while taking into account the risks to human health, ecological and environmental concerns.

MEXICO

Add the following item:

X. (a) In risk assessment the Parties should take into account the risk assessment techniques devised by competent international organizations, available scientific information, relevant production methods and processes and inspection, sampling and testing methods; and

(b) In establishing an appropriate level of protection, the Parties shall avoid making arbitrary or unjustifiable distinctions in the levels considered appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on trade.

NEW ZEALAND

Modified Option 1

Risks assessments, upon which decisions made under Articles 6, 7 and 8 are based, shall be undertaken in a scientifically sound and transparent manner based on information supplied by the applicant in accordance, inter alia, with Annex I and any additional information required by the competent national authority of the Party of import.

NORWAY

Add at p. 25 in the first para. 2: «Each Party shall require any natural or legal person under its jurisdiction to undertake a risk assessment on the basis of Annex II prior to the first release of an LMO into a specific environment and for a specific use or purpose».

Add also in the same para 2 after the competent authority of the Party of import «prior to the first import of a specific LMO into a specific environment and for specific uses or purposes».

Add as a para 2 bis: «Each Party shall require its exporter to provide the Party of import results of the risk assessment carried out by it as required by Annex I prior to the first export of a specific LMO for specific uses or purposes into a new state.»

PERU

Option 1

1. Risk assessment should be undertaken on a case-by-case basis in a scientifically sound and transparent manner and be based exclusively on the information provided by the Party of export in accordance with Annex I, scientific grounds, the precautionary principle, socio-economic and cultural concerns and experience, on scientific information provided by the exporter and other available scientific evidence, to identify and evaluate the possible adverse effects due to the genetic modification of that LMO or products thereof on the conservation and sustainable use of biological diversity, taking into account the risks to human health, agriculture, human and animal health, ecological stability concerns and social and ethical considerations as the basis for decisions under the AIA procedure.

2. The importing Party may ask the exporter notifier to carry out the risk assessment. The importing Party may then ask for the results of the risk assessments carried out by the exporter or verify that the assessment was carried out according to international standards. The importing Party shall then be responsible for the risk assessment.

3. Each Party shall determine for itself, in accordance with its own legislation, the institutional arrangements for the conduct of risk assessments under this Protocol and for the preparation of technical findings in relation to requests for transboundary movement.

4. Risk assessment shall be required to be undertaken prior to the import, use, transboundary movement or handling of LMOs to or within the State Party of import and for subsequent imports of the same LMO into the same State of import at the discretion of the State of import, except for the following cases where alternative procedures for risk assessment shall be required:

(a) Where there is a change in the intended use of the LMO;

(b) Where there is a variation in the receiving environment; or

(c) Where there are other factors likely to affect the risk assessment or risk management of the LMO.

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

6. The exporter is responsible for the reliability of the information provided.

7. The financial responsibility for risk assessment shall rest with the Party of export.

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

9. Parties shall ensure that risk-assessment and management processes of microorganisms are conducted in contained conditions.

SLOVENIA

Option 1:

1. Risk assessment shall be undertaken on a case-by-case basis on scientific information provided by the importing and/or exporting Party to identify and evaluate the possible adverse effects of that LMOs or products of an LMOs on the environment of the State of import as regards in particular conservation and sustainable use of biological diversity as the basis for decision under the AIA procedures.

2. Risk assessment as described in Annex X and as referred to in paragraph 1 above shall be undertaken by the Party of import who intends to undertake a transfer of an LMO and the Party of export.

THAILAND

1. [Risk assessment] [shall] be undertaken [on a case-by-case basis] [in a scientifically sound [and transparent] manner] on [the information provided by the Party of export in accordance with Annex I] [scientific grounds, the precautionary principle, socio-economic and cultural concerns and experience] [on scientific information provided by the [exporter] [importer] and other available scientific evidence] to identify and evaluate the possible adverse effects [due to the genetic modification] of [that] LMO[s] [or products [of an LMO]] [thereof] on [the environment of the State of import as regards in particular] conservation and sustainable use of biological diversity, [taking into account the risks to human health], [agriculture, human and animal health], [ecological stability concerns] [and social and ethical considerations][as the basis for decisions under the AIA procedure[s]].

2. The importing Party may ask the exporter [notifier] to carry out the risk assessment. The importing Party may then ask for the results of the risk assessments carried out by the exporter [notifier] or verify that the assessment was carried out according to international standards. The importing Party shall then be responsible for the risk assessment.

3. Each Party shall determine for itself, in accordance with its own legislation, the institutional arrangements for the conduct of risk assessments under this Protocol and for the preparation of technical findings in relation to requests for transboundary movement.

4. Risk assessment [shall] be [required to be] undertaken [prior to the [first] [release] of an LMO [a specific LMO for specific uses or purposes] [into the environment]][and for subsequent imports of the same LMO into the same State of import at the discretion of the State of import, except for the following cases where [alternative procedures for] risk assessment shall be required:

(a) Where there is a change in the intended use of the LMO;

(b) Where there is a variation in the receiving environment; or

(c) Where there are other factors likely to affect the risk assessment or risk management of the LMO].

5. Risk assessments as described in paragraph X of this article [shall] [be carried out in accordance with Annex X] [and take into account existing guidelines relevant to biosafety]. A Party of import may, however, apply parameters additional to those specified in that Annex.

6. The [importer] is responsible for the reliability of the information provided.

7. No provision on financial responsibility for risk assessment is necessary.

OR

7. The financial responsibility for risk assessment shall rest with the [notifier].

9. Parties shall ensure that risk-assessment and management processes of microorganisms are conducted in contained conditions.

VENEZUELA

1. Risk assessment should be undertaken by the exporter on a case-by-case basis and be based exclusively on the information provided by the Party of export in accordance with Annex I, scientific grounds, the precautionary principle, socio-economic and cultural concerns and experience, on scientific information provided by the exporter and other available scientific evidence, to identify and evaluate the possible adverse effects of that LMO or products thereof on the conservation and sustainable use of biological diversity, on the environment of the State of import as regards, in particular, conservation and sustainable use of biological diversity, taking into account the risks to human and animal health, agriculture, ecological stability concerns and social and ethical considerations as the basis for decisions under the AIA procedure.

2. Each Party shall determine for itself, in accordance with its own legislation, the institutional arrangements for the conduct of risk assessments under this Protocol and for the preparation of technical findings in relation to requests for transboundary movement.

3. Risk assessment shall be carried out before obtaining the corresponding AIA for the transboundary movement of an LMO and/or the products thereof to or within the Party of import

3. A new risk assessment shall be required in each of the following cases:

(a) Where there is a change in the intended use of the LMO;

(b) Where there is a variation in the receiving environment; or

(c) Where there are other factors likely to affect the risk assessment or risk management of the LMO and/or products thereof.

5. The Conference of the Parties shall establish a minimum standard of risk assessment of LMOs and/or products thereof. The minimum standard shall be reviewed periodically by the Conference of the Parties in light of the most recent and best available scientific, socio-economic and cultural knowledge and experience, as well as other relevant information. The Conference of the Parties may establish a technical advisory body for providing them with scientific backgrounds for reviewing the standard.

6. The exporter is responsible for the reliability of the information provided.

7. The financial responsibility for risk assessment shall rest with the exporter.

8. The Parties shall, taking into account in particular the needs of developing countries and countries with economies in transition, cooperate in order to promote capacity-building for development and the transfer of technology, as well as international harmonization in risk-assessment and risk-management procedures.

ARTICLE 13 - RISK MANAGEMENT

AUSTRALIA

Australia wishes to see the following included as an alternative to the current Option 2 paragraph 3:

3. Parties of import and Parties of export are encouraged, where appropriate, to cooperate in the development of risk management procedures.

ECUADOR

Ecuador accepts the second alternative of option 2, page 32, modifying the wording "human health" to read: "human and animal health, the socio-economic and cultural welfare of societies, agriculture and the environment."

NEW ZEALAND

We favour at most a general and non-prescriptive provision but believe that it is not essential to the objectives of the Protocol.

PERU

1. In accordance with Article 8(g) of the Convention, Parties intending to undertake any transfer, handling or use of living modified organisms to or within the Party of import shall establish and maintain appropriate national mechanisms to regulate, manage or control risks identified under the risk assessment provision of the Protocol associated with the safe use, handling and transboundary movement of LMOs or products of an LMO.

2. The type of risk management to be employed shall be appropriate to the living modified organisms and activity in question and those risk- management strategies and measures that are set out in Annex X shall be employed as a minimum.

3. If the Party of import lacks the financial and technical capacity to do so, it may request the Party of export for technical and financial assistance and the latter shall collaborate with the Party of import for risk management.

4. Without prejudice to paragraph X above, each Contracting Party shall see to it that, in order to ensure genomic and trait stability in the environment, any LMO or products of an LMO, whether imported or locally developed, shall undergo a period of observation commensurate with its life-cycle or generation time, as the case may be, before it is put to its intended use. Risk-management schemes shall take due account of the different purposes or uses for which the living modified organisms or the products thereof are being developed or produced.

5. Parties shall cooperate with the view to ban or phase out, LMOs or products of an LMO or specific traits of LMOs or products of an LMO, that may have global adverse effects on the conservation and sustainable use of biological diversity or human health.

6. Parties shall require producers of living modified organisms to phase out all antibiotic resistance marker genes in living modified organisms by the year 2002.

7. Import restrictive measures based on risk assessment and in particular on sound and scientific information shall be imposed to prevent adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, human health and socio-economic considerations within the territory of the State of import. Lack of full scientific certainty or of scientific concern regarding the level of risk shall not be used as a reason for postponing measures to prevent harm.

SLOVENIA

Option 2, OR:

1. The Party of export shall ensure that the risk-management strategies and measures proposed for implementation by the Party of import shall prevent or mitigate the potential negative socio-economic effects and impacts within the Party of import.

2. The type of risk management to be employed shall be appropriate to the living modified organisms and activity in question and such risk-management strategies and measures shall correspond to the result of the risk assessment. The type and risk management and measures set out in Annex X shall be employed as a minimum:

3. If the Party of import lacks the financial and technical capacity to do so, the Party of export shall offer technical and financial assistance and shall collaborate with the Party of import for risk management.

4. Without prejudice to paragraph paragraph x above, each Contracting Party in order to ensure genomic and trait stability in the environment, any LMO and products of an LMO, (rest the same)

5. Parties shall co-operate with the view to ban or phase out, LMOs and products of an LMO or specific traits of LMOs and products of an LMO], that may have global adverse effects on the conservation and sustainable use of biological diversity or human health.

6. no comment

7. Import restrictive based on risk assessment and in particular on sound and scientific information shall be imposed to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity,within the territory of the State of import.

THAILAND

1. The Party of export shall ensure that the risk-management strategies and measures proposed for implementation by the Party of import shall [incorporate strategies and measures that will minimize, [prevent or mitigate] the potential socio-economic effects and impacts within the Party of import].

2. The type of risk management to be employed shall be appropriate to the living modified organisms and activity in question and such risk-management strategies and measures shall [correspond to the results of] the assessment of risk. The type of risk management and the [measures] set out in Annex X shall be employed as a minimum.

3. [If the Party of import lacks the financial and technical capacity to do so,] the Party of export shall collaborate with the Party of import [for risk management].

4. Without prejudice to paragraph x above, each Contracting Party in order to ensure genomic and trait stability in the environment, any LMO [or products of an LMO], whether imported or locally developed, shall undergo a period of observation commensurate with its life-cycle or generation time as the case may be before it is put to its intended use. Risk-management schemes shall take due account of the different purposes or uses for which the living modified organisms or the products thereof are being developed or produced.

5. Parties shall cooperate with the view to ban or phase out, LMOs[or products of an LMO] or specific traits of LMOs[or products of an LMO], that may have global adverse effects on the conservation and sustainable use of biological diversity or human health.

6. Parties shall require producers of living modified organisms to phase out all antibiotic resistance marker genes in living modified organisms by the year 2002.

7. Import restrictive measures based on risk assessment [and in particular on sound and scientific information] [shall] be imposed [to the extent necessary] to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, [human health and socio-economic considerations] within the territory of the State of import.

VENEZUELA

1. In accordance with Article 8(g) of the Convention, Parties to this Protocol shall establish and maintain appropriate national mechanisms and strategies to regulate, manage or control risks associated with the use, handling and transboundary movement of LMOs or products of an LMO.

2. The Party of export shall ensure that the risk-management strategies and measures proposed incorporate the potential socio-economic effects and impacts that may be caused by the use, handling and transboundary movement of the LMOs or products thereof, on agriculture and on the livelihood of the local people.

4. Without prejudice to paragraph 1 above, each Contracting Party shall see to it that, in order to ensure genomic and trait stability in the environment, any LMO or products of an LMO, whether imported or locally developed by the country, shall undergo a period of observation commensurate with its life-cycle or generation time, as the case may be, before it is put to its intended use. Risk-management schemes shall take due account of the different purposes or uses for which the living modified organisms or the products thereof are being developed or produced.

5. Parties shall establish the necessary measures to restrict the import of such LMOs and/or products thereof which, after being subjected to risk assessment, afford little scientific certainty regarding the effects that such organisms and products may have on the environment, biological diversity, human and animal health, agriculture, ecological stability concerns and socio-economic considerations.

ARTICLE 14 - MINIMUM NATIONAL STANDARDS

ECUADOR

Ecuador accepts option 1 with the following wording in paragraph 1: "upon the entry into force of this Protocol for that Party".

KENYA

Each Party shall ensure that appropriate legal, institutional and administrative measure concerning the safe research and development, manufacture, transfer, handling and use of living modified organisms are in place. In addition to establishing such measures at the national level, Parties shall also cooperate in establishing at the international or regional level, procedures to carry out risk assessment.

NEW ZEALAND

We favour at most a general and non-prescriptive provision but believe that it is not essential to the objectives of the Protocol.

PERU

Option 1

1. Each Party shall ensure that appropriate legal, institutional and administrative measures concerning the safe research and development, manufacture, transfer, handling and use of living modified organisms are in place upon the date of entry into force of this Protocol for that Party. In addition to establishing such measures at the national level, Parties shall also cooperate in establishing at the international or regional level, procedures to carry out risk assessment under Article X.

2. Such measures shall adequately regulate both contained use and deliberate release. With regard to contained use of living modified organisms or products thereof, each Party shall apply the measures set out in Annex X.

3. National measures shall, as a minimum, fulfil the requirements set out in this Protocol with regard to the safe transfer, handling and use of living modified organisms, including those relating to risk assessment under Article 12 and enforcement conditions or prohibitions under Article 13.

4. Parties may impose more stringent or comprehensive requirements, based on the precautionary principle.

SLOVENIA

Option 1:

1. Each Party shall ensure that appropriate legal, institutional and administrative measures concerning the safe research and development, manufacture, transfer, handling and use of living modified organisms are in place upon the date of entry into force of this Protocol for that Party. In addition to establishing such measures at the national level, Parties shall also co-operate in establishing at the international or regional level, procedures to carry out risk assessment under Article X.

2. Such measures shall adequately regulate both contained use and deliberate release. With regard to contained use of living modified organisms and products thereof, each Party shall apply the measures set out in Annex X.

3. no comment

4. Parties may impose more stringent or comprehensive requirements, based on the precautionary principle.

THAILAND

Such measures shall adequately regulate both contained use and deliberate release. With regard to contained use of living modified organisms [or products thereof], each Party shall apply the measures set out in

Annex X.

VENEZUELA

1. Each Party shall ensure that appropriate legal, institutional and administrative measures concerning the safe research and development, manufacture, transfer, handling and use of living modified organisms are in place two years after the date of ratification of this Protocol or accession to it.

2. Such measures shall adequately regulate contained use, semi-contained use and deliberate release. With regard to contained use of living modified organisms or products thereof, each Party shall apply the measures set out in Annex X.

3. National measures shall, as a minimum, fulfil the requirements set out in this Protocol with regard to the safe transfer, handling and use of living modified organisms, including those relating to risk assessment under Article 12 and enforcement conditions or prohibitions under Article 13.

MERGER OF ARTICLE 15 AND ARTICLE 16 -
UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

ECUADOR

Paragraph 1 should begin: "The Parties should take the necessary measures and ... notify", and for "human health" insert "human and animal health, the socio-economic and cultural welfare of communities, agriculture and the environment". Paragraph 2 should read: "Each notification should include information regarding inter alia:...". Paragraph 3 should retain the words "at its own cost".

NEW ZEALAND

Modified Option 1

1. The Parties concerned shall immediately notify the competent national authority of affected and potentially affected Parties in the event of:

(a) An accident; and/or

(b) Unintentional transboundary movement of LMOs.

2. The notification should include information regarding, inter alia:

(a) The circumstances of the accident and/or unintentional transboundary movement;

(b) The information specified in Annex I and any other information required by the affected Party to assess the effects of the accident and/or unintentional transboundary movement;

(c) Emergency measures taken or needing to be taken.

PERU

1. The Parties shall take the necessary measures and, as soon as it comes to their knowledge, notify affected and potentially affected Parties, generally through the competent authorities of the States concerned and the Clearing-house mechanism of the Protocol in the event of:

(a) An accident; and/or

(b) Unintentional transboundary movement of living modified organisms and known domestic releases of LMOs which may result in unintentional transboundary movements;

2. Such notification should include information considered relevant regarding inter alia:

(a) Adverse effects on human health, the conservation and sustainable use of biological diversity and/or the environment and agricultural production in other States;

(b) The circumstances of the accident and/or unintentional movement;

(c) The identity, relevant characteristics and numbers/volumes/ quantities of the LMOs involved and released;

(d) Any available information necessary to assess the effects of the accident and/or unintentional movement, including their effects on human and animal health, the environment, and biological diversity;

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

(f) Emergency measures taken or needed to be taken, including measures identified under Article 14 (1) of the Convention;

(g) The information specified in Annex I;

(h) Any other [available] information considered relevant.

3. The Party which is the origin of an accident and/or unintentional transboundary movement which is likely to present a threat shall immediately notify and take action, in consultation with the affected Party, to minimize negative impacts on the environment and to prevent further release or transboundary movement of the LMO.

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

5. The States concerned shall, where information is provided, 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.

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

SLOVENIA

Revised: 1. The parties shall take the necessary measures and ensure that it comes to their knowledge, immediately notify affected and potentially affected Parties, the competent authorities of the States concerned of the Protocol in the event of:

(a) An accident, and

(b) Unintentional transboudary movement of living modified organisms which occur in the course of a transboundary movement and would otherwise be subject to AIA or to conditions imposed by previous AIA decision and which are likely to have significant adverse effects on the conservation and sustainable use of biological diversity.

2. Such notification should include information regarding inter alia:

(a) Adverse effects on human health, the conservation and sustainable use of biological diversity and the environment and agricultural production in other States;

(b) The circumstances of the accident or unintentional movement;

(c) The identity, relevant characteristics and numbers and volumes quantities of the LMOs involved and released;

(d) Any available information necessary to assess the effects of the accident and/or unintentional movement including their effects on human and animal health, the environment, and biological diversity;

(e) An assessment of the risks to the conservation and sustainable use of biological diversity and human health as well as risk-management measures needed, including those regarding the handling of the organisms;

f and g; no comment;

h) Any other available information considered relevant.

3. The Party which is the origin of an accident or unintentional transboudary movement which is likely to present a treat shall immediately notify and take action, at its own cost in consultation with the affected Party , to minimize negative impacts on the environment and to prevent further release or transboundary movement of the LMO.

4 to 7; no comments

THAILAND

[1. The Parties shall [take the necessary measures] and [ensure that], [as soon as] [it comes to their knowledge], [immediately] [notify] affected and potentially affected Parties, [generally through] the competent authorities of the States concerned [and the Clearing-house mechanism] [of the Protocol] [are immediately notified] in the event of:

[(a) An accident, and/or]

[(b) Unintentional transboundary movement of living modified organisms [and known domestic releases of LMOs which may result in unintentional transboundary movements]]

[which occur in the course of a transboundary movement and would otherwise be subject to AIA or to conditions imposed by a previous AIA decision and] which are likely to have significant adverse effects on the conservation and sustainable use of biological diversity, [taking also into account human health, [welfare and the environment]].

[2. Such notification should include information [considered relevant] regarding inter alia:

(a) Adverse effects on human health, the conservation and sustainable use of biological diversity and/or the environment [and agricultural production] in other States;

(b) The circumstances of the accident and/or unintentional movement;

(c) The identity, relevant characteristics and numbers/volumes/ quantities of the LMOs involved and released;

(d) Any available information necessary to assess the effects of the accident and/or unintentional movement, including their effects on human and animal health, the environment, and biological diversity;

(e) An assessment of the risks to the conservation and sustainable use of biological diversity and/or human health, [as well as] risk-management measures needed, including those regarding the handling of the organisms;

(f) Emergency measures taken or needed to be taken, including measures identified under Article 14 (1) of the Convention.

(g) The information specified in Annex I;

(h) Any other [available] information considered relevant.

[3. The Party which is the origin of an accident and/or unintentional transboundary movement [which is likely to present a threat] shall immediately [notify and] take action, [at its own cost] in consultation with the affected Party, to minimize negative impacts on the environment and to prevent further release or transboundary movement of the LMO.]

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

[5. The States concerned shall, where information is provided, 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.]

[6. The affected State(s) may ask for consultations among the concerned States.]

UNITED STATES OF AMERICA

-- Paragraph 1, first line, after "The Parties shall" insert "endeavor to".
-- Paragraph 1(a) modify "accident" to "accidental release of LMOs".
-- Paragraph 1, tenth line, in lieu of "a transboundary movement" add "the international transport of LMOs".

VENEZUELA

1. The Parties shall take the necessary measures and, as soon as it comes to their knowledge, notify affected and potentially affected Parties, through the competent authorities of the States concerned and the Clearing-house mechanism [of the Protocol] in the event of:

(a) An accident; and/or

(b) Unintentional transboundary movement of living modified organisms and known domestic releases of LMOs which may result in unintentional transboundary movements, which are likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account human health, welfare and the environment.

2. Such notification should include information regarding inter alia:

(a) Adverse effects on human health, the conservation and sustainable use of biological diversity and/or the environment and agricultural production in other States;

(b) The circumstances of the accident and/or unintentional movement;

(c) The identity, relevant characteristics and numbers/volumes/ quantities of the LMOs involved and released;

(d) Any available information necessary to assess the effects of the accident and/or unintentional movement, including their effects on human and animal health, the environment, and biological diversity;

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

(f) Emergency measures taken or needed to be taken, including measures identified under Article 14 (1) of the Convention;

(g) The information specified in Annex I;

(h) Any other [available] information considered relevant.

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

4. The States concerned shall, where information is provided, 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.

5. The affected State(s) may ask for consultations among the concerned States.

6. Each Party shall avoid any activity that may lead to accidental or unintended releases of aquatic living modified organisms, in particular into freshwater and marine ecosystems.

ARTICLE 17 - HANDLING, TRANSPORT, PACKAGING AND LABELLING

ECUADOR

Ecuador accepts option 2.

KENYA

Parties shall ensure that LMOs subject to AIA within the scope of the protocol and subject to transboundary movement are handled, packaged, labelled and transported under safe conditions in accordance with the international rules and standards in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

NEW ZEALAND

We favour no provision.

PERU

1. Parties shall ensure that LMOs [subject to AIA]/[within the scope of the Protocol] and subject to transboundary movement are:

(a) Clearly [identified]/[labelled] as LMOs, including information on the type of LMO, names and contact details of the importer, exporter and focal points of the importing and exporting Parties;]

[(b) Subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export;]

[(c) Handled, packaged, [labelled] and transported under safe conditions [in accordance with international rules and standards,] [particularly in accordance with the United Nations Recommendations on the Transport of Dangerous Goods] in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;]

[(d) Accompanied by [relevant][information on the LMOs [and products thereof]], [movement document/documentation from the point at which the transfer commences to the point of use] [and] [appropriate labelling] [as

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

SLOVENIA

Option 2:

1. Parties shall ensure that LMOs subject to AIA and within the scope of the Protocol and and subject to transboundary movement are:

(a) Clearly identified and labelled as LMOs, including information on the type of LMO, names and contact details of the importer, exporter and focal points of the importing and exporting Parties;

(b) no comment;

(c) Handled, package, labelled and transported under conditions particularly in accordance with the United Nations recommendations on the Transport of Dangerous Goods in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;

(d) Accompanied by relevant information on the LMOs and the products thereof and appropriate labelling as specified in Annex XX.

2. no comment

THAILAND

[1. Parties shall ensure that LMOs [subject to AIA] and subject to transboundary movement are:

[(a) Clearly [labelled] as LMOs, including information on the type of LMO, names and contact details of the importer, exporter and focal points of the importing and exporting Parties;]

[(b) Subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export;]

[(c) Handled, packaged, [labelled] and transported under safe conditions [in accordance with international rules and standards,] [particularly in accordance with the United Nations Recommendations on the Transport of Dangerous Goods] in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;]

[(d) Accompanied by [relevant][information on the LMOs [and the products thereof]], [documentation from the point at which the transfer commences to the point of use] [and] [appropriate labelling] [as specified in Annex [xx].]]

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

URUGUAY

The LMOs covered by this agreement, that may be subject to transboundary movement and AIA should:

- Be clearly identified as LMOs;

- Be labelled and handled so as to prevent accidental release to the environment;

- Have information included in the labelling that permits proper identification of the consent granted.

VENEZUELA

1. Parties shall ensure that LMOs subject to transboundary movement are:

(a) Clearly identified/labelled as LMOs, including information on the type of LMO or products thereof, names and contact details of the importer, exporter and focal points of the importing and exporting Parties;

(b) Subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export;

(c) Handled, packaged, labelled and transported under safe conditions in accordance with international rules and standards, particularly in accordance with the United Nations Recommendations on the Transport of Dangerous Goods in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human and animal health;

(d) Accompanied by information on the LMOs and products thereof, movement document/documentation from the point at which the transfer commences to the point of use and appropriate labelling as specified in Annex [xx].

2. The Meeting of the Parties shall develop standards with regard to packaging, handling, labelling and transport practices under the Protocol.

ARTICLE 18 - COMPETENT AUTHORITY/FOCAL POINT

ECUADOR

Ecuador accepts the wording: "no later than the date of entry into force of the Protocol". In paragraph 4 it accepts the wording: "and the Biosafety Clearing-house immediately", and, in paragraph 6, the wording: "Clearing-house mechanism".

NEW ZEALAND

In addition to settling throughout the text for the term "competent national authority", we favour the following modification of the article.

(1) Each Party shall designate one or more competent national authorities that shall be authorised to perform the administrative functions required by this Protocol.

(2) Each Party shall, no later than the date of entry into force of this Protocol for it, notify the name and address of such authority or authorities to the Secretariat. Where it designates more than one competent national authority, the Party shall convey to the Secretariat with its notification relevant information on the division of responsibility, if any, amongst its competent national authorities for the administrative functions required by this Protocol. It shall forthwith notify the Secretariat of any changes in the name and address or responsibilities of such authority or authorities.

(3) The Secretariat shall forthwith inform the Parties of the notification it receives under Paragraph 2.

PERU

1. To facilitate the implementation of this Protocol, each Party shall designate and, if it does not have one, establish one or more national focal points which shall be responsible for liaison with the Secretariat on behalf of that Party. Each Party shall also designate one or more competent government authorities, that shall be authorized to deal with all aspects relating to the stipulations of the Protocol, and whose responsibilities shall include, inter alia, establishing national guidelines and/or regulations] receiving applications and notifications and communicating decisions on living modified organisms in accordance with the Advance Informed Agreement procedure set out in articles 3, 4 and 5 and ensuring that risk assessments are undertaken, as necessary, in accordance with article 12.

2. Where a Party designates more than one competent authority, and/or more than one focal point, it shall specify the areas of responsibility for each [with sufficient precision for a notifier to know which competent authority deals with which type of living modified organisms/area of responsibility]. The competent authorities shall be authorized to act on behalf of the Party with respect to these responsibilities. A Party may designate a single agency to fulfil both functions of focal point and competent authority.

3. 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(s) and its competent authority(ies).

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 Secretariat shall forthwith inform the Parties of notifications received under paragraphs 2 and 3 above.

6. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1, 2, 3 and 4 above for inclusion in the Clearing-house mechanism provided for in Article 19, on information-sharing.

SLOVENIA

Revised:

1. To facilitate the implementation of this Protocol, each Party shall designate one or more focal points which shall be responsible for liaison with the Secretariat on behalf of that Party. Each Party shall also designate one or more competent government authorities, who is authorised to deal with all aspects relating to the stipulations of the Protocol whose responsibilities shall include, inter alia, establishing national guidelines and/ regulations receiving applications and (rset the same)

2. Where a party designates more than one competent authority and/or more than one focal point, it shall specify the areas of responsibility for each with sufficient precision for a notifier to know which competent authority deals with which type of area responsibility. (rest the same)

3. Each Party shall inform the Secretariat no later that the date of entry into force of the Protocol for that Party in question, which agencies have been designated as its focal points and its competent authorities.

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

5. no comment

6. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1, 2, 3 and 4 above for inclusion in the database of Clearing-house mechanism provided for in Article 19, on information sharing.

THAILAND

[1. To facilitate the implementation of this Protocol, each Party shall designate one national focal point which shall be responsible for liaison with the Secretariat on behalf of that Party. Each Party shall also designate one or more competent [government] authority(ies), whose responsibilities shall include, [inter alia, establishing national guidelines and/or regulations] receiving applications and notifications and communicating decisions on living modified organisms in accordance with the Advance Informed Agreement procedure set out in articles 3, 4 and 5 and ensuring that risk assessments are undertaken, as necessary, in accordance with article 12.

2. Where a Party designates more than one competent authority, and/or more than one focal point, it shall specify the areas of responsibility for each [with sufficient precision for a notifier to know which competent authority deals with which type of living modified organisms/area of responsibility]. The competent authorities shall be authorized to act on behalf of the Party with respect to these responsibilities. A Party may designate a single agency to fulfil both functions of focal point and competent authority.

3. Each Party shall inform the Secretariat [within three months of the date of entry into force of the Protocol] for that Party in question, which agencies have been designated as its focal point(s) and its competent authority(ies).

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

5. The Secretariat shall forthwith inform the Parties of notifications received under paragraphs 2 and 3 above.

6. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1, 2, 3 and 4 above for inclusion in the [database] [Clearing-house mechanism] provided for in article 19, on information-sharing.]

VENEZUELA

1. To facilitate the implementation of this Protocol, each Party shall designate and, if it does not have one, establish a national focal point which shall be responsible for liaison with the Secretariat on behalf of that Party. Each Party shall also designate one or more competent government authorities, that shall be authorized to deal with all aspects relating to the stipulations of the Protocol.

2. Where a Party designates more than one competent authority, it shall specify the areas of responsibility for each with sufficient precision for a notifier to know which competent authority deals with which type of living modified organisms/area of responsibility]. The competent authorities shall be authorized to act on behalf of the Party with respect to these responsibilities. A Party may designate a single agency to fulfil both functions of focal point and competent authority.

3. Each Party shall inform the Secretariat, within three months of the date of entry into force of the Protocol, which agencies have been designated as its focal point and its competent authorities.

4. Parties shall inform the Secretariat and the Biosafety Clearing-house immediately of any changes regarding the designation made by it under paragraphs 1 and 2 above.

5. The Secretariat shall forthwith inform the Parties of notifications received under paragraphs 2 and 3 above.

6. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1, 2, 3 and 4 above for inclusion in the Clearing-house mechanism provided for in Article 19, on information-sharing.

ARTICLE 19 - INFORMATION SHARING/BIOSAFETY CLEARING-HOUSE/BIOSAFETY DATABASE

ECUADOR

Ecuador accepts the title: "Biosafety Clearing-house". It accepts option 3, page 38. Within this option, it accepts alternative 2B with the wording: "A Biosafety Clearing-house should be established". It accepts alternative 4B with the wording: "Biosafety Clearing-house". In paragraph 5, it accepts the wording: "Biosafety Clearing-house". In subparagraph (p) of paragraph 5, the wording should read: "Information on unintentional transboundary movements including contingency or mitigation plans to be used in such event".

KENYA

A mechanism for exchange of information and cooperation shall be established under the Convention on Biological Diversity in from the Biosafety Clearing House.

The secretariat shall transmit the information from parties to the biosafety clearing house.

NEW ZEALAND

We favour the following modification to option 1.

The Parties shall facilitate the collection and exchange of information on LMOs to enable Parties to make informed decisions related to biosafety, taking into account the special needs of developing countries and the countries with economies in transition.

PERU

Option 3

1. The Parties shall facilitate the collection and exchange of publicly available scientific, technical, environmental and legal information on, and experience with, LMOs to enable Parties to make informed decisions related to biosafety, taking into account the special needs of developing countries and the countries with economies in transition, through a Biosafety Clearing-house.

2A. The mechanism for the exchange of information and cooperation under the Protocol shall be the clearing-house mechanism established by the Convention in its Article 18, paragraph 3.

3. 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 Conference of the Parties serving as the Meeting of the Parties to this Protocol 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.

4A. Each Party of import shall make available to the Clearing-house mechanism, subject to appropriate protection of confidential, business

information identified in 5(b), 5(h) and 5(j) below;

5. Without prejudice to the protection of confidential information Article 20 (Confidential Information), the Clearing-house mechanism shall contain and provide public access to information [relevant to the implementation of the Protocol as follows:

(a) Information on measures adopted under national legislation;

(b) 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 LMOs;

(c) Information on risk assessments or environmental reviews generated by the regulatory process, including the time taken for import decisions to be made;

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

(e) Information on decisions regarding the importation, field testing, or commercial use of any LMO, including the time taken for import decisions to be made];

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

(g) All living modified organisms which have been subject to bans or restrictions in that Party;

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

(i) A list of LMOs subject to advance informed agreement which have been assessed or imported into or used in its territory at the time of coming into force of this Protocol for that Party, including a description of any conditions attached to imports of such LMOs;

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

(k) Any other information regarding LMOs 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;

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

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

(n) [Information on] any decision on a notification of an intentional transboundary movement [and the summary of the risk assessment] [decisions adopted by countries regarding the transboundary movement of LMOs];

(o) Information concerning the biosafety regulatory framework on LMOs [of each Party];

(p) [Information on]/[A summary of] any [notified] unintentional [accidental] transboundary movements [including contingency or mitigation plans to be used in such event] [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];

(q) The text of decisions taken pursuant to Article [safeguard clause as referred to in UNEP/CBD/BSWG/3/3/Add 1.];

(r) Relevant data on designated competent authority or focal points provided under Article 18.

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. Each Party shall inform its public about the contents of, and mode of public accessibility to, the Biosafety Clearing-house.

SLOVENIA

OR 4B. Each Party shall make available to the Clearing-house Biosafety database shall contain and provide public access to information as follows:

(a) no comment;

(b) no comment;

(c) Information on risk assessments or environmental reviews generated by the regulatory process, including the time taken for import decision to be made;

(d) no comment;

(e) Information on decision regarding the importation, field testing, or commercial use of any LMO, including the time taken for import decision to be made;

f to m: no comments

(n) Information on any decision on a notification of an intentional transboundary movement and decisions adopted by countries regarding the transboundary movement of LMOs;

(o) Information concerning the Biosafety regulatory framework on LMOs of each Party;

(p) Information on any notified unintentional accidental transboudary movements including contingency or mitigation plans to be used in such event which are likely to have significant adverse effects in another Party or non-Party on the conservation and sustainable use of biological diversity, taking

into account risk to human health;

(q) The text of decisions taken pursuant to Article safeguard clause as refereed to in UNEP/CBD/BSWG/3/3/Add 1.;

(r) no comment

6. no comment

7. no comment

THAILAND

1. The Parties shall facilitate the collection and exchange of [publicly available] [scientific, technical, environmental and legal] information on, and experience with, LMOs to enable Parties to make informed decisions related to biosafety, taking into account the special needs of developing countries and the countries with economies in transition, through a [Biosafety Clearing-house].

2. Each Party shall make available to the [Biosafety Clearing-house] whenever it comes to its knowledge, relevant [publicly available] information when an unintentional release of a LMO is likely to present risks to the conservation and sustainable use of biological diversity.

[3. The terms of reference and functioning of the Clearing-house, including elements of information, and the conditions under which that information is submitted by the Parties, should be determined by the first meeting of the Parties to the Protocol.]

URUGUAY

The Parties shall facilitate the collection and exchange of publicly available scientific, technical, environmental and legal] information on, and experience with, LMOs to enable Parties to make informed decisions related to biosafety, taking into account the special needs of developing countries and the countries with economies in transition, through a Biosafety Clearing-house.

The information to be made available by the Parties to the Clearing-house should include, inter alia:

- Designations of competent authorities, focal points and changes in such designations;

- National biosafety requirements and regulatory framework;

- LMOs subject to bans or restrictive use in the State Party;

- Any other information relating to LMOs which that Party may consider of interest to other Parties and the public, including information on risk assessment and management and other scientific information.

VENEZUELA

1. The Parties shall facilitate the collection and exchange of publicly available scientific, technical, environmental and legal information on, and

experience with, LMOs to enable Parties to make informed decisions related to biosafety, taking into account the special needs of developing countries and the countries with economies in transition, through a Biosafety Clearing-house.

2. The mechanism for the exchange of information and cooperation under the Protocol shall be the clearing-house mechanism established by the Convention in its Article 18, paragraph 3.

3. 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 Conference of the Parties serving as the Meeting of the Parties to this Protocol 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.

4. Each Party shall make available to the Biosafety Clearing-house, information pertaining to that Party with respect to paragraph 5(b) and publicly available information pertaining to that Party with respect to 5(c) and 5(e) below.

5. Without prejudice to the protection of confidential information, the Clearing-house mechanism shall contain and provide public access to information as follows:

(a) Information on measures adopted under national legislation;

(b) 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 LMOs and/or products thereof;

(c) Information on risk assessments or environmental reviews generated by the regulatory process, including the time taken for import decisions to be made;

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

(e) Information on decisions regarding the importation, field testing, or commercial use of any LMO and/or products thereof, including the time taken for import decisions to be made;

(f) Information on decisions adopted by countries with regard to the transboundary movement of LMOs and/or products thereof;

(g) All living modified organisms and/or products thereof which have been subject to bans or restrictions in that Party;

(h) Information on accidental or unintended movements of LMOs and/or products thereof, including contingency or mitigation plans to be used in such event;

(i) A list of LMOs and/or products thereof subject to advance informed agreement which have been assessed or imported into or used in its territory at the time of coming into force of this Protocol for that Party, including a description of any conditions attached to imports of such LMOs;

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

(k) Any other information regarding LMOs and/or products thereof 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;

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

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

(n) Information on any decision on a notification of an intentional transboundary movement [and the summary of the risk assessment] [decisions adopted by countries regarding the transboundary movement of LMOs and/or products thereof;

(o) Information concerning the biosafety regulatory framework on LMOs of each Party;

(p) Information on any notified accidental transboundary movements including contingency or mitigation plans to be used in such event 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;

(q) The text of decisions taken pursuant to Article [ ] (safeguard clause);

(r) Relevant data on designated competent authority or focal points provided under Article 18.

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. Each Party shall inform its public about the contents of, and mode of public accessibility to, the Biosafety Clearing-house.

ARTICLE 20 - CONFIDENTIAL INFORMATION

ECUADOR

Ecuador accepts option 1. Paragraph 3 should begin with the wording: "A Party shall protect and not disclose confidential information..." It accepts the following wording in paragraph 6: "in no case may the following information be kept confidential".

NEW ZEALAND

Modified Option 1

(1) The Party of import shall permit the applicant to identify information submitted under the procedures of this Protocol that should be treated as confidential. Justification must be given in such cases upon request.

(2) The Party of import shall consult with the applicant if it believes that information identified by the applicant as confidential does not qualify for such treatment and shall inform the applicant of its decision prior to disclosing the information. If the applicant withdraws an application, the confidentiality of the information shall be protected by the Party of import.

(3) In no case may the following information be kept confidential:

(a) The general description of the LMO or LMOs, the name and address of the applicant and the purpose of the transboundary movement;

(b) A summary of the risk assessment; and

(c) Any methods and plans for emergency response.

PERU

1. The importing Party shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the importing Party as part of the Protocol's Advanced Informed Agreement process that should be treated as confidential. Justification must be given in such cases upon request.

2. The importing Party shall consult with the notifier if it believes that information identified by the notifier as confidential does not qualify for such treatment and shall inform the notifier of its decision prior to disclosing the information.

3. A Party shall protect and not disclose confidential information, including commercial in confidence information received under the Protocol, including any confidential information received in the context of the Protocol's Advanced Informed Agreement process. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a way no less favourable than its treatment of confidential information in connection with domestic LMOs.

4. A receiving Party may not use such information for a commercial purpose, except with the agreement of the notifier.

5. If, for whatever reason, including in cases where the competent authority 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, subject to national legislation.

[6. Without prejudice to paragraph 5 of this Article, 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, the name and address of the notifier [, and the purpose of the transboundary 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; and

(c) Any methods and plans for emergency response.

SLOVENIA

Option 1: 1 and 2. no comment

3. A Party shall protect confidential information, including commercial in confidence information received under the Protocol including any confidential information received in the context of the Protocol's Advanced Informed Agreement process. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentially of such information in a way no less favourable than its treatment of confidential information in connection with domestic LMOs.

4. no comment

5. If, for whatever reason, including cases where the competent authority and notifier disagree, a notifier withdraws a notification, the confidentiality of all the information supplied and indicated as confidential must be respected by the completed authorities and focal points, subject to national legislation.

6. Without prejudice to paragraph 5 of this Article the following information should not generally be considered confidential:

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

(b) and (c) no comments

THAILAND

Option 2

1. The importing Party shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the importing Party as part of the Protocol's Advanced Informed Agreement process that should be treated as confidential. Justification must be given in such cases upon request.

2. The importing Party shall consult with the notifier if it believes that information identified by the notifier as confidential does not qualify for such treatment and shall inform the notifier of its decision prior to disclosing the information.

3. A Party shall [protect] confidential information, [including commercial in confidence information] received under the Protocol, including any confidential information received in the context of the Protocol's Advanced Informed Agreement process. [Each Party shall ensure that it has procedures

to protect such information [and shall protect the confidentiality of such information in a way no less favourable than its treatment of confidential information in connection with domestic LMOs]].

4. A receiving Party may not use such information for a commercial purpose, except with the agreement of the notifier.

[5. If, for whatever reason, including in cases where the competent authority 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, [subject to national legislation].]

[6. Without prejudice to paragraph 5 of this Article, [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, the name and address of the notifier [, and the purpose of the transboundary 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; and

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

VENEZUELA

1. The importing Party shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the importing Party as part of the Protocol's Advanced Informed Agreement process that should be treated as confidential. Justification must be given in such cases upon request.

2. The importing Party shall consult with the notifier if it believes that information identified by the notifier as confidential does not qualify for such treatment and shall inform the notifier of its decision prior to disclosing the information.

3. A Party shall protect and not disclose confidential information, including commercial in confidence information received under the Protocol, including any confidential information received in the context of the Protocol's Advanced Informed Agreement process. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a way no less favourable than its treatment of confidential information in connection with domestic LMOs.

4. A receiving Party may not use such information for a commercial purpose, except with the agreement of the notifier.

5. If, for whatever reason, including in cases where the competent authority 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, subject to national legislation.

[6. Without prejudice to paragraph 5 of this Article, in no case may the following information be kept confidential:

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

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

(c) Any methods and plans for emergency response.

ARTICLE 21 - CAPACITY-BUILDING

ECUADOR

Ecuador accepts option 2. Paragraph 1 should begin: "The Parties should..." In paragraph 2, it accepts the wording: "The Parties shall cooperate towards..." Subparagraph (b) of paragraph 5 should read: "Acquire and/or develop..."

NEW ZEALAND

Option 1

(The Parties shall adopt appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety, through the appropriate international, regional 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.)

PERU

Option 2

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, through the appropriate international, regional and national institutions. Capacity-building programmes should maximize the use of existing multilateral, regional and bilateral mechanisms, including those addressed under the Convention and should be particularly aimed at developing countries.

2. Capacity-building shall aim to ensure that Parties develop and strengthen their capacities to implement the Protocol, including the development of national legislation, frameworks and guidelines related to biosafety. Capacity-building shall also aim to ensure that States involved in the transfer, handling and/or use of living modified organisms and/or products thereof are aware of any associated risks and are able to achieve safety through the development of procedures for risk-assessment and risk-management of living modified organisms prior to their introduction. Capacity-building shall also ensure that regional or subregional activities/centres for training and capacity-building regarding the safe

management of living modified organisms shall be established according to the specific needs of different regions and subregions, with financial assistance provided through the financial mechanism under the Convention on Biological Diversity.

3. The Parties shall promote capacity-building, in particular, cooperation, and scientific and technical assistance, which may include training of personnel, exchange of experts, exchange of information, and educational and institutional strengthening, in order to strengthen the ability of Importing States to build capacity, to perform risk assessments and to develop and implement decision-making and risk-management procedures.

4. The building of national capacity shall be achieved, inter alia, through:

(a) New and additional financial resources;

(b) Training and technical assistance and cooperation;

(c) Technology transfer relevant to the scope of this Protocol;

(d) Technical and financial assistance from the private sector, which should be facilitated and encouraged.

(e) Educational and institutional strengthening.

5. The developed country Parties, recognizing the need for 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 through the transfer of relevant knowledge [in biotechnology and biosafety] on fair and most favourable terms, including on concessional and preferential terms, shall establish effective measures to:

(a) Enhance the capacity of developing country Parties for strengthening and developing human resources and institutional capacities in biotechnology and biosafety;

(b) Develop relevant biotechnology, and its proper and safe management;

(c) Build up their local, technological and institutional competence encompassing technical, financial and institutional provisions.

6. The Secretariat shall for the purpose of this article:

(a) Develop and implement programmes based on the identified needs of the concerned parties;

(b) Assist, in particular, developing countries in their efforts to identify, plan and implement their capacity-building requirements, and secure funds including new and additional resources;

(c) Provide, upon request by the Parties to this Protocol or any of its Signatories, any relevant information, scientific, technical or other

assistance in particular in the context of risk assessment and risk management, in the event of accidents, application of emergency measures and dispute settlement.

SLOVENIA

Option 2:

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, through the appropriate international, regional and national institutions. Capacity-building programmes should maximise the use of existing multilateral, regional, bilateral mechanisms, including those addressed under the Convention and should be particularly aimed at developing countries.

2. including a, b and c: no comments

THAILAND

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, through the appropriate international, regional 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.

VENEZUELA

1. 1The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety, through the appropriate international, regional 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.

2. Capacity-building shall aim to ensure that Parties develop and strengthen their capacities to implement the Protocol, including the development of national legislation, frameworks and guidelines related to biosafety. Capacity-building shall also aim to ensure that States involved in the transfer, handling and/or use of living modified organisms and/or products thereof are aware of any associated risks and are able to achieve safety through the development of procedures for risk assessment and risk management of living modified organisms prior to their introduction. Capacity-building shall also ensure that regional or subregional activities/centres for training and capacity-building regarding the safe management of living modified organisms shall be established according to the specific needs of different regions and subregions with financial assistance provided through the financial mechanism under the Convention on Biological Diversity.

3. The Parties shall cooperate towards capacity-building, in particular, scientific and technical cooperation, which may include training of personnel, exchange of experts, exchange of information, and educational and

institutional strengthening, in order to strengthen the ability of Importing States to perform risk assessments and to develop and implement decision-making and risk-management procedures.

4. The building of national capacity shall be achieved, inter alia, through:

(a) New and additional financial resources;

(b) Training and technical assistance and cooperation;

(c) Technology transfer relevant to the scope of this Protocol;

(d) Technical and financial assistance from the private sector, which should be facilitated and encouraged.

(e) Educational and institutional strengthening.

5. The developed country Parties, recognizing the need for 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 through the transfer of relevant knowledge in biotechnology and biosafety on fair and most favourable terms, including on concessional and preferential terms, shall establish effective measures to:

(a) Enhance the capacity of developing country Parties for strengthening and developing] human resources and institutional capacities in biotechnology and biosafety];

(b) Acquire and or develop relevant biotechnology, and its proper and safe management;

(c) Build up their local, technological and institutional competence encompassing technical, financial and institutional provisions.

6. The Secretariat shall for the purpose of this article:

(a) Develop and implement programmes based on the identified needs of the concerned parties;

(b) Assist, in particular, developing countries in their efforts to identify, plan and implement their capacity-building requirements, and secure funds, including new and additional resources;

(c) Provide, upon request by the Parties to this Protocol or any of its Signatories, any relevant information, scientific, technical or other assistance in particular in the context of risk assessment and risk management, in the event of accidents, application of emergency measures and dispute settlement.

ARTICLE 22 - PUBLIC AWARENESS/PUBLIC PARTICIPATION

ECUADOR

Paragraph 1 should read: "Parties shall ensure, in accordance with national laws and regulations, that adequate information on the safe transfer, handling and use of LMOs is provided to the public to encourage understanding of the safe use, handling and management of LMO's in relation to the transboundary movement and the conservation and sustainable use of biological diversity, including human health, and to enhance adequate public information on and/or public participation in the implementation of the protocol, whilst respecting confidential information." In paragraph 2, we accept the wording: "on safety in modern biotechnology".

NEW ZEALAND

We favour the following modification.

1. Each Party shall promote and facilitate as appropriate, and in accordance with its national laws and regulations, the development of public awareness programmes on safety in biotechnology.

2. Each Party shall, in accordance with its national laws and regulations, provide the public with an opportunity for involvement in the decision-making processes for the release of LMOs, and information on the results of these processes.

PERU

1. Parties shall ensure, in accordance with national laws and regulations, that adequate information on the safe transfer, handling and use of LMOs is provided to the public and shall take appropriate measures to encourage understanding of the safe use, handling and management of LMO's in relation to the transboundary movement and the conservation and sustainable use of biological diversity, including human health, and to enhance public awareness, adequate public information on the implementation of the protocol, whilst respecting confidential commercial information.

3. Each Party 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 public awareness programmes on safety in biotechnology.

4. Parties are encouraged to facilitate public participation in and access to information on risk-assessment results and decisions concerning the transboundary movement of LMOs.

5. Each Party shall, in accordance with its national laws and regulations, provide the public with an opportunity for involvement in the processes for approving the release of living modified organisms, and information on the results of these processes.

SLOVENIA

1. Parties shall ensure, in accordance with national laws and regulations, that adequate information on the safe transfer, handling and use of LMOs is provided to the public shall take appropriate measures to encourage understanding of the safe use, handling and management of LMO's in relation to biological diversity, including human health, and to enhance public awareness and public participation in the implementation of the Protocol, whilst respecting commercial-in-confidence information.

2. The Parties shall co-operate, as appropriate, with other States and international organizations in developing educational and public awareness programmes with respect to any risk and benefits associated on safety in modern biotechnology.

3. Each Party shall promote and facilitate, at national, sub-regional and regional levels, as appropriate, and in accordance with national laws and regulations, and within their respective capacities, the development and implementation of educational public awareness programmes on safety in biotechnology.

4. Parties are encouraged to facilitate public participation in and access to information on risk assessment results and decision concerning the transboudary movement of LMOs.

5. Each Party shall, in accordance with its national laws and regulations, provide the public with an opportunity for involvement in the process for approving the release of such living modified organisms, and information on the results of these processes.

THAILAND

1. Parties shall [ensure, in accordance with national laws and regulations, that adequate information on the safe handling and use of LMOs is provided to the public and shall] [take appropriate measures] [to encourage understanding of the safe use, handling and management of LMO's in relation to the transboundary movement and the conservation and sustainable use of biological diversity, including human health,] [and] to enhance [public awareness] [and/or public participation in] the implementation of the protocol whilst respecting [confidentiality] information.

[2. The parties shall cooperate , as appropriate, with other States and international organizations in developing educational and public awareness programmes [on safety in] modern biotechnology.]

[3. Each Party shall promote and facilitate, [at the national, subregional and regional levels], as appropriate, and in accordance with the national laws and regulations , [and within their respective capacities,] the development [and implementation] of educational public awareness programmeson safety in biotechnology.]

[4. Parties are encouraged to facilitate public participation in [and access to information on] risk assessment results and decisions [concerning the transboundary movement of LMOs.]

[5. Each Party shall, in accordance with its national laws and regulations, provide the public with an opportunity for involvement in [the processes for] approving the release of [such] living modified organisms, and information on the results of these processes.]

VENEZUELA

1. Parties shall ensure, in accordance with national laws and regulations, that adequate information on the safe transfer, handling and use of LMOs and/or products thereof is provided to the public and shall take appropriate measures to encourage understanding of the safe use, handling and management of LMO's in relation to the transboundary movement and the conservation and sustainable use of biological diversity, including human health, and to enhance public awareness, adequate public information on and/or public participation in the implementation of the Protocol, whilst respecting confidential information.

2. 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 with modern biotechnology.

3. Each Party shall promote and facilitate, at the national, subregional and regional levels, as appropriate, and in accordance with national laws and regulations, the development and implementation of educational public awareness programmes on safety in biotechnology.

4. Parties are encouraged to facilitate public participation in and access to information on risk-assessment results and decisions concerning the transboundary movement of LMOs and/or products thereof.

5. Each Party shall, in accordance with its national laws and regulations, provide the public with an opportunity for involvement in the processes for approving the release of living modified organisms, and information on the results of these processes.

ARTICLE 23 - NON-PARTIES

ECUADOR

Ecuador accepts option 3.

JAPAN

Parties shall not be restricted from trade in LMOs with non-Parties, provided that adequate measures required in this Protocol to ensure the safe transboundary movement of LMOS are observed. Such measures include the conclusion of bilateral, multilateral or regional agreements or arrangements with non-Parties with the purpose referred to in Article 11(3).

NEW ZEALAND

Modified Option 4

Parties shall not be restricted from trade in LMOs with non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of LMOs in accordance with the objectives of this Protocol.

PERU

1C. Notwithstanding the provisions in paragraph 1 above, imports and exports of living modified organisms may be permitted from and to any State not party to this Protocol, if that State has submitted data and is determined on the basis thereof by the Meeting of the Parties to be in full compliance with the provisions of this Protocol.

2B. Parties shall conduct their relations with non-Parties in such a way that non-Parties shall not be allowed a more favourable treatment than Parties.

3. A Party shall require that transboundary movement from a non-Party to it takes place in conformity with the notification and/or AIA requirements of the Protocol.

4. Transboundary movements from a Party to a non-Party shall take place in accordance with the regulatory framework of the non-Party provided that the framework does not result in a lower level of protection of biological diversity than the one provided for by the Protocol. In the absence of such a framework, the Parties shall endeavour to ensure that the transboundary movement takes place in accordance with the notification and/or AIA requirements of the Protocol.

SLOVENIA

Option 4:

1 A. 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 LMOs resulting from modern biotechnology, in accordance with the objectives of this Protocol.

THAILAND

[Non-Parties in compliance with the substantive provisions of this Protocol shall be treated on an equal basis with Contracting Parties.]

URUGUAY

A Party shall require that any transboundary movement with a non-Party State takes place in conformity with the provisions of the Protocol, with no type of ban or additional restriction on trade with such States.

VENEZUELA

1. Notwithstanding the provision of paragraph 5 of Article 1bis, Parties

may enter into arrangements and/or bilateral, regional or multilateral agreements with non-Party States regarding transboundary movement of LMOs and products thereof, provided that such arrangements and/or agreements are not detrimental to the sound environmental management of LMOs and/or products thereof as stipulated in this Protocol.

2. Parties shall inform the Secretariat of all bilateral, regional and multilateral agreements and/or arrangements referred to in paragraph 1 above, as well as of those entered into before the entry into force of the Protocol for such Parties, in order to monitor transboundary movements of LMOs and/or products thereof carried out between the parties to such agreements. The provisions of this Protocol shall not affect such transboundary movements of LMOs and/or products thereof, provided that such agreements are compatible with the sound environmental management of the LMOs and/or products thereof as stipulated in this Protocol.

ARTICLE 24 - NON-DISCRIMINATION

ECUADOR

Ecuador accepts option 1.

MEXICO

So that the title of the article and its content may correspond more closely, we propose that it be entitled "National treatment", that is to say, the consolidated title would be "Non-discrimination (National treatment)".

NEW ZEALAND

We favour no provision.

PERU

Option 1

1. During the course of the AIA procedures, in particular the risk-assessment procedures, the recipient Parties shall not treat LMOs of foreign origin that are imported from other Parties, or non-Parties with which an agreement or arrangement mentioned in Article 23 has been concluded, more restrictively than those of domestic origin merely on the grounds that the LMOs in question are of foreign origin.

2. The recipient Contracting Parties may impose specific conditions when living modified organisms of foreign origin are imported from non-Parties with which no agreement or arrangement mentioned in Article 11 has been concluded, as far as such conditions are not more restrictive than the provisions of this Protocol as well as being consistent with the non-discriminatory provisions of the WTO Agreement.

3. The importing Party shall ensure that any ban or condition with respect to the import of an LMO does not result in treatment which is less favourable than with regard to such LMOs produced domestically or which are imported from any other country.

4. Parties shall not discriminate between imported living modified organisms and those produced locally and/or those that have been previously authorized to be imported from a third party.

5. Parties shall ensure that measures taken to regulate the safe transfer, handling and use of living modified organisms resulting from biotechnology under this Protocol do not create unnecessary obstacles to, and/or constitute means of arbitrary or unjustified discrimination or disguised restrictions on international trade.

THAILAND

[Parties shall ensure that measures taken to [implement this Protocol] shall not discriminate between imported living modified organisms and those produced locally and/or those that have been previously authorized to be imported from a third party, nor create unnecessary obstacles to, and or constitute means of arbitrary or unjustified discrimination or disguised restrictions on international trade.]

URUGUAY

The importing Party shall ensure that any ban or condition with respect to the import of an LMO does not result in treatment which is less favourable than with regard to such LMOs produced domestically or which are imported from any other country.

VENEZUELA

1. Parties shall ensure that measures taken to implement this Protocol do not discriminate between imported living modified organisms and those produced domestically and/or those whose import from a third party has been authorized, and do not create unnecessary obstacles to, and/or constitute means of arbitrary or unjustified discrimination or disguised restrictions on international trade.

ARTICLE 25 - ILLEGAL TRAFFIC

ECUADOR

Ecuador accepts option 2. In paragraph 2 it accepts the wording: "Data concerning... should be included...".

KENYA

In case of illegal traffic of LMOs or products thereof, the state of import should have the right to destroy or dispose of the organisms or products in question or to request the state of origin (if known) to remove at its own expense the organisms or products from the environment of the state of import.

NEW ZEALAND

We favour option 1.

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

PERU

Option 2

1. In the case of illegal traffic of living modified organisms or products thereof, the State of import shall have the right to destroy or dispose of the organisms or products in question or to request the State of origin, if known, to remove at its own expense the organisms or the products from the environment of the State of import.

2. Each Party shall immediately inform the Secretariat and the Biosafety Clearing-house of any illegal traffic.

3. The Secretariat shall record all known cases of illegal traffic and transmit as quickly and efficiently as possible to all Parties, particularly to Parties that are likely to be affected, all available relevant information concerning the illegal traffic and any associated risks.

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

SLOVENIA

Option 1:

Each party shall adopt appropriate domestic legislation that prevents and penalises illegal traffic. Parties shall co-operate in this respect with a view to achieving the objective of this protocol.

THAILAND

1. In the case of illegal traffic of living modified organisms or products thereof, the State of import shall have the right to destroy or dispose of the organisms or products in question or to request the State of origin, if known, to remove at its own expense the organisms or the products from the environment of the State of import.

2. Each Party shall immediately inform the Secretariat [and the Biosafety Clearing-house] of any illegal traffic. [Data concerning known cases of illegal traffic should [shall] be included in the information-exchange mechanism established under article 19.]

3. The Secretariat shall record all known cases of illegal traffic and transmit as quickly and efficiently as possible to all Parties, particularly to Parties that are likely to be affected, all available relevant information concerning the illegal traffic and any associated risks.

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

VENEZUELA

1. In the case of illegal traffic of living modified organisms or products thereof, the State of import shall have the right to destroy or dispose of the organisms and/or products in question or to request the State of origin, if known, to remove at its own expense the organisms and/or the products from the environment of the State of import.

2. Each Party shall immediately inform the Secretariat and the Biosafety Clearing-house of any illegal traffic. Data concerning known cases of illegal traffic shall be included in the information-exchange mechanism established under article 19. The Secretariat shall record all known cases of illegal traffic and transmit as quickly and efficiently as possible to all Parties, particularly to Parties that are likely to be affected, all available relevant information concerning the illegal traffic and any associated risks.

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

ARTICLE 26 - SOCIO-ECONOMIC CONSIDERATIONS

ECUADOR

Ecuador accepts option 3.

HAITI

1. The Parties agree that socio-economic considerations should be taken into account from the placement of living modified organisms on the market up to their use in the country of destination.

2. The Party originating the transboundary movement shall ensure that the socio-economic impacts are addressed under Articles 12 and 13 of the present Protocol. The risk assessment shall, as a matter of priority, stigmatize the dangers presented by any transfer/handling of LMOs on the germplasm of the whole range of living organisms and the consequences that it might have on the lifestyles of farmers in developing countries.

KENYA

Parties shall ensure that the socio-economic impacts of the introduction, transfer, handling or use of living modified organisms and products thereof on or within the importing party and its environment, are considered during the assessment and management of risks, in particular with the aim of ensuring the conservation and sustainable use of biological diversity, and also taking into account impacts on human health, agriculture

and welfare. The user shall also 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.

NEW ZEALAND

We favour no provision (but have included appropriate references in our preferred Preamble).

PERU

Option 2

1. The Parties shall ensure that the socio-economic impacts specific and unique to the use of LMOs 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 considerably from Party to Party. In particular, the importing country shall take into account such adverse consequences as genetic erosion and associated loss of income and dislocation of traditional farmers and farm products.

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

SLOVENIA

Option 2:

1. The Parties shall ensure that the socio-economic impacts specific and unique to the use of LMOs that may manifest adverse consequences are appropriately considered during the assessment and management of risks. In particular, the importing country shall take into account such adverse consequences as genetic erosion and associated loss of income and dislocation of traditional farmers and farm products.

2. no comment

THAILAND

1. Parties shall ensure that the socio-economic impacts of the introduction, transfer, handling or use of living modified organisms and products thereof in or within the importing Party and its environment, are considered during assessment and management of risks, in particular with the aim of ensuring the conservation and sustainable use of biological diversity, and also taking into account impacts on human health, agriculture and welfare. The user shall also 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. Parties shall ensure that the risk-management strategies and measures developed and implemented in accordance with the relevant provisions of this

Protocol incorporate strategies and measures that prevent, or mitigate the potential socio-economic adverse impacts of living modified organisms and products thereof.

3. A Party that intends to produce, using a living modified organism, a hetherto imported commodity, shall notify the other Party or Parties whose export is to be affected long enough, and in no 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 disruption of production of the commodity in question. The Party substituting its import in such a unnatural way shall, when the affected Party is a developing country, provide financial and technical assistance to the affected Party.

4. Each Party shall develop or maintain appropriate policy and legislation that protect the general public from a monopolistic manipulation of the biotechnological, seed, chemical and related industries by individual private-sector entities.

5. Each Party shall ensure that activities involving LMOs by both public and private entities are adequately regulated in order to ensure fair and effective implementation of the provisions of this Protocol and to protect the fundamental moral and socio-economic interests of the general public.

VENEZUELA

1. Parties shall ensure that the socio-economic impacts of the introduction, transfer, handling or use of living modified organisms and products thereof on or within the importing Party and its environment, are considered during the assessment and management of risks, in particular with the aim of ensuring the conservation and sustainable use of biological diversity, and also taking into account impacts on human health, agriculture and welfare. The user shall also 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. Parties shall ensure that the risk-management strategies and measures developed and implemented in accordance with the relevant provisions of this Protocol incorporate strategies and measures that prevent, or mitigate the potential socio-economic adverse impacts of living modified organisms and products thereof.

3. 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 an unnatural way shall, when the affected Party is a developing country, provide financial and technical assistance to the affected Party in order to contribute towards the transition of the affected Party during the adjustment period, which should not exceed the period of seven years indicated..

4. Each Party shall develop or maintain appropriate policy and legislation that protect the general public from a monopolistic manipulation of the biotechnological, seed, chemical and related industries by individual private-sector entities.

5. Each Party shall ensure that activities involving LMOs and/or products thereof by both public and private entities are adequately regulated in order to ensure a fair and effective implementation of the provisions of this Protocol and to protect the fundamental moral and socio-economic interests of the general public.

ARTICLE 27 - LIABILITY AND COMPENSATION

ECUADOR

Ecuador accepts option 5.

HAITI

The strict liability of the exporting Party shall be engaged in any event of damage resulting from transboundary movements of LMOs and the affected Party shall receive full and complete compensation for any harm related to the depletion of genetic resources, in accordance with the provisions of the present Protocol.

KENYA

Signatory Parties to this Protocol, recognizing the risk involved in the transboundary movement of living modified organisms as well as the procedures of Advanced Informed Agreement and risk assessment, adopt within this Protocol liability of States for damage arising from the transboundary movement of living modified organisms, when they occur.

Given a contingency in the transboundary movement of living modified organisms compatible with paragraph (liability), the state of origin shall ensure that compensation is made for harm caused to receiving Parties. The State of origin shall bear the costs of the contingency plan 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 in full, agreement may be reached on compensation, monetary or otherwise, by the State of origin for the deterioration suffered.

MEXICO

Add the following wording at the end of paragraph 6 of option 5: "The Fund will be constituted by contributions from all signatory Parties [in proportion to the number of transboundary movements they carry out].

NEW ZEALAND

Modified Option 1

The Parties shall, at their first meeting, examine how to establish procedures in accordance with Article 14, paragraph 2, of the Convention, for developing appropriate rules and procedures in the field of liability and

redress, including restoration and compensation for damage resulting from LMOs to biological diversity.

PERU

1. Liability

Signatory Parties to this Protocol, recognizing the risk involved in the transboundary movement of living modified organisms as well as the procedures of Advanced Informed Agreement and risk assessment, adopt within this Protocol liability of States for damage arising from the transboundary movement of living modified organisms, when they occur as:

(a) The consequence of an action or omission attributable to the State under the provisions established by this Protocol;

(b) Conduct that constitutes a breach of an international obligation of the State under the terms of this Protocol.

2. Civil liability

States, through national legislation and procedures are sovereign to determine whether liability is deemed as an act of a public, civil or individual party under national jurisdiction.

3. Compensation

Given a contingency in the transboundary movement of living modified organisms compatible with paragraph (liability), the State of origin shall ensure that compensation is made for harm caused to receiving Parties. The State of origin shall bear the costs of the contingency plan 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 in full, agreement may be reached on compensation, monetary or otherwise, by the State of origin for the deterioration suffered.

4. Measures of reinstatement

Any reasonable measures aiming to reinstate or restore damage or destroyed components of the environment, or to introduce, where reasonable, the equivalent of these components into the environment. National Competent Authorities are entitled to take such measures.

5. Prescription of liability

Proceedings in respect of liability under this Article shall lapse after a period of NNN 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 of the transboundary movement of the living modified organism causing damage.

6. Emergency Fund

Signatory Parties decide to establish an Emergency Fund to fulfil requirements arising from contingencies in the transboundary movement of living modified organisms. This Fund will be constituted by contributions from all signatory Parties.

7. Exceptions

There shall be no liability on the part of the State of origin if the harm was directly due to an act of war, hostilities, civil war, insurrection or a natural phenomenon of an exceptional, inevitable and irresistible character.

SLOVENIA

Option 5: from 1 to 7 , no comments

THAILAND

1. While importing Parties remain responsible for the use of LMOs, and products thereof, within their national territories, exporting Parties shall be liable for any negative or harmful effects of LMOs, 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. Exporters shall also be liable for any negative or harmful effects produced as a result of any breach of the obligations under this Protocol.

3. Exporters shall also be liable for all forms of transboundary movement of LMOs and products thereof deemed illegal traffic under Article 25 of this Protocol.

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

5. If necessary, the importing Parties may impound, destroy or re-export unauthorized LMOs, or products thereof, at the cost of the exporter.]

VENEZUELA

1. In the event that harm including transboundary harm, that proves detrimental to the conservation of biological diversity, the environment, human or animal health or socio-economic welfare of societies, arises as a consequence of transboundary movement, handling or use of LMOs or products thereof, the exporter shall be strictly liable for such harm, which must be promptly and adequately compensated. Independently of the duty of compensation, the States involved should implement the necessary contingency plans, to restore as far as possible the conditions that existed prior to the occurrence of the harm.

2. The exporter shall also be responsible for the harm caused by inadequate risk assessment that produces adverse effect on the conservation of biological diversity, the environment, human or animal health and the socio-economic welfare of societies.

3. No liability shall be imputed to the exporter if he proves that harm from pollution:

(a) Was caused by negligence of the importer in carrying out risk management in the handling and use of the LMO and products thereof. In such a case, the liability for harm falls on the importer;

(b) Is due to an act of war, hostilities, civil war, insurrection or a natural phenomenon of an exceptional, inevitable and irresistible character.

4. Where the exporter is a State Party to the Protocol, it shall be liable for the harm and shall renounce any defence protecting it because of its condition as a sovereign State.

5. The Parties shall ensure that those responsible for any harm caused by the transboundary movement, handling or use of LMO and products thereof shall promptly and justly compensate the affected Parties, including the State of transit.

6. If the harm is produced in areas outside any national jurisdiction, the Parties shall procure that those responsible take the necessary measures to reduce to the minimum the negative effect produced on the environment, biological diversity and human and animal health.

7. Parties which are Parties of export, Parties of export, Parties of transit or Parties of import shall ensure, with respect to persons within their jurisdiction, that liability is covered by insurance, indemnity bond or other financial guarantee, in order to undertake transboundary movements, handling or use of LMOs and products thereof.

8. If, as a consequence of the harm, there is also harm to persons and/or damage to property in the affected States, the payments made by those responsible shall also include compensation for such harm or damage, and an insurance policy, indemnity bond or other financial guarantee shall be entered into for this end.

9. The parties to this Protocol shall establish an International Fund, for the implementation of immediate measures in emergency cases and for the payment of compensation to the extent that compensation for harm is inadequate or impossible to obtain because of the civil liability regime. This Fund will be contributed by all signatory Parties.

10. Civil proceedings brought to demand compensation for harm caused as a consequence of transboundary movements, the handling and use of LMOs and products thereof shall be brought before the courts of the Parties to the Protocol or of the States where the harm has been suffered or the incident has occurred; in the State of the defendant's nationality or where such defendant is domiciled or has the head office of his business. Parties shall take steps to ensure that their courts have the necessary jurisdiction to hear petitions for compensation.

11. Proceedings in respect of liability shall lapse after a period of NNN years from the date on which the affected Party learned or could reasonably be expected to have learned of the harm, its causes and the identity if the person or persons responsible.

ARTICLE 28 - FINANCIAL MECHANISM AND RESOURCES

ECUADOR

Ecuador accepts option 1.

NEW ZEALAND

We favour option 2.

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

PERU

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 of this Protocol.

2. The developed country Parties shall, in a predictable and timely manner, provide new and additional financial resources to the financial mechanism to enable developing countries to meet the agreed full incremental costs to them of implementing measures which will fulfil the obligations of this Protocol.

3. On matters related to activities under the provisions of this Protocol, the financial mechanism shall function under the authority and guidance of, and be accountable to, the Conference of the Parties serving as the meeting of the Parties to this Protocol.

4. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply mutatis mutandis to the provisions of this Article.

5. 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.

SLOVENIA

Option 2: no comment

THAILAND

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 of this Protocol.

2. The developed country Parties shall, in a predictable and timely manner, provide new and additional financial resources to the financial mechanism to enable developing countries to meet the agreed full incremental costs to them of implementing measures which will fulfil the obligations of this Protocol.

3. On matters related to activities under the provisions of this Protocol, the financial mechanism shall function under the authority and guidance of, and be accountable to, the Conference of the Parties serving as the meeting of the Parties to this Protocol.

4. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply mutatis mutandis to the provisions of this Article.

5. 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.

VENEZUELA

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 of this Protocol.

2. The developed country Parties shall, in a predictable and timely manner, provide new and additional financial resources to the financial mechanism to enable developing countries to meet the agreed full incremental costs to them of implementing measures which will fulfil the obligations of this Protocol.

3. On matters related to activities under the provisions of this Protocol, the financial mechanism shall function under the authority and guidance of, and be accountable to, the Conference of the Parties serving as the meeting of the Parties to this Protocol.

4. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply mutatis mutandis to the provisions of this Article.

5. 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.

ARTICLE 29 - CONFERENCE OF THE PARTIES

PERU

1. The Conference of the Parties to the Convention shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 35 of this protocol and, as well, reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are determined necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied mutatis mutandis under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this

Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, which is qualified in matters covered by this Protocol and which has informed the Secretariat of its wish to be represented at a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

SLOVENIA

Revised, from 1 to 8, no comments

THAILAND

1. The Conference of the Parties to the Convention shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 35 of this protocol and, as well, reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are determined necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied mutatis mutandis under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, which is qualified in matters covered by this Protocol and which has informed the Secretariat of its wish to be represented at a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

VENEZUELA

1. The Conference of the Parties to the Convention shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 35 of this protocol and, as well, reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are determined necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied mutatis mutandis under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties

serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, which is qualified in matters covered by this Protocol and which has informed the Secretariat of its wish to be represented at a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

ARTICLE 30 - SUBSIDIARY BODIES AND MECHANISMS

PERU

1. Any subsidiary body established by or under the Convention may, upon a decision by the meeting of the Parties, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of a subsidiary body of the Protocol. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by the Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the Bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

SLOVENIA

Revised, from 1 to 3, no comments

THAILAND

1. Any subsidiary body established by or under the Convention may, upon a decision by the meeting of the Parties, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of a subsidiary body of the Protocol. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by the Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the Bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

UNITED STATES OF AMERICA

Add a new paragraph: 4. The provisions of Article 29(8) shall apply to meetings of a subsidiary body of the Protocol.

VENEZUELA

1. Any subsidiary body established by or under the Convention may, upon a decision by the meeting of the Parties, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of a subsidiary body of the Protocol. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by the Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the Bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

ARTICLE 31 - SECRETARIAT

PERU

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

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply mutatis mutandis to this Protocol.

3. [To the extent that these are distinct, the costs of the Secretariat services for this Protocol shall be met by the Parties hereto. [The Conference of the Parties to this Protocol shall decide at its first meeting the necessary financial arrangements to this end.]]

SLOVENIA

Revised, from 1 to 2, no comments

3. The Conference of the Parties to this protocol shall decide at its first meeting the necessary financial arrangements to this end.

THAILAND

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

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply mutatis mutandis to this Protocol.

VENEZUELA

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

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply mutatis mutandis to this Protocol.
3. To the extent that these are distinct, the costs of the Secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties to this Protocol shall decide at its first meeting the necessary financial arrangements to this end.

ARTICLE 32 - JURISDICTIONAL SCOPE

New Zealand

Deleted

PERU

Deleted.

SLOVENIA

Deleted

THAILAND

Deleted

VENEZUELA

Deleted

ARTICLE 33 - RELATIONSHIP WITH THE CONVENTION

NEW ZEALAND

We have no comment to make on these articles.

PERU

Unless otherwise provided by this Protocol, the provisions of the Convention relating to its Protocols shall apply to this Protocol.

SLOVENIA

no comment

THAILAND

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol. 1/

VENEZUELA

Unless otherwise provided by this Protocol, the provisions of the Convention relating to its Protocols shall apply to this Protocol.

ARTICLE 34 - RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

ECUADOR

Ecuador accepts option 2.

NEW ZEALAND

We favour 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.)

PERU

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.

1/ The issue of information-sharing remains until further substantive issues from other articles of the Protocol are developed.

SLOVENIA

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.

THAILAND

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.

URUGUAY

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.

VENEZUELA

No provision is necessary.

ARTICLE 35 - MONITORING AND REPORTING

EUROPEAN COMMUNITY

After careful consideration of the proposals currently on the table as regards Articles 5 and 6 it appears that additional mechanisms need to be developed to address cases of failure to respond, in particular when bilateral efforts pursued by the Party of export have not been successful in triggering a response by the Party of import.

The EC and its Member States would like to suggest that Parties have the possibility to refer such cases to a monitoring and assistance process operating through a body under the Protocol, which should aim at helping Parties having failed to respond to a notification:

"1. Parties are encouraged to provide assistance to any Party of import, especially in responding to notifications under the AIA procedure.

2. Parties may refer cases for which a Party of import has not responded within the period specified in Article 6 to a monitoring and assistance process operating through a standing body composed of a limited number of experts and acting in accordance with the provisions of Article [Z](this article will describe the terms of reference of the standing body.)

3. The process should be guided by the need of all Parties to co-operate in good faith and participate fully. Therefore it should be simple, advisory and transparent."

On a preliminary basis we would suggest to include this provision in

Article 35.

NEW ZEALAND

No comment.

PERU

1. Each Party shall monitor the implementation of its obligations under this Protocol and establish and/or maintain systems for this purpose.

2. Each Party shall, at intervals to be determined by the meeting of the Parties to this Protocol, report to the meeting of the Parties to this Protocol on measures taken to implement this Protocol.

SLOVENIA

New, 1. each party shall monitor the implementation of its obligations under this Protocol and establish and maintain system for this purpose.

2. no comment

THAILAND

[1. Each Party shall monitor the implementation of its obligations under this Protocol and establish and/or maintain systems for this purpose.]

2. Each Party shall, at intervals to be determined by the meeting of the Parties to this Protocol, report to the meeting of the Parties to this Protocol on measures taken to implement this Protocol.

VENEZUELA

1. Each Party shall monitor the implementation of its obligations under this Protocol and establish and/or maintain systems for this purpose.

2. Each Party shall, at intervals to be determined by the meeting of the Parties to this Protocol, report to the meeting of the Parties to this Protocol on measures taken to implement this Protocol.

ARTICLE 35 Bis - COMPLIANCE

ECUADOR

Ecuador accepts option 1 with the following wording: "The Parties shall consider and approve procedures and institutional mechanisms for determining non-compliance with the provisions of this Protocol and for the treatment..."

NEW ZEALAND

We favour the following modification of option 1.

The Parties shall consider and approve procedures for determining non-compliance with the provisions of this Protocol and for the treatment of parties found to be in non-compliance.

PERU

Option 1

The Parties shall at their first meeting consider and approve procedures and institutional mechanisms for determining non-compliance with the provisions of this Protocol and for the treatment of Parties found to be in non-compliance.

SLOVENIA

New, Option 1:

The Parties shall consider and approve procedures and institutional mechanisms for determining non-compliance with the provisions of this Protocol.

THAILAND

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

VENEZUELA

No provision is necessary.

[ARTICLE 36 - ASSESSMENT AND REVIEW OF PROCEDURES/ANNEXES]

ECUADOR

Ecuador accepts option 1.

NEW ZEALAND

We favour option 2 (brackets removed).

(The Meeting of the Parties shall undertake three years after the entry into force of this Protocol, and at least every six years thereafter, an evaluation of its effectiveness.)

PERU

Option 2

The Meeting of the Parties shall undertake three years after the entry into force of this Protocol, and at least every six years thereafter, an evaluation of its effectiveness.

SLOVENIA

Revised, Option 2:

The meeting of the Parties shall undertake three years after the entry into force of this protocol, and at least every six years thereafter, an evaluation of its effectiveness.

THAILAND

The Meeting of the Parties shall undertake [three] years after the entry into force of this Protocol, and at least every [six] years thereafter, an evaluation of its effectiveness.

VENEZUELA

Beginning in three years, 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 should consider the need to convene an 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

PERU

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 [ ].

SLOVENIA

The Conference of the Parties to this Protocol shall decide at the meeting....

THAILAND

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 [ ].

VENEZUELA

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

NEW ZEALAND

Deleted

PERU

Deleted

SLOVENIA

Deleted

THAILAND

Deleted

VENEZUELA

Deleted

ARTICLE 39 - ACCESSION

PERU

Deleted

ARTICLE 39 - ACCESSION

New Zealand

Deleted

PERU

Deleted

SLOVENIA

Deleted

THAILAND

Deleted

VENEZUELA

Deleted

ARTICLE 40 - ENTRY INTO FORCE

NEW ZEALAND

No comment.

VENEZUELA

Deleted

ARTICLE 40 - ENTRY INTO FORCE

NEW ZEALAND

No comment.

PERU

1. 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 the Convention 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.

SLOVENIA

Revised: 1. This Protocol shall enter into force on the ninetieth day after the date of deposit of its instrument of ratification acceptance, approval or accession.
2 and 3: no comments

THAILAND

1. 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 the Convention 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.

VENEZUELA

1. 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 the Convention 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

ECUADOR

Ecuador accepts option 1

NEW ZEALAND

Option 1

(No reservations may be made to this Protocol.)

PERU

Option zero

No provision is necessary.

Option 1

No reservations may be made to this Protocol.

SLOVENIA

Option 1

THAILAND

Option 1

No reservations may be made to this Protocol.

VENEZUELA

No reservations may be made to this Protocol.

ARTICLE 42 - WITHDRAWAL

PERU

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 notification 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.

SLOVENIA

1 and 2: no comments

THAILAND

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 notification 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.

VENEZUELA

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 notification 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.

ARTICLE 43 - AUTHENTIC TEXTS

NEW ZEALAND

No comment.

PERU

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.

THAILAND

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.

VENEZUELA

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.

Annexes

I.. INFORMATION REQUIRED IN NOTIFICATIONS FOR ADVANCE INFORMED AGREEMENT

NEW ZEALAND

We favour the following modification .

(a) Name and address of applicant

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

(c) Common name and taxonomic status of the organism

(d) Centre of origin/genetic diversity relevant to the organism that has been modified

(e) Description of nucleic acid fragment(s)/trait introduced or modified and resulting characteristics of the LMO

(f) Intended use of the LMO

(g) Quantity of LMOs to be transferred or volume and physical state of culture

(h) A risk assessment report in accordance with the risk assessment guidelines outlined in Annex II of the Protocol

(i) Suggested methods to ensure safe handling, storage, transport and use, including packaging, documentation, disposal and contingency methods where appropriate

(j) Intended date of first movement

(k) Declaration that the information is factually correct

NORWAY

Add in Annex I on Information required for AIA as a new element m) «the status of the LMO in question within the exporting state and if known, also in the importing state (whether it is prohibited in the state of export/import or whether there are other restrictions)

PERU

(a) Designation [and classification of biosafety levels] of LMO(s) [or products thereof].

(b) Name and address of the exporter.

(c) Name and address of the importer.

(d) Common name, taxonomic status, [source and characteristics] of recipient organism [and donor organism].

(e) Centre of origin/genetic diversity [if known] relevant to the organism that has been modified.

(f) Description of DNA/RNA fragment(s)/traits introduced or modified and resulting characteristics of the LMO [or products thereof].

(g) Intended use of the LMO [or products thereof][if known].

(h) Quantity of LMOs [or products thereof] to be transferred or volume and physical state of culture.

(i) A [known and available] risk assessment report [carried out on the LMO [or products thereof] in question] in accordance with the risk assessment parameters as stated in Annex II of the Protocol.

(j) Suggested methods to ensure safe handling, storage, transport and use, including packaging, [labelling,] documentation, disposal and contingency procedures.

(k) Intended date[s] of [first] [transfer] [movement].

(l) Declaration that the information is [factually] correct.

SLOVENIA

(a) Designation and classification of Biosafety level of LMOs and products thereof.

(b) and (c) no comments

(d) Common name, taxonomic status, source and characteristics of recipient organism and donor organism.

(e) no comment

(f) Description of DNA/RNA fragment(s) /traits introduced or modified and resulting characteristics of the LMOs and products thereof.

(g) Intended use of the LMOs and products thereof.

(h) Quantity of LMOs and products thereof.

(I) A known and available risk assessment report carried out on the LMOs and products thereof in accordance with the risk assessment parameters as stated in Annex II of the Protocol.

(j) Suggested methods to ensure safe handling, storage, transport and use, including packaging and labelling, documentation, disposal and contingency procedures.

(k) Intended date of first transfer movement.

(l) Declaration that the information is correct.

THAILAND

(a) Designation [and classification of biosafety levels] of LMO(s) [or products thereof].

(b) Name and address of the exporter.

(c) Name and address of the importer.

(d) Common name, taxonomic status, [source and characteristics] of recipient organism [and donor organism].

(e) Centre of origin/genetic diversity relevant to the organism that has been modified.

(f) Description of DNA/RNA fragment(s)/traits introduced or modified and resulting characteristics of the LMO [or products thereof].

(g) Intended use of the LMO [or products thereof].

(h) Quantity of LMOs [or products thereof] to be transferred or volume and physical state of culture.

(i) A [known and available] risk assessment report [carried out on the LMO [or products thereof] in question] in accordance with the risk assessment parameters as stated in Annex II of the Protocol.

(j) Suggested methods to ensure safe handling, storage, transport and use, including packaging, [labelling,] documentation, disposal and contingency procedures.

(k) Intended date[s] of [first] [movement].

(l) Declaration that the information is [factually] correct.

II. RISK ASSESSMENT

AUSTRALIA

Australia wishes to see the following alternative option included:

1. The objectives of risk assessment in relation to the transboundary movement of living modified organisms under the Protocol are:

(a) identification of any hazardous characteristics associated with the novel trait(s) introduced into the LMO that may have adverse effects on the conservation and sustainable use of biological diversity;

(b) an evaluation of the likelihood of these hazards being realized, taking into account the level and kind of exposure of the receiving environment to the LMO;

(c) an evaluation of the consequences for biological diversity should these hazards be realized;

(d) an evaluation of the overall risk posed by the LMO based on the assessed likelihood and consequences for biological diversity of the identified hazards; and

(e) an evaluation of whether or not the risks are acceptable or manageable, including identification of strategies to manage these risks and minimise the possibility of adverse consequences.

2. Risk assessment should be carried out in a scientifically sound and transparent manner, taking into account relevant scientific evidence, expert technical and technological advice, experience and techniques developed by relevant international organizations.

3. Risk assessment shall, inter alia, take into account:

(a) characteristics of the recipient organism;

(b) characteristics of the donor organism;

(c) characteristics of the vector;

(d) characteristics of the living modified organism;

(e) information concerning the intended use of the LMO;

(f) characteristics of the potential receiving environment related to biological diversity.

NEW ZEALAND

Modified Option 1

1. The objective of risk assessment is to consider, as appropriate the following points:

(a) Identification of any characteristics of the LMO linked to genetic modification that may have adverse effects in the receiving environment

(b) Estimation of the risk of each adverse effect by determining the likelihood and extent of the consequences of the adverse effect being realised.

(c) Application of management strategies, when appropriate, for risks from the release of the LMO. The management strategies should be commensurate with the results of the risk assessment.

2. Any new risks associated with the LMO or its use should be considered in the context of the risks posed by other organisms not subject to this risk assessment or risks that my be posed if the LMO is not deliberately released.

3. Full regard should be paid to the experience gained and to the relevant literature and consultation with available experts and public authorities.

4. The information required for a scientifically sound risk assessment will vary case by case, but should include, as appropriate:

(a) Characteristics of the LMO itself (including the organisms from which the novel trait is derived, the donor, the vector, and the inserted nucleic acid)

(b) Intended use (in containment or for deliberate release)

(c) Characteristics of the receiving environment

NORWAY

Contained use of LMO

«The containment of LMOs must be based on the principle that a precautionary approach as regards safety to human health and the environment shall be followed in order to ensure that the expected benefits can develop safely.

When facilities are to be used for the first time for activities involving the contained use of LMOs, the users shall be required to submit to the competent authority an application for approval. The facility shall be suitable and equipped for the intended purpose, and shall be classified according to the risk, the type of acitivity and the LMOs to be used.

The LMOs intended for contained use and the type of acitiviy planned, shall be reigstered or approved by the competent authority according to the risk involved. The use shall carry out a prior risk assessment of the contained use as regards risks to human health and the environment.

All activities with LMOs that take place within the approved facility shall be registered by the responsible person (s) in a protocol. The protocol shall be available for the competent authorities when required.

Information required for approval of contained use of LMOs:

(a) name of company or institution, location and address of the facility

(b) responsible person (s)

(c) the date of when the facility received the approval for contained use

(d) information to, and training of, employees and other personnel handling the LMOs

(e) summary of the risk assessment

(f) the intended use and application of the LMO

(g) planned containment measures (physical and biological)

(h) plans for preventing accidents and unexpected events

(i) contingency plans if accidental release

(j) plans for waste treatment

(k) possible interactions between the LMOs and the environment associated with an unintended release into the environment

PERU

Option 1

RISK ASSESSMENT FACTORS

1. The objective of risk assessment is to consider, as appropriate, the following points:

(a) Identification of any [hazardous] characteristics of the LMO [or products thereof] linked to the genetic modification [that may have adverse effects on the conservation and sustainable use of biological diversity [or] [taking also into account risks to] human health];

(b) The extent of the consequences of the [hazard][adverse effect] resulting from the genetic modification being realized;

(c) The likelihood of the [hazard][adverse effect] being realized;

(d) Estimation of the risk posed by each identified [hazard][adverse effect];

(e) Application of management strategies, when appropriate, for risks from the release of the LMO [or products thereof]. The management strategies should be commensurate with the results of the risk assessment;

(f) Determination of the overall risk of adverse effects.

2. Any new risks associated with the LMO [or products thereof] or its use should be considered in the context of the risks posed by using other organisms not subject to this risk assessment or risks that may be posed if the LMO [or products thereof] is not released.

3. Full regard should be paid to the experience gained and to the relevant literature and consultation with available experts and public authorities.

4. [The level of risk can be minimized either by applying risk-management strategies or by deciding not to proceed with the intended use of the LMO [or products thereof].]

5. The information required for a scientifically sound risk assessment could include the following, depending on the LMO [or products thereof], the application, the receiving environment and the interaction between the environment and the LMO [or products thereof], as appropriate. The application of this list may vary from LMO [or products thereof] to LMO [or products thereof]. Risk assessment may require more specific information about individual topics, which may be obtained during the assessment process, while other topics may not be relevant in some instances. Discussion of the scientific rationale for including particular data in particular instances is often appropriate in deciding how to conduct the assessment.

INFORMATION RELATING TO THE LMO [OR PRODUCTS THEREOF]

A. Characteristics of the recipient organism

6. The relevant biological, physiological and genetic and environmental characteristics of the recipient/parental/host organism include, as appropriate:

(a) The name and identity of the organism;

(b) Pathogenicity and toxicity;

(c) The natural habitat and the geographic origin of the organism, its distribution and its role in that habitat;

(d) Mechanisms by which the organism survives, multiplies and disseminates in the environment;

(e) Means for transfer of genetic material to other organisms.

B. Characteristics of the organisms from which the DNA/RNA fragments [nucleic acid] are obtained (the donor)

7. The relevant characteristics include, in particular, pathogenicity and toxicity.

C. Characteristics of the vector

(a) Identity, origin, natural habitat, integrative properties and the relevant safety characteristics of the vector.

(b) The frequency at which the vector can be mobilized or can transfer itself to other organisms.

(c) Factors which would influence the ability of the vector to become established in other hosts.

D. Characteristic of the inserted DNA/RNA fragments [nucleic acid] (the insert)

(a) Functions as specified by the insert, including any residual vector.

(b) Information on the expression of the insert and the activity of the gene products.

E. Characteristics of the LMO [or products thereof]

8. The LMO [or products thereof] should be compared with the organism from which it is derived, examining, where relevant, the following points:

(a) Pathogenicity and toxicity to other organisms;

(b) Survival, persistence, competitive abilities and dissemination in the environment or other relevant interactions;

(c) Capacity to transfer genetic material and the way in which this might occur;

(d) Functions which might affect its ecological range;

(e) Characterization of the products of the inserted genes and, where appropriate, the stability of the modification.

INFORMATION RELATING TO THE INTENDED USE

9. The amount of information required will vary with the characteristics of the LMO [or products thereof] and use, frequency and the scale of the intended use. Also consider possible new or changed use or practice, compared to traditional use or practice with similar non-modified organisms (for example, new or changed farming, forestry and aquaculture practice, etc. as a consequence of the living modified organism).

[10. For contained uses, this can include:

(a) Number or volume of LMO [or products thereof] to be used;

(b) Scale of the operation;

(c) Proposed containment measures, including the verification of their functioning;

(d) Training and supervision of personnel carrying out the work;

(e) Plans for waste management;

(f) Plans for safety of the health of personnel;

(g) Plans for handling accidents and unexpected events;

(h) Relevant information from previous uses.]

11. For deliberate releases, this can include:

(a) Purpose and scale of the release;

(b) Geographical description and location of the release;

(c) When relevant, proximity to residences and human activities;

(d) Method and frequency of release;

(e) As appropriate, training and supervision of personnel carrying out the work;

(f) Likelihood of unintended transboundary movement;

(g) Time and duration of the release;

(h) Expected environmental conditions during the release;

(i) As appropriate, proposed risk-management measures, including verification of their functioning;

(j) As appropriate, subsequent treatment of the site and plans for waste management;

(k) Plans for handling accidents and unexpected events;

(l) Relevant information from any previous releases.

CHARACTERISTICS OF THE POTENTIAL RECEIVING ENVIRONMENT

12. The potential for an organism to cause harm is related to the environment into which it may be released and its interaction with other organisms. Relevant information can include:

(a) The geographical location of the site, the identity and any special features of the receiving environments that expose them to damage;

(b) Where relevant, the proximity of the site to humans and to significant biota;

(c) 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;

(d) The potential of any organism in the potential receiving environment to receive genes from the released LMO [or products thereof].

13. Note should be taken of any likely changes to interaction between the LMO [or products thereof] and non-target organisms, or between any target organisms of the LMO [or products thereof] and other organisms in the ecosystems.

SLOVENIA

Option 1

THAILAND

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

2. The guiding principle of risk assessment is the precautionary approach. Where the transboundary movement, or use or handling of LMOs [or products thereof] may cause, or has the potential to cause harm to biodiversity, human or animal health, the lack of full scientific certainty or consensus regarding the level of risk should not be interpreted as the lack of risk, or as acceptable risk.

3. The risk assessment should, inter alia, take into account all relevant scientific evidence and experience, including previous risk assessments. This enables the risk assessment to evolve in the light of new evidence and knowledge; an LMO [or products thereof] previously considered acceptable may no longer be acceptable, and vice versa.

4. The 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(s), the vector(s) used, the genetic modification(s) and the novel trait(s), including marker trait(s) and other sequences even when not expressed;

(c) The native environments or host range of the recipient organism and donor organism(s);

(d) The intended use(s) of the living modified organism and the nature of the receiving and surrounding environments;

(e) Potential impact of the LMO [or products thereof] on the environment(s), including long-term ecological impacts, particularly on centers of origin and areas with high genetic diversity of taxa related to the living modified organism;

(f) Effects of the LMO [or products thereof] on human health and

animals;

(g) Socio-economic impacts;

(h) Conformity with ethical norms of receiving party/State;

(i) Details of risk assessments completed elsewhere.

5. The information required for risk assessment should include the following:

B. Specific information requirements

6. Characteristics of donor and recipient organisms or parental organisms:

(a) Scientific name and taxonomy;

(b) Strain, cultivar or other name;

(c) Species it is related to and degree of relatedness;

(d) The degree of relatedness between the donor and recipient organisms, or between the parental organisms;

(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) Description of identification and detection techniques for the organisms, and the sensitivities of these techniques;

(j) Geographic distribution and natural habitats of the organisms including information on natural predators, prey, parasites, competitors, symbionts and hosts;

(k) Climatic characteristics of original habitats;

(l) Ability of the organisms to survive and colonize the environment to which release is intended or otherwise;

(m) Genetic stability of the organisms, and factors affecting the stability;

(n) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;

(o) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;

(p) Pathogenicity to humans or animals, if any;

(q) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;

(r) Known allergenicity and/or toxicity of biochemical and metabolic products;

(s) Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

7. Characteristics 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 marker 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) Complete nucleotide sequence of the vector(s);

(e) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;

(f) Potential for pathogenicity and virulence;

(g) Natural and host range of vectors;

(h) Natural habitat and geographic distribution of natural and potential hosts;

(i) Potential impacts on human and animal health and the environment;

(j) Measures for counteracting adverse impacts;

(k) Potential to survive and multiply in the environment, or to form genetic recombinants;

(l) Genetic stability of vector(s), such as hypermutability.

8. Characteristics of living modified organism:

(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) are integrated or extrachromosomal;

(f) Number of insert(s) and its/their structure(s), for example, the copy number whether in tandem or other types of repeats and the position of each insert;

(g) Nucleotide sequence of each insert, including at least one kilobase up and down stream from the insert;

(h) Product(s) of the transferred gene(s), levels of expression and methods for measuring expression;

(i) Stability of the introduced gene(s) in terms of expression and integration;

(j) Biochemical and metabolic differences of living modified organism compared with the unmodified organism;

(k) Probability of vertical or horizontal gene transfer to other species;

(l) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;

(m) Allergenicities, toxicities, pathogenicities and unintended effects;

(n) Autecology of the living modified organism compared with that of the unmodified organism;

(o) Susceptibility of the living modified organism to diseases and pests compared with the unmodified organism;

(p) Detailed information on past uses including results on all experiments leading to previous releases.

9. Characteristics of resuscitated organism(s) and gene(s) and fossil DNA sequences:

Resuscitated organism

(a) Scientific name and taxonomy;

(b) Identity of nearest species and their characteristics which are of relevance to the intended use;

(c) Site at which it was found;

(d) Method used for resuscitation;

(e) Purpose of introducing the organism and benefits, if any;

(f) Impacts on human and animal health and the environment;

(g) Measures for counteracting adverse impacts;

(h) Length of time the organism has been in use;

(i) Genetic stability;

(j) Likelihood of gene transfer to other organisms;

(k) Fossil and living nearest relative species;

(l) Biological and biochemical differences from related living species;

(m) Information on previous uses since resuscitation.

DNA sequences from fossils or from resuscitated organism

(a) Scientific name and taxonomy of the species whether resuscitated or a fossil;

(b) Site of origin of the fossil;

(c) Site of the gene in the resuscitated genome, if known;

(d) Base sequence of the extracted gene;

(e) Method used in extracting the gene;

(f) Function of gene, if known;

(g) Purpose of use and benefits, if any

(h) Environment in which it lived before fossilization;

(i) Fossil species related to the species from which the gene was taken;

(j) Living species related to the species from which the gene was taken.

10. 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.

11. 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.

12. 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 or products thereof;

(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 the product thereof].

III. LIST OF ANNEXES TO THE DRAFT PROTOCOL

EUROPEAN COMMUNITY

i. as regards the Annex referred to in Article 3A option 1 paragraph 2(a) and listed in Annex III, item 3(a), of doc. UNEP/CBD/BSWG/5/Inf.1, the EC and its Member States propose the inclusion of:

" - LMOs which are pharmaceuticals for humans;"

ii. as regards the Annex listed in Annex III, item 29(e), of doc. UNEP/CBD/BSWG/5/Inf.1, the EC and its Member States propose the following:

"Annex 2 (e):Information requirements for unintentional release /transboundary movement (Article 15)

- use of LMO in the originating Party;
- identity, relevant characteristics/traits of the LMO
- estimated amount of the LMOs unintentionally moved;
- estimated date of the unintentional movement;
- assessment of the methods for monitoring, control and mitigation or emergency measures, as appropriate, including possible contingency measures or methods for the removal or the safe disposal of the LMO from the areas affected;
- assessment of possible adverse effects
- contact point for further information;"

iii. as regards the Annex referred to in Option 2 paragraph 1 d of Article 17 and listed in Annex III, item 3(f), of doc. UNEP/CBD/BSWG/5/Inf.1, the EC and its Member States propose the following:

Annex 3 (f): Information required for the transfer of LMOs (Article 17)

- statement as to the presence of LMOs in the shipment;
- identity and the relevant characteristics/traits of the LMO
- relevant requirements to ensure safe handling, storage, transport and use;
- name and address of the exporter and importer or contact point for further information;
- declaration that the movement is in conformity with the requirements of the Protocol;"

as regards the Annex referred to in Option 1 paragraph 1 c of Article 9 and listed in Annex III, item 2(j) [information requirements for simplified procedures], of doc. UNEP/CBD/BSWG/5/Inf.1, the EC and its Member States are of the view that its content should be identical to that of Annex I of doc. UNEP/CBD/BSWG/5/Inf.1 [information required in notifications for AIA].

THAILAND

1. Consolidated text from Contact Group I

Annex I: Information required in notifications for Advance Informed Agreement.

Annex II: Risk assessment.

2. Annexes in government submissions

(a) Risk management;

(b) Function of focal points/competent authorities;

(c) Information to be provided to the Secretariat under information-sharing/clearing house;

(d) (i) Contained use of the living modified organism;

(ii) Requirements/guidelines for the use of LMOs in contained facilities;

(e) Information requirements for unintentional release/transboundary movement;

(f) Information requirements for notifications;

(g) Lists of, and criteria for, LMOs, genes/traits and activities with LMOs to which the Protocol shall not apply;

(h) Relevant information on LMOs (in relation to the European Union submission for Article 4, paragraph 4);

(i) Cases of explicit consent;

(j) Information requirements for simplified procedures.

3. Annexes referred to in the consolidated text of the sub-working groups

(a) LMOs not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 3);

(b) Criteria for LMOs to be included in the AIA procedure (Article 3);

(c) Cases of transboundary movement subject to explicit consent (Article 6);

(d) LMOs to be exempted from AIA procedure (Article 9 (cf. Article 3));

(e) Information required in the notification of transboundary movement (Article 9);

(f) Information required for the transfer of LMOs (Article 17).

3. RESPONSE TO THE AIDE-MÉMOIRE FROM THE CO-CHAIRS OF CONTACT GROUPS 1 AND 2

RESPONSE TO THE AIDE-MÉMOIRE FROM THE CO-CHAIRS OF CONTACT GROUPS 1 AND 2

EUROPEAN COMMUNITY

i. Will the Protocol apply to transboundary movement of LMOs between Parties only, or also between Parties and non-Parties?

The EC and its Member States are of the view that the definition of "transboundary movement" and the application of the Protocol to movement between Parties and Non-Parties are separate issues and should be treated as such.

The views of the EC and its Member States on the applicability of the Protocol to non-Parties are set out in Article 23 on non-Parties, option 4, paragraphs 1B, 2B, 3 and 4. These aim at striking the appropriate balance between the need to adopt specific provisions in respect to non-Parties in order to achieve the environmental objectives of a multilateral environmental agreement such as the protocol and the particular care that should be taken over how measures with potential trade implication may be considered for application to non-Parties.

ii. Will the Protocol apply to transboundary movement outside the area of jurisdiction of any country (e.g. international waters, Antarctica)?

We would like first of all to make it clear that in our view this issue does not have to be considered for cases where only part of an intentional transboundary movement is taking place outside the area of jurisdiction of any country, i.e. transit through international waters from an area under national jurisdiction to another area under national jurisdiction.

We note that the international community has developed and adopted several legally binding instruments specifically to protect the environment of areas outside national jurisdiction, such as the Antarctic Treaty and its Protocol on Environmental Protection, the Convention on the conservation of Antarctic marine living resources[1] and the UN Convention on the Law of the Sea. Since one or more States might not be Parties to the Protocol whilst they are Parties to international agreements containing provisions on the protection on the environment in areas not under national jurisdiction (e.g. UNCLOS), provisions under the Protocol may not allow for proper consideration of the rights of these States and may be incompatible with these provisions.

We note further that these instruments already include provisions on co-operation between Parties[2] and provisions on the introduction of alien or new species[3] .

Although Article 1 bis on general obligations should certainly apply we conclude that for transboundary movements taking place from an area under

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[1] To which the Community is a Party since 1981 (see Council Decision 81/691/EEC).

[2] For example Art. 197 of UNCLOS.

[3] Art. 196 of UNCLOS, Art. II(3) c of the Convention on the conservation of Antarctic marine living resources, Art. 4 of the Protocol on Environmental Protection.

national jurisdiction to an area outside national jurisdiction it will be more effective to rely on provisions under the previously mentioned instruments than to elaborate provisions under the protocol on biosafety. However, to make it quite clear to the Parties to these instruments that measures should be taken to ensure an adequate level of protection in the field of biosafety when moving an LMO into these areas, a preambular paragraph to that effect could be inserted in the biosafety protocol.

In light of the replies to questions i. and ii. and bearing in mind the history of these questions the EC and its Member States conclude that the definition of transboundary movement can be relatively simple and framed along the following line:

"transboundary movement means movement from or to an area under national jurisdiction"

iii. Will the Protocol apply to transit?

In order to achieve the overall environmental objective of the protocol, notably in the case of unintentional transboundary movement and emergency measures the EC and its Member States believe that certain provisions of the protocol should apply to transit. In this respect the EC and its Member States are of the view that only Article 1 bis on general obligations and merged Articles 15 and 16 on unintentional transboundary movement should apply to transit.

iv To which entities (natural or legal persons, States/parties) are the obligations regarding transboundary movements addressed?

As a matter of international law, the Protocol binds states and REIOs which are Parties to it, not individuals. In order to be implemented some of the obligations will have to be placed on individuals, in accordance with the domestic legal systems of Parties. In this context, the EC and its Member States are of the view that the Parties shall ensure that obligations for notification of intentional transboundary movement should be placed on the exporter i.e. the natural or legal person under the jurisdiction of the Party of export who is responsible for the intentional transboundary movement.
