UNEP

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CONVENTION ON
BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/BSWG/3/5
18 August 1997

ORIGINAL: ENGLISH

OPEN-ENDED AD HOC WORKING
GROUP ON BIOSAFETY
Third Meeting.
Montreal, Canada
13 to 17 October 1997

GOVERNMENT SUBMISSIONS

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AFRICAN REGION

/...

FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

ENVIRONMENTAL PROTECTION AUTHORITY

DRAFT PROTOCOL TO THE CONVENTION ON BIOLOGICAL DIVERSITY CONCERNING SAFETY IN BIOTECHNOLOGY

ADDIS ABABA
October 1996

FOREWORD

In July 1996, the African delegates in the biosafety negotiations at Aarhus, Denmark, asked the Ethiopian delegation to prepare a draft of a Protocol for Safety in Biotechnology on their behalf. The result is the present draft.

The drafting of this Protocol and the holding of the meetings that reviewed it were made possible through funding raised by the Third World Network (TWN). The head office of TWN is in Penang, Malaysia, but as its name suggests it has individual and institutional members in various developing countries.

The Institute for Sustainable Development (ISD) which is based in Addis Ababa, is a member of TWN. The funds from TWN were directed through it. ISD also provided logistical support to the Environmental Protection Authority (EPA) to develop this Protocol.

The drafting committee of this Protocol consisted of representatives from EPA, the Ethiopian Science and Technology Commission, the Biodiversity Institute and the Addis Ababa University.

The draft made by the committee was reviewed internally at these institutions and nationally in a two-day workshop (17–18 October 1996) held in Addis Ababa attended by representatives of concerned government offices and research and teaching institutions.

The present version of the draft Protocol, accommodating the outcomes of previous reviews, was discussed in Addis Ababa on 23–25 October 1996, by representatives from various African countries for a final review before being presented to the Third Conference of the Parties to the Convention on Biological Diversity as the African position on biosafety.

DRAFT PROTOCOL TO THE CONVENTION ON BIOLOGICAL DIVERSITY CONCERNING SAFETY IN BIOTECHNOLOGY

Preamble

The Parties to this Protocol:

Being Parties to the Convention on Biological Diversity;

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

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

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

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

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

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

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

Considering the importance of promoting international cooperation in the exchange of information on the transboundary transfer and release of living modified organisms and the development of appropriate containment measures and emergency plans required to deal with accidents;

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

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

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

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

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

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

Have agreed on the following Draft Protocol.

Article 1
Definitions

[The following definitions are neither complete nor

exhaustive.]

For the purpose of this Protocol:

"Advance informed agreement" means an agreement by the competent authority of the State of import to the transfer of any living modified organisms or products thereof based on the information supplied by the State of export with the understanding that the information is accurate and complete.

"Affected Party" means any Party or Parties affected or likely to be affected by the transboundary transfer or release of living modified organisms or products thereof.

"Capacity building" means any facilitating scheme for the effective implementation of this Protocol, in particular the strengthening and/or development of trained human resources and institutional capacities in terms of techniques and skills necessary to carry out the assessment and management of risks associated with living modified organisms or products thereof, and to implement the procedure of advance informed agreement.

"Competent authority" means an authority designated or established by a Party to be responsible, for receiving application and notification of a transboundary transfer or release of a living modified organism or organisms and for providing advance informed agreement in the case of receiving or importing living modified organisms or products thereof resulting from modern biotechnology.

"Contained use" or "containment" means any use of living modified organisms where the contact between the organisms and the environment is prevented by physical barriers or a combination of physical, chemical and/or biological barriers.

"Convention" means the Convention on Biological Diversity adopted on 5 June 1992.

"Deliberate release" means any intentional introduction into the environment of living modified organisms or products thereof.

"Exporter" means any user under the jurisdiction of the State of export who arranges for living modified organisms or products thereof to be exported.

"Importer" means any user under the jurisdiction of the State of import who arranges for living modified organisms or products thereof to be imported.

"Illegal traffic" means any transboundary movement or transfer of living modified organisms or products thereof as specified in Article 8.

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

"Modern biotechnology" means the use of modern biological techniques of genetic modification, and new cell and tissue culture methods for specific purposes.

"Parties" means, unless the text otherwise indicates, Parties to this Protocol.

"Party of origin" means the Party or Parties to this protocol from whose jurisdiction a transboundary release or transfer of living modified organisms or products thereof has taken place or is envisaged to take place.

"Person" means any natural or legal person.

"Risk assessment" means the identification and evaluation of potential benefits versus harm of living modified organisms and products thereof in accordance with the criteria and procedure set out by this Protocol and based on the characteristics of the organism used, the characteristics of the site and the surrounding environment including socio-economic impacts and conditions of the release.

"Risk management" means any appropriate measure for the management of potential risk, including experimental design, post-release monitoring, emergency plans and other measures indicated in this Protocol.

"Secretariat" means the Secretariat of the Convention.

"State of import" means a Party to which a transboundary transfer of living modified organisms or products thereof is planned to take place or is made.

"State of export" means a Party from which a transboundary transfer of living modified organisms or products thereof is planned to be Initiated or is initiated.

"States concerned" means Parties which are States of export or import, or transit States.

"Transboundary harm" means serious harm within the jurisdiction of a party as a result of transboundary transfer or release of living modified organisms or products thereof from within the jurisdiction of another party.

"Transboundary transfer" means any transfer of living

modified organisms or products thereof resulting from modern biotechnology from an area under the national jurisdiction or control of one State to or through an area under the national jurisdiction or control of another State or to or through an area not under the national jurisdiction or control of any State.

"Transboundary release" means any unintended release of living modified organisms or products thereof from the jurisdiction of one party to the other or to areas beyond the limits of a national jurisdiction or control.

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

"User" means any person responsible for the development, production, use, handling, testing, marketing, transfer, release, or distribution of living modified organisms or products thereof. Any member of the general public who purchases and/or uses locally a living modified organism is not a user in the meaning of this Protocol.

Additional terms requiring definition:

"Acceptable level of risks"

"Products of living modified organisms"

Article 2
Objective

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

Article 3
Scope

1. This Protocol applies to living modified organisms and to activities involving those organisms and the products thereof.

2. This Protocol should not apply to organisms modified by traditional breeding techniques or to alien species.

3. Subject to the rights of other States, and except as otherwise provided in this Protocol, the provisions of this Protocol apply to each Party in relation to living modified organisms and to activities and products involving those organisms, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

Article 4
General obligations

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

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

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

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

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

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

7. Each Party shall take the appropriate measures to:
   (a) Ensure safety in biotechnology, especially in the transboundary transfer and release of living modified organisms resulting from modern biotechnology.
   (b) Ensure that persons involved in the development, handling, transfer, use or release of living modified organisms and products thereof take such steps as are necessary to avoid unacceptable risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies.
   (c) Require that information about a proposed transboundary transfer of any living modified organisms or products thereof be provided to

the States concerned according to the appropriate procedures of notification set out in Article 7 of this Protocol.

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

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

8. Furthermore, each Party shall:

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

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

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

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

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

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

12. Nothing in this Protocol shall prevent a Party or group of Parties from imposing additional requirements that are consistent with the objective and provisions of this Protocol and are in accordance with the rules of international law, in order to better protect human and animal health, biological diversity, the environment and the socio-economic welfare of societies.

Article 5
Designation of a Competent Authority

To facilitate the implementation of this Protocol, each Party shall:

1. Designate or establish a competent authority which shall receive applications and notifications and communicate decisions on living modified organisms and products thereof in accordance with the advance informed agreement procedure set out in Articles 6 and 7 and Annex 1.

2. Inform the Secretariat and the Biosafety Clearing House within 90 days of the date of the entry into force of this Protocol for it, which agency it has designated as their competent authority

3. Inform the Secretariat and the Biosafety Clearing House within 30 days of the date of decision, of any changes regarding the designation made by it under paragraph 2 above.

Article 6
Advance informed agreement

1. A Party shall permit the export of living modified organisms or products thereof only when it confirms that the agreement of the State of import has been obtained in advance based on the necessary information that the State of import has received in accordance with the provisions of Article 7 and Annex 1.

2. The competent authority of the State of export shall require the exporter to submit, inter alia, information on:

(a) The living modified organism:

- its taxonomy, ecology and reproductive behaviour;
- if genetically modified, information on the

donor, recipient and vector organisms, the gene(s) introduced, including marker genes, stability of the introduced genes and risks of transfer of those to other organisms, methods of managing unintended release, and methods of use;

- if the organism is not genetically modified, information on whether it is known to exist in present day nature or not, methods of using it, and methods of managing any unintended release.

(b) The product of living modified organisms:

- information on methods of using it, whether it is a novel chemical, or one which occurs in nature, the living modified organism which produced it as referred in (a) above, and management methods in case of accidents.

3. The competent authority of the State of import shall provide information to the exporter, through the competent authority of the State of export concerning its laws, regulations, guidelines, legal and administrative procedures and other requirements related to the safe development, handling and use of living modified organisms and products thereof.

Article 7
Transboundary transfer and notification procedures

1. The State of export shall notify, or shall require the exporter to notify by application in writing, through the channel of the competent authority of the State of export, the competent authority of the States concerned of any proposed transboundary transfer of living modified organisms or products thereof. Such application shall contain the declarations and information specified in Annex 1, written in a language acceptable to the State of import. One application or notification shall be sent to each of the States concerned and to the Biosafety Clearing House.

2. The States of import and transit shall respond to the applicant in writing, consenting to the transfer with or without conditions, denying permission for the transfer, or requesting additional information. A copy of the advance informed agreement of the States of import, if obtained, or any final decision thereto, shall be submitted to the competent authority of the State of export and to the Biosafety Clearing House.

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

4. If, at any time before, during or after the transboundary transfer, the exporter becomes aware of relevant new information on the living modified organism or the product in question which could have significant consequences for the associated risks, the competent authorities of the States concerned and the Biosafety Clearing House shall be informed within 30 days of being aware and the notification under paragraph 1 and the terms of the agreement under paragraph 2 above changed accordingly.

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

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

7. No transboundary transfer of living modified organisms or products thereof shall be allowed by the State of export unless risk assessment has been undertaken and such organisms or products are adequately and effectively tested by well recognized procedures and test methods in the State of export or State of origin, as agreed to by the State of import, so as to fully evaluate their safety in the various anticipated conditions in the State of import.

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

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

those states are immediately informed.

Article 8
Illegal traffic and right to destroy

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

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

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

Article 9
Labelling, packaging, and transportation

1. The Parties shall ensure that products, particularly food products incorporating living modified organisms or products thereof, are clearly labelled.

2. The Parties shall ensure that living modified organisms and products thereof which have not been approved for consumption are packaged in such a way as to ensure their complete isolation.

3. The *means for transporting living modified* organisms and the products thereof shall minimize risks by using the most efficient form of transport with regard to time and distance.

4. The Secretariat shall develop guidelines on good labelling, packaging, and transportation practices.

Article 10
Risk assessment and management

1. Each Party shall ensure that, in accordance with the provisions of this Protocol, assessments prior to the use, transfer and release of living modified organisms or products thereof are undertaken as regards the risks or possible adverse impacts in their respective territories as well as in the territories of States of import, including the transboundary effects to human and animal health, the environment, biological diversity and the socio-economic welfare of societies.

2. Such assessments shall identify and characterize the risks associated with the living modified organism in question or the product thereof and specify actions to be taken in response. The risk assessment documentation to be submitted to the competent authorities of the States concerned shall contain, as a minimum, the information described in Annex 2.

3. Each Party shall ensure that appropriate decisions are taken based on the outcome of the risk assessment and on a case-by-case basis. If the assessment shows that risks cannot be avoided or reduced to an acceptable level, the States concerned shall refuse authorization to the development, use, release, import, export or transfer of that particular living modified organism or product thereof.

4. Each Party shall ensure that, in accordance with the provisions of this Protocol, appropriate management of the risks identified is undertaken until such risks have been avoided or reduced to an acceptable level. The type of risk management and the practices thereto set out in Annex 3 shall be employed as a minimum.

5. Without prejudice to paragraph 4 above, each contracting Party in order to ensure genomic and *trait stability in the environment, any living* modified organism 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 developed or produced.

Article 11
Emergency measures

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

information shall include, *inter alia*, the circumstances of the accident, the identity and numbers or quantities of the living modified organisms released, other facts necessary to assess the effects of the accident on human and animal health, the environment and biological diversity, and the emergency measures taken or needed to be taken.

2. The States concerned shall, where information is provided under paragraph 1 above, ensure that in any emergency, the medium and long-term measures necessary are taken, including the immediate alerting of any other State which could be affected by the accident.

Article 12
Socio-economic impacts

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

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

Article 13
Capacity building

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.

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

3. The Parties agree that, according to the specific needs of different regions and sub-regions, regional or sub-regional centres for training and capacity building regarding the safe management of living modified organisms or products thereof should be established.

Article 14
International cooperation

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

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

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

Article 15
Biosafety Clearing House

1. A Biosafety Clearing House shall be established to provide the Parties and, as appropriate the Secretariat, with timely advice and information relating to the implementation of this Protocol. This body shall be composed of recognized experts from developing and developed countries and shall be multidisciplinary. It shall report regularly to the meeting of the Parties on all aspects of its work and to the Secretariat regarding the implementation of procedures on notification and advance informed agreement. The modalities of establishment of the Biosafety Clearing House shall be considered and decided upon by the Parties at their first meeting.

2. The Biosafety Clearing House shall serve as a body for information exchange, monitoring of implementation, and scientific and technical cooperation among Parties. It shall, in particular:

   (a) Collect and disseminate to Parties information concerning:

      - the development, use and transfer of living modified organisms and products thereof;

- methodologies, techniques, experts, equipment, materials, available results of research relating to the response to unintended releases of living modified organisms and which could be used in the event of accidents or emergencies.

(b) Assist Parties, particularly developing country Parties, when requested, in any of the following or other appropriate matters:

- preparing or evaluating risk assessment reports or impact statements;
- developing or evaluating risk management schemes and appropriate monitoring programmes, procedures and standards;
- preparing emergency plans and other safety measures;
- transmitting requests for assistance and relevant information in the event of accidents;
- providing information that may be relevant to the settlement of disputes.

3. Each Party shall ensure that timely information pertaining to biosafety is provided to the Biosafety Clearing House.

Article 16
National arrangements to implement the Protocol

1. Parties shall ensure that appropriate legal, institutional, and administrative frameworks are in place at the national level within two years after the date of ratification or accession. National and institutional biosafety committees and National biosafety sub-committees shall be established to oversee the safe development and use of living modified organisms and products thereof. There shall be institutional biosafety committees to control safety mechanisms and approval requirements at the institution level, national biosafety sub-committees to control activities involving living modified organisms or products thereof carried out by those users who have no institutional frameworks, and a national biosafety committee to act as the highest approving body at the national or country level.

2. National biosafety committees and sub-committees and institutional biosafety committees shall be involved, within their respective capacities, in coordinating, monitoring and approving activities related to the development, use and release of living modified organisms and products thereof. They shall develop appropriate procedures and guidelines for safety in biotechnology and establish contact and maintain liaison with similar bodies in other countries through the relevant competent authorities.

3. This Protocol shall constitute the minimum standards and conditions of safety in biotechnology for Parties, when they adopt relevant laws, regulations and guidelines at the national level.

Article 17
Liability and compensation

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

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

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

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

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

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

5. Proceedings in respect of liability under this Article shall lapse after a period of five years from the date on which the affected Party learned, or could reasonably be expected to have learned, of the harm and of the identity of the state of origin or the user, as the case may be. In no event shall proceedings be instituted once 150 years have

elapsed in the case of trees, and 30 years in all other cases since the date of the occurrence of events or the accident that caused the harm. If the cause of the harm consisted of a series of occurrences, the 150 or the 30 years duration shall start from the date of the last occurrence.

6. The preceding subparagraphs shall not prevent:

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

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

(c) A Party, or any individual or legal entity represented by a Party, that considers it has been injured as a consequence of an activity or product involving living modified organisms, from submitting a claim to the courts of the State of origin or, where access to courts is permitted by domestic law, to the courts of the affected State. In that case, however, the affected State may not use the diplomatic channel to claim for the same harm for which such claim has been made.

Article 18
Monitoring

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

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

Article 19
Public awareness and participation

1. Each party shall ensure that adequate information on the use and release of living modified organisms or products thereof is provided to the public.

2. The Parties shall promote and facilitate, at the 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, both formal and informal, and public awareness programmes on safety in biotechnology.

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

Article 20
Exchange of information

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

Article 21
Meetings of the Parties

1. The Parties shall hold meetings at regular intervals. The Secretariat shall convene the first meeting of the Parties not later than one year after the date of the entry into force of this Protocol and in conjunction with a meeting of the Conference of the Parties to the Convention, if the meeting of the latter is scheduled within that period.

2. Subsequent ordinary meetings of the Parties shall be held, unless the Parties otherwise decide, in conjunction with meetings of the Conference of the Parties to the Convention. Extraordinary meetings of the Parties shall be held at such other times as may be deemed necessary by a meeting of the Parties, or at the written request of any Party, provided that within six months of such a request being communicated to them by the Secretariat, it is supported by at least one-third of the Parties.

3. The Parties, at their first meeting shall.

(a) Adopt rules of procedure for their meetings.

(b) Adopt the financial rules referred to in Article 23.

(c) Adopt the modalities on how to establish the Biosafety Clearing House and the Statutes of the World Biosafety Court.

(d) Article 6(d)

4. The Parties may at their regular or extraordinary meetings review the protocol and its implementation.

Article 22
Secretariat

1. The Secretariat of this Protocol is the Secretariat of the Convention.

2. The functions of the Secretariat, in addition to those functions set out in Article 24 of the Convention, shall be to:

   (a) Prepare and transmit reports based upon information received in accordance with Articles 6, 7 and 8 as well as upon information derived from the Biosafety Clearing House and from relevant intergovernmental and non-governmental organizations;

   (b) Prepare reports on its activities carried out in the execution of its functions under this Protocol and present them to the meeting of the Parties;

   (c) Communicate with the competent authorities established by the Parties in accordance with Article 5 of this Protocol;

   (d) Receive, compile, and disseminate, in collaboration with the Biosafety Clearing House, information regarding any living modified organisms or products thereof the export or import of which is banned by any Party;

   (e) Receive and convey information from and to Parties on capacity building, sources of technical assistance, available technical and scientific know-how, sources of advice and expertise, and availability of resources, with a view to assisting them, upon request, in such areas as the handling of the notification procedure, the system of advance informed agreement, and the assessment and management of risks and emergencies;

   (f) Assist Parties, upon request, in their identification of cases of illegal traffic and immediately inform the Parties concerned any information it has received regarding illegal traffic;

   (g) Co-operate with Parties and with relevant and competent international organizations and agencies, including the Biosafety Clearing House, in the provision of experts and equipment for the purpose of emergency assistance; and

   (h) Perform other functions relevant to the objective of this Protocol as may be determined by the meeting of the Parties.

Article 23
Financial matters

1. Parties shall, at their first meeting, agree on a scale of contributions to the recurrent budget of the Secretariat, the Biosafety Clearing House, and the World Biosafety Court.

2. The Parties shall also consider the establishment of a contingency fund to be replenished from cases of indemnification and used in case of emergency situations to minimize damage from accidents arising from the use, release and transfer of living modified organisms or products thereof.

3. The Parties agree that appropriate funding mechanisms of a voluntary nature be established to cover the cost of regional or sub-regional centres for training and capacity building as specified under Article 13 (3).

Article 24
Amendments to the Protocol or Annexes

The procedures set out in Article 29 of the Convention regarding amendments to the Convention and its protocols, and Article 30 regarding amendments to annexes of the Convention and its protocols, shall apply respectively to the amendments of this Protocol and its Annexes.

Article 25
Settlement of disputes

1. In the event of a dispute between Parties concerning the interpretation or application of this Protocol, the Parties concerned shall seek solution by negotiation.

2. If the Parties concerned cannot reach agreement by negotiation, they may seek the good offices, or request mediation by, a third party.

3. When ratifying, accepting, approving or acceding to this Protocol, or at any time thereafter, a State or regional economic integration organization, may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory:

   (a) Arbitration in accordance with the procedure laid down in Part 1 of Annex 2 of the Convention;

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

4. If the Parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex 2 of the Convention, unless the Parties otherwise

agree.

Article 26
Right to Vote

1. Except as provided for in paragraph 2 below, each Party to this Protocol shall have one vote.

2. Regional economic integration organizations shall exercise their right to vote with a number of votes equal to the number of their member states which are Parties to this Protocol. Such organizations shall not exercise their right to vote if their member states exercise theirs, and vice versa.

Article 27
Relationship of this Protocol to the Convention

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

Article 28
Signature

This Protocol shall be open for signature at _____ by all States and any regional economic integration organization from _____ to _____ and at the United Nations Headquarters in New York from _____ to _____.

Article 29
Ratification, Acceptance, Approval and Accession

1. This Protocol shall be subject to ratification, acceptance or approval by States and by regional economic integration organizations. Instruments of ratification, acceptance or approval shall be deposited with the Depositary.

2. Any organization referred to in paragraph 1 above which becomes a Party to this Protocol without any of its member States being Parties shall be bound by all the obligations under the Protocol. In the case of such organizations one or more of whose member States is a Party to this Protocol, the organization and its member States shall decide in their respective responsibilities for the performance of their obligations under the Protocol. In such cases, the organizations and the member States shall not be entitled to exercise rights under the Protocol concurrently.

3. In their instruments of ratification, acceptance or approval, the organizations referred to in paragraph 1 shall declare the extent of their competence with respect to the matters governed by the Protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

4. This Protocol shall be open for accession by States and by regional economic integration organizations from the date on which it is closed for signature. The instruments of accession shall be deposited with the Depositary.

5. The provisions of paragraphs 2 and 3 shall apply to regional economic integration organizations which accede to this Protocol.

Article 30
Entry into force

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the sixteenth instrument or ratification, acceptance, approval or accession.

2. This Protocol shall enter into force for a Party that ratifies, accepts or approves it or accedes to it 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 Protocol enters into force for that Party, whichever shall be the later.

Article 31
Reservations

No reservations may be made to this Protocol.

Article 32
Withdrawals

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 three years 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 33
Depositary

The Secretary-General of the United Nations shall assume the functions of Depositary of this Protocol.

Article 34
Authentic texts

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.

In witness whereof the undersigned, being duly authorized to that effect, have signed this Protocol.

Done at _____ on this _____ of _____ one thousand and ninety _____.

Annex 1
Information required in order to obtain advance informed agreement

The exporter of living modified organisms or products thereof shall provide the competent authorities of the States concerned with the following information in order to obtain advance informed agreement in accordance with the provisions of Articles 6 and 7.

1. Names and addresses of the exporter and the importer.

2. A complete risk assessment report on the living modified organism or the product thereof in accordance with the risk assessment parameters as stated in Annex 2 of the Protocol.

3. Number or quantity of organisms or products to be transferred or volume of culture and physical form.

4. The step reached in the testing and observation of the living modified organism or the product thereof according to the legal or administrative requirements of the State of export.

5. The applicable laws, procedures and guidelines of the State of export.

6. Any requirements to manage risks and to ensure safe handling and use, and methods for safe disposal and appropriate emergency procedures in case of accidents.

7. Intended dates of transfer.

8. Intended means of transport.

9. Information relating to insurance.

10. Declaration by the exporter that the information is correct.

Annex 2
Risk assessment parameters in accordance with Article 10(2)

The user shall carry out an assessment prior to the use and release of living modified organisms or products thereof as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies. This assessment shall take the following parameters into consideration including any other parameter deemed to be relevant:

1. 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 allogenicity and/or toxicity of biochemical and metabolic products;
   (s) Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

2. 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) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
   (e) Potential for pathogenicity and virulence;
   (f) Natural and host range of vectors;
   (g) Natural habitat and geographic distribution of natural and potential hosts;
   (h) Potential impacts on human and animal health and the environment;
   (i) Measures for counteracting adverse impacts;
   (j) Potential to survive and multiply in the environment, or to form genetic recombinants;
   (k) Genetic stability of vector(s), such as hypermutability.

3. Characteristics of living modified 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) 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;

(g) Product(s) of the transferred gene(s), levels of expression and methods for measuring expression;

(h) Stability of the introduced gene(s) in terms of expression and integration;

(i) Biochemical and metabolic differences of living modified organism compared with the unmodified organism;

(j) Probability of vertical or horizontal gene transfer to other species;

(k) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;

(l) Allogenicities, toxicities, pathogenicities and unintended effects;

(m) Autecology of the living modified organism compared with that of the unmodified organism;

(n) Susceptibility of the living modified organism to diseases and pests compared with the unmodified organism;

(o) Detailed information on past uses including results on all experiments leading to previous releases.

4 Characteristics of resuscitated organism(s) and gene(s) and fossil DNA sequences:

4.1 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.

4.2 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.

5. 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.

6. 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.

7. 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.

Annex 3
Risk management schemes in accordance with Article 10 (4)

The user shall employ the following risk management schemes and procedures from the development, through all stages of testing of the living modified organism or the product thereof, to its intended use or commercialization.

1. Imported products of living modified organisms used for human or animal health (e.g. antibodies, drugs and hormones):
   (a) Observation to ensure that changes in food habitats, nutrition and other factors that could conceivably modify the expected impacts are insignificant;
   (b) Such observation can be limited in scope when it is shown that adequate trials on the specific products have been made on humans or animals, as appropriate, in areas other than the State of import.

2. Imported microbial living modified organisms for human and animal health:

   Besides the limited observation specified in 1, experiments shall be carried out to evaluate viability and risks of reacquiring virulence or lending virulence to other micro-organisms when in the body and in the environment, since some spilling is inevitable.

3. Imported living modified organisms for contained use:
   (a) The products of living modified organisms will be treated as in 1;
   (b) Experiments will be made in complete laboratory containment to determine: (i) longevity of the living modified organism in cases of unintended release in the premises and in the surrounding environment, and (ii) genetic transfer into other micro-organisms and implications thereof on human and animal health and the environment.
   (c) Methods for counteracting adverse impacts resulting from unintended releases should be specified.

4. Products of living modified organism made locally:
   (a) Trial on experimental animals will be made when the product of the living modified organisms is intended to be used on humans;
   (b) In all other cases, trials will be made on species for which the product of the living modified organism has been designed.

5. Living modified organisms made locally for human or animal vaccines:
   (a) Initial molecular, tissue culture, serology and other related studies in the laboratory complete containment;
   (b) Trials with experimental animals under containment;
   (c) Experiments in complete containment to evaluate the extent of transfer of the genes of the vector introduced or of other genes through the agency of the vector to the living modified organism or to other species which will be found in association with the living modified organism to ensure that virulence is not acquired by the living modified organism in question or by other micro-organisms;
   (d) Trials on animals completely contained from their species and from related species and species known to be susceptible to the gene recipient micro-organism from which the living modified organisms has been made;
   (e) Statistically valid trials in conditions in which the vaccinated individuals live in their communities.

6. Imported plant or microbial living modified organism for release:
   (a) The reports from releases in areas other than the State of import shall be thoroughly evaluated by the National Biosafety Committee. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;
   (b) If the regulations mentioned in (a) above have not been found adequate, the National Biosafety Committee will decide at which step in item 8 the observations should begin;
   (c) If it is decided that the previous release mechanisms have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but otherwise kept at the same soil community, moisture, air temperature and plant and animal community conditions as the intended area of release;
   (d) The observations will include the health of the living modified organism, the health of the organism within the area of limited release, and the biological diversity and the ecology of

the area;

(e) Nationally approved limited field releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

7. Imported animal living modified organism for release:

(a) The reports from releases in areas other than the State of import shall be thoroughly evaluated by the National Biosafety Committee. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;

(b) If the regulations mentioned in (a) above have not been found adequate, the National Biosafety Committee will decide at which step in item 9 the observations should begin;

(c) If it is decided that the regulations used in the previous release have been rigorous enough, then observations will be made in complete containment in the expected ambient climatic, nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers;

(d) When the results have met the stated requirements, then a trial release may be authorized with adequate emergency plans put in place to deal with cases of escape.

8. Plant or microbial living modified organisms produced locally for eventual release:

(a) Laboratory biomolecular experiments on transformation or resuscitation and other phenomena will be carried out in complete containment;

(b) Tissue culture experiments to develop the living modified organism, when required, will be carried out in complete containment;

(c) Observations aimed at understanding the nature of the living modified organism shall be carried out in complete containment;

(d) Experiments with the soil, soil micro-organisms, plant and animal species, under the environmental conditions of the area of intended release, will be carried out in complete containment;

(e) Complete observations of the interactions of the living modified organism with the environment (soil including micro-organisms and terrestrial communities) will be made in enclosed fields but not fully contained. At the end of the experiment, the products of the living modified micro-organisms may be used on an experimental basis, otherwise they shall be destroyed;

(f) The product from the living modified organism shall be subjected to the procedure in 4;

(g) The monitoring of the spread and behaviour of any released plant or micro-organism living modified organism shall continue for at least 150 years in the case of trees, and for at least 30 years in the case of annuals and micro-organisms, the duration for perennials which live shorter than trees being in between. The user who was responsible for releasing the living modified organisms or its successor shall provide annual reports to the competent authority.

9. Animal living modified organism produced locally for eventual release:

(a) Laboratory biomolecular experiments on transformation (or resuscitation if it is possible) and other phenomena will be carried out in complete containment;

(b) Methods of incubating the transformed generative cell or the resuscitated animal will be carried out in complete containment;

(c) The rearing of and observations on the living modified organism will be carried out under complete containment;

(d) The living modified organism shall be observed under complete ~~isolation~~ containment in an experimental environment which simulates the intended area of release in climatic, microbial, animal and plant communities. The observations shall include the condition of the transgenic animal and those of its micro-organisms especially in the context of gene transfer and those of the microbial, plant and animal communities in the experiment, again including gene transfer;

(e) A limited release will be carried out in an area with appropriate enclosure and emergency measures put in place to prevent escape. Observations will include the condition of the living modified organism, its micro-organisms focusing on gene transfer, and the ecology of the microbial, plant and animal communities in the area, again including gene transfer;

(f) If the animal is intended to yield a product, the regulation of the product will follow the procedure in item 4;

(g) The monitoring of the spread and behaviour of any released animal living modified organism will continue for at least 30 years.

10. General Requirements:

(a) All trials, experiments or observations specified in all the above cases (1-9) are put in their logical sequence and shall be subjected to the hierarchical procedures of approval by the lower institutional and the higher national level bodies, namely the Institutional Biosafety Committees or the National Biosafety Sub-committees and the National Biosafety Committee.

(b) Experiments starting from transformation of living organisms or resuscitation of fossil organisms carried out under completely contained laboratory conditions and continuing in the development of living modified organisms or products thereof shall be subject to approval by the Institutional Biosafety Committee or by National Biosafety Committees as the case may be. All experiments outside of strict laboratory isolation and initial experiments involving imported living modified organisms or products thereof shall be subject to approval by the National Biosafety Committee. All final approval for the use of living modified organisms or products thereof shall be made by the National Biosafety Committee.

(c) Once approval from the National Biosafety Committee is obtained at the completion of the final stage of the trials, experiments or observations, the living modified organism in question or the product thereof can be employed for its intended use. The National Biosafety Committee shall notify its decision in writing to the competent authority.

(d) Whenever there is a need to dispose of the living modified organism or the product thereof upon the completion of every trial or experiment, it shall be made through complete incineration or other approved means of complete destruction.

(e) The release of living modified organisms or products thereof shall be monitored appropriately and emergency plans to prevent

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OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

AUSTRALIA

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ANNEX I

INFORMATION REQUIRED FOR NOTIFICATION OF IMPORT OF A LIVING MODIFIED ORGANISM

- Name and address of exporter.
- Name and address of importer.
- Taxonomic identification of living modified organism.
- Taxonomic identification of donor organism.
- Nature of introduced trait.
- Intended date of transfer of living modified organism.
- Quantity of living modified organisms to be transferred in shipment.
- Centre of origin of the organism that has been modified.
- Any other information considered relevant by the exporter.

ANNEX II

INFORMATION REQUIRED FOR NOTIFICATION OF UNINTENTIONAL TRANSBOUNDARY MOVEMENT OF A LIVING MODIFIED ORGANISM

- Contact details for the Party providing the notification.
- Taxonomic identification of the living modified organism.
- Taxonomic identification of donor organism.
- Nature of introduced trait.
- Quantity of living modified organisms unintentionally released or transferred.
- Centre of origin of the organism that has been modified.
- Site of the unintentional release.
- Details of any action taken to prevent further release or movement of the living modified organism.

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

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

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

(a) impound the living modified organisms, or:

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

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

Article 21

Monitoring and Compliance

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

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

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

Protocol on Biosafety

Proposed Submission by Australia

Title

Protocol on Biosafety

Article 1

Objective

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

Article 2

Scope

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

Article 3

General Obligations

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

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

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

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

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

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

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

Article 4

Information Sharing

1. Parties shall cooperate in sharing information relevant to the safe use, handling and transboundary movement of living modified organisms, on a bilateral and multilateral basis, as appropriate.

2. Parties shall establish a Clearing House for the purpose of promoting and contributing to the sharing of information between Parties. Parties shall make available to the Clearing House details of:

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

(b) all risk assessments and import decisions relating to living modified organisms, including the relevant timeframes;

(c) national risk management procedures for use and handling of living modified organisms;

(d) any unintentional transboundary movements of living modified organisms, and;

(e) any unintentional domestic releases of living modified organisms which could result in unintentional transboundary movements of living modified organisms.

Article 5

Competent Authorities and Focal Points

Parties shall:

(a) designate a Focal Point;

(b) designate one or more Competent Authorities;

(c) inform the Clearing House, within three months of the date of entry into force of the Protocol for them, which agencies have been designated as the Focal Point and the Competent Authority, and;

(d) inform the Clearing House, within one month of the date of decision, of any changes regarding the above designations.

Article 6

Notification For First Import

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

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

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

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

Article 7

Risk Assessment

1. On receipt of a notification for first import of a living modified organism, the importing Party shall undertake, or have undertaken, an assessment of the risk of the living modified organism having an adverse effect on the conservation and sustainable use of biological diversity in the importing Party. Parties may take into account the details of risk assessments completed elsewhere, as appropriate.

2. Risk assessments shall be carried out in a scientifically sound and transparent manner.

3. Risk assessments should, *inter alia*, take into account:

Article 9

Review of Import Decisions

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

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

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

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

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

3. 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.

Article 10

Notification For Subsequent Imports

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

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

(b) a variation in the receiving environment: or

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

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

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

(a) advice that a risk assessment has been or is to be carried out, in accordance with Article 7, and;

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

Article 17

Capacity Building

1. Parties shall cooperate in relation to capacity building for risk assessment, decision making and risk management. Capacity building may include technical assistance, information exchange, training, education and institutional capacity building.

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

Article 18

Trade with Non-Parties

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

Article 19

Public Education and Awareness

Parties shall:

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

(b) make available to the public the results of risk assessments for living modified organisms, undertaken for either domestic release or transboundary movement, while respecting the need to protect commercial-in-confidence information.

Article 20

Illegal Traffic

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

(a) occurs without compliance with the advance informed agreement provisions outlined in this Protocol, including notification and approval, except as provided under Article 15 for Bilateral, Regional and Multilateral Agreements, or;

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Definitions

Biosafety (Safety in bitechnology): safety aspects related to the application of biotechnologies and any activity (handling, transfer, use) associated with LMOs which may have adverse effects on the conservation and sustainable use of biological diversity.

Living organism: any biological entity capable of replication or of transferring genetic information. This definition covers plants, animals, fungi, microorganisms, viruses and viroids, including cell and tissue culture, germinal cells, seeds, pollen and spores.

Living modified organisms (LMOs): organisms whose genome have been altered by the insertion of foreign DNA. The DNA insert is gene construction created through chemical manipulations with certain DNA fragments isolated from different sources (organisms, taxa) or synthesized artificially. In the context of the Protocol the term "LMOs" also covers products thereof (food, feed and pharmaceutical ones).

DNA: deoxyribonucleic acid, the molecule that carries the genetic information for most organisms.

Genom: the total genetic complement of an organism.

Modern biotechnology, Genetic engineering: "The formation of new combinations of heritable material by the isolation of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur, but in which they are capable of continued propagation" (The Language of Biotechnology: A Dictionary of Terms. John M. Walker and Michael Cox 1988. American Chemical Society Professional Reference Book, p. 110).

Adverse Effects: includes any effect on biodiversity that is direct or indirect, positive or adverse, immediate or delayed, potential or probable, temporary or permanent, adverse consequences, on inter alia (i) human beings, flora and fauna; (ii) soil, water, air and landscape; (iii) the interaction between factors in (i) and (ii).

Advanced Informed Agreement: agreement by the competent authority/focal point of the State of Import to the import of LMOs based on its adequate risk assessment. Explicit consent implies that the absence of a reply from the State of Import within a specified time is not consent. Implicit consent implies that consent is deemed to have been given if no reply from the State of Import has been received within the specified time.

Transboundary movement: any transfer of LMOs from an area under the national jurisdiction or control of one State to or through an area under the national jurisdiction or control of another State or to or through an area not under the national jurisdiction or control of any state. Intended transboundary movement: the deliberate transfer of LMOs across national borders according to AIA procedure. Unintended transboundary movement: natural movement of LMOs released into environment (by wild animals, wind etc.) or movement of LMOs following an

accidental release across national borders. Illegal transboundary movement: any transboundary transfer of LMOs with violation of the AIA procedure.

Exporter: any jurisdictional person in the State of Export who arranges for LMOs to be exported.

State of Export: a Party from which an intended transboundary movement of LMOs is planned to be initiated or is initiated.

State of Import: a Party to which an intended transboundary movement of LMOs is planned to be initiated or is initiated.

Competent authority/ Focal Point: an authority/ focal point designated by the government of the Party to be responsible for the implementation of the Protocol, primarily those its provisions that concern AIA, notification, unintenional releases of LMOs and exchange of information.

Risk assessment: the identification and evaluation of harm to the conservation and sustainable use of biological diversity and human health might be caused by an LMO in accordance with criteria set out by the Protocol.

Risk management: the implementation of any appropriate measures to minimize the identified risks associated with LMOs to the acceptable level and mitigate their effects while achieving the anticipated results.

Acceptable level of risk: defined in the procedure of risk assessment level of hazard for biological diversity and human health that makes it possible considering the LMO to be safe for use.

"Case by case" approach: means that adequate risk assessment of each specific LMO should be carried out in each specific situation (having regard to peculiarities of receiving environment, socio-economic considerations and so on).

Contained use: any activity in which LMOs are cultured, stored, transported, destroyed, disposed or used in any other way, and for which specific containment measures are used to limit their contact with the environment (including humans).

Intended/ Deliberate release: intentional introduction of an LMO into environment, including for scientific or commercial purposes.

Accidental release: any incident involving a significant release of LMOs in the course of their contained use which could present an immediate or delayed hazard to human health and/or the environment.

Emergency measures: measures developed to minimize the adverse effects of accidental release of LMOs.

Transboundary effect: harm or risk of harm to biological diversity in the affected state as a result of unintended transboundary movement of LMOs.

Affected Party: a Party affected or likely to be affected by the unintentional transboundary movement of LMOs.

Advanced informed agreement

"All initial transfers of LMOs to another country shall be subject to the AIA procedure.

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

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

The competent authority/focal point in the State of Import shall be obliged to respond to the application within 90 days. The absence of a reply within this time is not consent. In delay with reply the question on obtaining AIA can be addressed according to the Protocol's dispute settling mechanism.

The respond of the competent authority of the State of Import may consist of either:
- explicit consent to import;
- not consent to (or prohibit) import;
- concent to import only under specified conditions;
- statement that final decision needs additional period of time;
- request of additional information about the LMO. In cases where competent authority/focal point in the State of Import considers that the documentation provided is not sufficient, the burden of proof lies with the Exporter.

A copy of the AIA, if obtained, or any final decision thereto, shall be submitted by the competent authority/focal point of the State of Import to the competent authority/focal point of the State of Export and to the Biosafety Clearing House (Biosafety Centralized Data Base).

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

If at any time before, during or after the transboundary transfer, the exporter/importer becomes aware of relevant new information on the LMO in questions, which could have significant consequences for the associated risks, the competent authority/focal point of the State of Import shall be informed within 30 days. In that cases the new AIA should be obtained for further export/import of LMOs".

Risk Assessment and Risk Management

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

A complete risk assessment shall be carried out prior to the transfer of an LMO for the first time into a new country. "Case by case" approach should be used in this process. The Exporter shall provide the competent authority/focal point in the State of Import with information related to the risk assessment carried out by it, and other relevant information, in order for the State of Import to conduct its own risk assessment on the basis of this information. The exporter is responsible for the reliability of the information provided.

The assessment of the risks associated with a transfer, handling, use and release of LMOs shall be based on up-to-date scientific data and experience and take account of:

a) The characteristics of the LMO, including:
- the recipient (host) organism ;
- the donor organism(s), vector(s) used;
- the genetic structure of DNA insert, encoded trait(s);
- the centre of origin of recipient and donor organisms.

b) The intended use, i.e. the specific application of the contained use or deliberate release or placing on the market, including the intended scale.

c) The characteristics of the potential receiving environment.

d) The socio-economic considerations in the country.

f) risk-benefit analysis of the LMO.

Minimum standards on the risk assessment procedure is described in "UNEP International Technical Guidelines for Safety in Biotechnology".

If the risk assessment shows that the level of identified risks associated with the LMO is not acceptable, risk management measures are to be taken by the exporter (the applicant) and implemented until the risks have been minimized to an acceptable level. It is up to the State of Import (competent authority/focal point of the country) to decide what is to be considered as "acceptable level of risk". The competent authority/ focal point in the State of Import shall estimate the reliability of risk management measures provided and possibility of their effective implementation in the country. If the risk cannot be minimized to an acceptable level by use of the risk management measures, the competent authority/ focal point shall decide not to allow the transfer, use and release of the LMO"

Unintentional transboundary movements

"The Parties shall:
a) whenever it comes to their knowledge, ensure that, in the case of an accident which may have transboundary effects on human health and/or the environment in other states, these states are immediately informed;
b) inform affected states about any planned activities associated with LMOs within their territories that are likely to have transboundary effects.

The information supplied shall include, inter alia, the identity, relevant characteristics and numbers/volumes of the LMOs involved and any available information necessary to assess the effects of the accident and emergency measures taken or needed to be taken.

The affected state(s) may ask for consultations between the concerned states".

Handling, Transportation, Packaging and Transit Requirements

"The Parties shall ensure safety levels during handling, transport and transit of LMOs. LMOs which have not been approved for use shall be handled and packaged in such a way as to ensure their complete isolation.

The Parties shall ensure that food products incorporating LMOs are clearly labelled. Other LMOs shall be labelled if necessary with regard to environmental, health or ethical concerns".

Competent Authority(s)/ Focal Point(s)

"To facilitate the implementation of this Protocol, each Party shall designate a national competent authority/ focal point. This authority/ focal point shall be responsible for procedures related to AIA, notification, exchange of information, implementation of emergency measures.

Designated national competent authority/ focal point should be nominated within 90 days from the date of ratification of the Protocol. The Secretariat and the Biosafety Clearing Hause (Biosafety Centralized Data Base) shall be informed of it and of any changes regarding the designation within 30 days from the date of decision".

Information-Sharing and Biosafety Clearing House

"The Parties shall facilitate and encourage the collection and exchange of information relevant to the implementation of this Protocol. This information shall include inter alia:
- designations of competent authorities/focal points and changes in such designations;
- national requirements/legislation, frameworks and guidelines on biosafety;
- national decisions/reviews about LMOs contained uses, releases, marketing and transboundary transfers;
- general matters relevant to risk assessment/management associated with LMOs;
- information on accidental/unintentional movements of LMOs and biosafety measures implemented in that cases;
- list of national experts, advisory bodies, training workshops/programmes;
- other relevant information.

Parties shall provide information through their national competent authorities/focal points to the Biosafety Clearing House/Bisafety Central Data Base to be shared by other Parties/general public. The information provided shall not include confidential data and those ones that can restrict the proprietary rights.

Each Party shall ensure that all affected states be timely informed about accidents/unintentional releases associated with LMOs, intended releases of LMOs which can be followed by their transboundary movement, with new information about LMOs under AIA (Art.X, Y)".

Capacity-building

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

- that Parties develop and strengthen their capacities to implement this Protocol;
- that national legislation, frameworks and guidelines related to biosafety are developed;
- that states involved in the transfer, handling and use of LMOs are aware of any associated risks and have the means to assess and manage the risks;
- that states are able to achieve safety when certain LMOs are transferred into and/or to be used in their territories and act adequately in cases of accidental release of LMOs".

Public Awareness and Public Participation

"The Parties shall ensure that adequate information on the transfer, handling and use of LMOs is provided to the public.

The Parties shall promote and facilitate the development and implementation of educational and public awareness programmes on biosafety.

In some cases (during the AIA procedure, making allowance for LMOs handling, use, marketing) competent authority/focal point may decide that public hearing is to be carried out. The decision to carry out a public hearing shall be publicly announced".

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BRAZIL

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BRAZILIAN PROPOSAL

for elements to be included in the
Protocol on Biosafety
to be established in accordance with decision II/5 of the
Conference of the Parties to the Convention on Biological Diversity.

Title:

PROTOCOL ON BIOSAFETY

Article 1

Objective

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

Article 2

Scope

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

Article 3

General Measures

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

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

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

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

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

a) based on scientific principles and supported by the best available scientific evidence

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

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

Article 4

Competent Authority and Focal Point

Each Party shall:

a) designate a Focal Point;

b) designate a Competent Authority;

c) inform the Clearing House, within three months of the date of entry into force of the Protocol for them, which agencies have been designated as the Focal Point and the Competent Authority; and

d) inform the Clearing House, within one month of the date of decision, of any changes regarding the above designations.

Article 5

Advanced Informed Agreement

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

2. The procedure for Advanced Informed Agreement is as follows:

a) The exporting Party shall submit the following information, in writing, to the importing Party:

- name and full address of the exporter;
- name and full address of the importer;
- taxonomic identification of the living modified organism;
- taxonomic identification of the donor organism;
- centre of origin of the organism that has been modified and areas with high genetic diversity relevant to the living modified organism;
- complete scientific description of the introduced trait, including methodology used for transformation;
- physical form of the living modified organism or product thereof;
- intended use of the living modified organism or product thereof in the territory of the importing Party;
- intended date of transfer of the living modified organism or product; means of transport and point of disembarkation;
- brief history of the living modified organism or product thereof and its uses in other countries;
- quantity of the living modified organism or product thereof to be transferred in shipment; and

- any other information considered relevant by the exporter.

b) the competent authority of the importing Party shall acknowledge receipt of the notification of intent to export, in writing, within ten working days;

c) the competent authority of the importing Party may request additional information, as deemed appropriate, at any point prior to final decision;

d) the importing Party will undertake a risk assessment, according to scientific principles and supported by the best available scientific evidence;

e) the importing Party shall make a decision, which may consists of:

i) approval to import, without conditions;

ii) approval to import, with specified conditions; or

iii) prohibition of import.

f) the importing Party will communicate its decision to the exporting Party in due time; and

g) the decision of the importing Party shall be justified, in writing, to both the exporting Party and the Clearing House Mechanism.

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

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

b) additional relevant scientific or technical information has become available.

4. Importing Parties shall respond to such requests, in writing, within a reasonable period of time.

Article 6

Risk Assessment

1. Upon receipt of a notification for first import of a living modified organism or product, the importing Party shall undertake a risk assessment of the living modified organism or product thereof.

2. Risk assessments shall be carried out in a scientifically sound and transparent manner.

3. Risk assessment should, *inter alia*, take into account:

a) all relevant scientific evidence and experience;

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

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

d) potential impact of the living modified organism or product thereof on the environment , particularly on centres of origin and areas with high genetic diversity relevant to the living modified organism;

e) possible effects of the living modified organism or product thereof on human health;

f) risk assessment techniques developed by relevant international organisations; and

g) details of risk assessments completed elsewhere, as appropriate.

4. Risk assessment for subsequent imports is at the discretion of the receiving Party, but should be undertaken where there may be:

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

b) a variation in the receiving environment; or

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

Article 7

Notification for Subsequent Imports

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

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

a) importation can proceed; or

b) a new risk assessment procedure will be undertaken.

Article 8

Notification for Transit

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

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

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

b) information to be provided with the notification.

3. When such notification is required, exporting Parties shall provide information, in writing, to the Party whose territory is to be transited.

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

Article 9

Information Sharing

1. Parties shall establish a Clearing House for the purpose of promoting and contributing to the sharing of information relevant to the safe use, handling and transboundary movement of living modified organisms and products thereof.

2. Parties shall make available to the Clearing House information *inter alia* on:

a) national risk management procedures for use and handling of living modified organisms and products thereof;

b) national institutional framework for monitoring and compliance within their territories;

c) all risk assessments and import decisions relating to living modified organisms, and products thereof, including the relevant timeframes;

d) all living modified organisms, and products thereof, which have been subject to bans or restrictions by that Party;

e) any unintentional transboundary movements of living modified organisms;

f) any unintentional domestic releases of living modified organisms which could result in unintentional transboundary movements of living modified organisms; and

g) any incidents of uninformed, unauthorised or otherwise illicit transboundary movements of living modified organisms or products thereof.

Article 10

Handling of Confidential Information

Parties shall respect the need to protect commercial-in-confidence information relevant to living modified organisms and products thereof. However, all information requested by the importing Party for the purpose of decision making must be provided by the exporting Party.

Article 11

Handling, Transport, Packaging and Labelling

Exporting Parties shall ensure that shipments containing living modified organisms and/or products thereof:

a) are clearly identified as containing living modified organisms;

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

c) include appropriate names and contact details for use in the case of accidental release.

Article 12

Unintentional Transboundary Movements

1. All possible precautions are to be taken to prevent accidental and unintentional release and to reduce natural movements of intentionally released living modified organisms which may result in unintentional transboundary movements.

2. Parties shall immediately notify affected Parties, potentially affected Parties and the Clearing House, in case of known unintentional transboundary movements of living modified organisms, or of known domestic releases of living modified organisms which may result in

unintentional transboundary movements. Such notification shall include the same information required for intentional transboundary movements, in addition to, *inter alia:*

a) the circumstances of the accident;

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

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

d) any other information considered relevant.

3. The Party which is the origin of the unintentional transboundary movement shall take immediate action, in consultation with the affected Party, to minimise negative impact on the environment and to prevent further release or transboundary movement of the living modified organism.

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

Article 13

Capacity Building

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

a) that national legislation related to biosafety is developed;

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

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

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

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

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

Article 14

Liability, Responsibility and Compensation

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

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

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

a) unsafe packaging;

b) fraud, falsification of approval; or

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

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

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

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

Article 15

Public Awareness and Education

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

a) endeavour to ensure full public awareness of the issues relevant to the transboundary movements of living modified organisms and products thereof; and

b) make available to the public risk assessment results and decisions concerning the transboundary movement of living modified organisms and products thereof;

2. Parties are encouraged to facilitate public participation in risk assessment decisions.

Article 16

Settlement of Disputes

1. In the event of a dispute between Parties concerning the interpretation or application of this Protocol, the Parties concerned shall seek solution by negotiation.

2. If the Parties concerned cannot reach agreement by negotiation, they may request arbitration according to Part 1 of Annex II of the Convention on Biological Diversity.

Article 17

Monitoring and Compliance

1. Parties shall submit concise annual country reports on all activities regulated by this Protocol. The Secretariat shall compile the national reports into a world-wide report to be examined by the Parties at each Conference of the Parties of the Convention on Biosafety.

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

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

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CAMEROON

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VIEWS OF THE GOVERNMENT OF THE REPUBLIC OF CAMEROON ON SOCIO - ECONOMIC IMPACTS AND LIABILITY AND CONPENSATION IN TRANSBOUNDARY MOVEMENTS OF LMOs FOR INCLUSION INTO THE BIOSAFETY PROTOCOL

INTRODUCTION

Developing countries constitute the major centres of concentration of the world's biodiversity. They equally harbour the richest centres of genetic resources. In order to conserve and sustainably use the biological resources of the world, it is vital that risks posed on biodiversity should be anticipated, prevented and their causes attacked.

Developing countries like Cameroon, lack the capacity (structures, human resources, technologies and funds) to keep and manage gene/seed banks for their traditional products (be they for local consumption or export) . They are not producers of modern biotechnology. The introduction of genetically engineered products into these countries will replace traditional export products such as cocoa, coffee, cotton etc. Which constitute the main economic income earner and impoverish already fragile economies.

Equally, the rural populations of most developing countries depend on traditional crop variety or animal breeding methods for livelihood. The chances of such populations loosing the basic means of their livelihood through the introduction of living modified organisms or other genetically modified organisms are high. This is so as the traditional varieties will be completely replaced through substitutions with modern biotechnological products. The consequences of substituting local varieties with imported products are several and include increased production costs on farmers.

There is documented evidence of ecological hazards created by the intentional or accidental release of living modified organisms (LMOs) into the environment especially in developing countries where the capacity to manage and mitigate the adverse effects of such hazards are non existent. Ecological hazards identified include invasiveness of some LMOs which call for the use of chemicals (herbicides, pesticides, fertilisers) which are not only costly for local farmers to acquire, but pollute the environment through their indiscriminate use by illiterate farmers.

Most genetically modified organisms have adverse impacts on the environment (since they mutate and become destructive weeds) by invading natural vegetation's, farmlands and endangering the production systems of the farming populations. Agricultural biotechnology will undermine the livelihoods of small organic farmers all over the world, resulting in increased loss of indigenous agricultural biodiversity.

It has also been scientifically documented that there is risk on human health posed by the transboundary movement of lmos within developing countries due to horizontal gene transfer, provoking adverse health effects which include amongst others; antibiotic resistance, viral resistance and contamination or allergenic effects from the consumption of certain species of genetically modified animals.

Indigenous farmers rights on seeds are usually substituted by biotechnology industries through seed certification. This in return procure intellectual property rights for the industries concerned and other restrictive practices associated with seed certification, further marginalising the rural farmers of the poor countries.

I SOCIO-ECONOMIC IMPACTS

Some of the socio-economic impacts of modern biotechnology in a developing country's economy already highlighted are :

- **EMPOVERISHMENT OF THE ECONOMY THROUGH**

  - loss of income from main cash crop earner due to substitution of products,
  - unemployment and generalised poverty,
  - social disorders (strikes by farmers, wars starvation and death) which will further destabilise the economy;
  - loss of biodiversity through attacks by alien species
  - marginalisation of rural farmers through IPRs;
  - increased costs to farmers through importation of modern biotechnologies

- **ENVIRONMENTAL IMPACTS**

  - dependance on herbicides, pesticides, fertilisers, fungicides (as transgenic crops make it necessary to use powerful chemicals and fertilisers) thus killing many species and making the user totally dependent on these products,
  - destruction of soil fertility and crop yield as bio-fertilisers replace organic manure
  - bio pesticidal resistance in major insect pests (promotion of insect pest resistance),
  - invasiveness of GMOs,
  - several cases of horizontal gene transfer with severe consequences on their wild relatives, insects, birds and human health have been documented,
  - natural predators of key insect pests which are important regulatory factors in ecosystems need protection to avoid extinction. These are affected in cases where biotechnology gene transfer occurs.

- **IMPACT ON HUMAN HEALTH**

  - anti biotic resistance,
  - viral resistance,
  - food allergenic effects,

MEASUREMENT OF SOCIO-ECONOMIC IMPACT

  - unequal terms of trade,
  - inequitable distribution of income generated from the exploitation of genetic resources,
  - lack of incentives to conserved biodiversity and consequent unsustainable use of biodiversity, socio-economic impact assessment should be on a case by case basis.

II LIABILITY AND COMPENSATION

Article 14(2) of the CBD calls for the Conference of Parties to examine on the basis of studies to be carried out, the issues of liability and redress including restoration and compensation for damage on biodiversity. Genetically modified organisms (GMOs) may produce unforeseen consequences to the environment and to human health. Where there is potential risk and damage is proven, compensation should be made. At times, potential hazard

might be difficult to be identified before hand, even when environmental impact assessment are carried out. Whether the damage caused by LMOs on the environment and health are accidental or unintentional, the responsibility of the author must be established and the international community should seek redress in favour of the affected countries especially if this country is a developing country. The future protocol on biosafety should protect the weaker nations and biotechnology products development and consumption.

Compensation in the cases of established responsibility should take the form of :

- financial and technical support to provide quick response to threatened species and affected human health;
- capacity building to developing countries to diversify on other crops in order to substitute former export products;
- compensation in the form requested by victim,
- compensation through the creation of other job opportunities (in cases of job loss) with sufficient time and means provided to victims to adapt to new jobs; and the provision of other income generating sources.
- mitigation of the effects of the hazards caused on the country's economy and public health by the GMOs.

Parties to the future biosafety protocol (especially developing countries) will feel protected only if a legal binding principle in the protocol protect their interest through consideration of the evaluation of risk to health and the environment, and the consequences related to social, economic, and ethical concerns of these countries.

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CANADA

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CANADA'S SUBMISSION TO THE SECRETARIAT OF THE BIODIVERSITY CONVENTION FOR A DRAFT PROTOCOL ON BIOSAFETY

The following provisions reflect Canada's views at this time and may evolve as the draft Protocol evolves. Canada notes that although the Chair of the Bureau requested that definitions not be submitted, there will be a necessity to define key terms, such as "living modified organism", and others. We will point these out in footnotes where they are crucial to our position.

1. Advance Informed Agreement

Article 1

Notification of Import

1. Each Party of import shall require notification to be given, by the importer, to the Party of import[1] of the first proposed transboundary movement of a living modified organism (LMO) subject to AIA[2] before it is imported[3].

2. The notification referred in Article 1(1) regarding LMOs subject to AIA shall include the following:

(a) the name of the exporter and importer

(b) information about the LMO, including source and characteristics

(c) available information about the potential adverse effects of the LMO on the conservation and sustainable use of biological diversity, including within the Party of import;

(d) intended use; and,

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[1] For the purpose of carrying out the administration of this paragraph, each Party of Import shall designate one or more responsible entities.

[2] The range of LMOs subject to AIA procedures are the LMOs that may have adverse effect on the conservation and sustainable use of biological diversity, including human health; therefore the expression "subject to AIA" is intended to provide a shorthand reference to those LMOs. The Protocol should also recognize that LMOs which have been previously assessed by Parties prior to the coming into force of the Protocol and reported under Article 6(1)(c) would not be considered "first" transboundary movements.

[3] Canada recognizes that the importer may need to have the exporter or owners of proprietary knowledge that they are not privy to, (but which is needed for the review for import,) supply information directly to the Party of Import. This exchange of information is subsumed under the heading of importer.

(e) available information about any notification to other governments regarding the import or development of the living modified organism, and the purpose thereof;

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

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

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

4. Each Party shall make its importers responsible for the accuracy of the information provided in a notification and for any new information provided pursuant to this Article.

5. Each Party of import shall acknowledge to the importer, not later than X days after receiving the notification under this Article, that the notification contains *prima facie* the information described under Article 1.2. Such acknowledgment does not limit the possibility to require further scientific information under Article 2(2)(d).

Article 2

Risk Assessment and Management

1. Upon providing acknowledgment to the importer in Article 1.5, the competent authority of the Party of import shall conduct a science-based risk assessment to evaluate the potential adverse effects of the living modified organism to the conservation and sustainable use of biological diversity within the territory of the Party of import, within predetermined time frames.[4]

2. On or before the expiration of the period in Article 2.1 and based on the result of the science-based risk assessment conducted under Article 2.1, the competent authority of the Party of import shall:

(a) allow the import,

or decide to:

(b) allow the import, subject to conditions;

(c) prohibit the import; or

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

[4] Consideration should be given to re-assessment following receipt of new information.

3. The competent authority of the Party of import shall provide an importer, subject to decisions under Article 2.2(b), (c) or (d), with reasons for such decisions.

4. Import-restrictive measures such as those referred to in Article 2.2(b),(c and (d) shall be imposed to the extent necessary to prevent the adverse effects of the living modified organism on the conservation and sustainable use of biological diversity within the territory of the Party of import, as demonstrated by the risk assessment conducted under Article 2.1.

5. Where the competent authority of the Party of import requires as a condition under sub-paragraph 2(b) of this Article that subsequent imports be notified, it shall establish for this purpose:

(a) notification procedures;

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

(c) procedures for risk assessment and decision making, alternative to those provided in paragraphs 1 and 2 of this Article.

Article 3

Capacity for Risk Assessment and Management

1. Each Party shall:

(a) establish at the national level, or co-operate in establishing at the multi-national regional level, procedures to assess the risks of living modified organisms under Article 2;

(b) ensure that it has appropriate domestic laws in place to manage the risks identified under its risk assessment procedures under Article 2; and

(c) ensure that it has appropriate domestic laws in place to enforce any conditions or prohibitions decided under Article 2.

Article 4

Reporting for Risk Assessment and Management

1. The Party of import shall provide to the clearing-house mechanism in a timely fashion notice of each allowance or prohibition made under Article 2, including any conditions forming part of the decision, and the reasons provided under Article 2.3.

2. Capacity-Building

Article 5

1. Each Party shall promote technical and scientific cooperation with other Parties, in particular developing countries, in implementing this Protocol, inter alia, through the development and implementation of national or regional policies. In promoting such cooperation, special attention should be given to the development and strengthening of national and regional capabilities, by means of human resources development and institution building.

2. The financial mechanism established under the Convention[5] will be a source of financial resources for capacity-building to help achieve the purposes of this Protocol, in particular for risk assessment and management.

3. Information Exchange and the Clearing House Mechanism

Article 6

1. Each Party of Import shall make available to the clearing-house mechanism[6] established under Article 18.3 of the Convention subject to appropriate protection of confidential business information:

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

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

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

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[5] "Convention" will be defined to mean the Convention on Biological Diversity.

[6] Canada envisages a two part clearing house. One that would be used primarily for information on decisions made after notification and assessment. Another that would be for more general use where information in general on LMOs, regulatory requirements, etc., could be housed and more open for people to put on or link information.

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

5. Public Awareness

Article 7

With respect to the safe transfer, handling and use of living modified organisms, specifically focusing on transboundary movement, each Party shall:

(a) promote and encourage understanding of the importance of, and the measures required for, such safe transfer, handling and use; and,

(b) cooperate, as appropriate, with other States and international organizations in developing public awareness material on these topics.

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OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

COLOMBIA

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REPUBLICA DE COLOMBIA
MINISTERIO DEL MEDIO AMBIENTE

PROTOCOLO DE BIOSEGURIDAD DEL CONVENIO DE BIODIVERSIDAD

PROPUESTA JURIDICA SOBRE ALGUNOS DE SUS ELEMENTOS

OBJETIVO DEL PROTOCOLO

El objetivo de este Protocolo es el de garantizar que el movimiento transfronterizo de OVM[1] se realice en condiciones seguras para la conservación, el uso sostenible de la biodiversidad y para la salud humana; así como el de fortalecer la capacidad de los países en desarrollo y de economías en transición , entre otros, mediante una financiación adecuada, para controlar el movimiento transfronterizo y para gestionar en forma ambientalmente segura los organismos objeto de este Protocolo

DEFINICIONES

OVM

Parte Receptora

Parte Originaria

Parte en Tránsito

Consentimiento Fundamentado Previo(CFP): Por procedimiento CFP se entiende el principio según el cual, el movimiento transfronterizo de todo OVM no debe realizarse sin la autorización, o contra la decisión, de la Autoridad Nacional Designada de la Parte Receptora.

Movimiento transfronterizo: Todo movimiento de OVM procedente del territorio de un Estado y destinado al territorio de otro Estado o de un Estado a través del cual se pretende efectuar el movimiento, siempre que el movimiento afecte, por lo menos, a dos Estados. Este término incluye el intercambio comercial (exportación o importación) y la donación, así como la transferencia sin ánimo de lucro con fines de investigación o desarrollo

Organismo Receptor

Organismo Donante

Vector o Inserto

[1] Organismo Vivo Modificados (en inglés Living Modified Organism)

Organismo Huésped

Condiciones contenidas

Condiciones confinadas

Condiciones semi confinadas

Condiciones comerciales

Liberación involuntaria

Liberación voluntaria

Liberación accidental

OBLIGACIONES GENERALES

- Cada Parte deberá aplicar el procedimiento de CFP previsto en el Artículo (CFP) respecto del movimiento transfronterizo de todo OVM
- Cada Parte garantizará que todo OVM que salga de su territorio contará con la debida autorización de la Autoridad Nacional Designada de la Parte Receptora
- Las Partes que reciban información y notificaciones sobre movimientos transfronterizos en virtud del presente Protocolo, deberán garantizar la confidencialidad de los datos recibidos con este carácter

APLICACION DEL PROCEDIMIENTO DEL CONSENTIMIENTO FUNDAMENTADO PREVIO (CFP)[2]

Notificación

- El procedimiento de CFP se iniciará con la notificación de una solicitud de movimiento transfronterizo de todo OVM por parte de la Autoridad Nacional Designada de la Parte Originaria a la Autoridad Nacional Designada de la Parte Receptora y, cuando proceda, a la Autoridad Nacional Designada de la Parte en Tránsito
- La solicitud del movimiento transfronterizo deberá contener la información especificada en el Anexo 1 del presente Protocolo

[2] En inglés Prior Informed Consent

Confidencialidad de la Información

- La solicitud de movimiento transfronterizo deberá identificar, debidamente justificada, la información que requiere de un tratamiento confidencial
- En ningún caso se considerarán confidenciales los siguientes datos:

a.. La siguiente información relativa al Organismo Huésped:

-Patogenicidad, toxicidad, alergenicidad frente a los humanos, y de existir, frente a otras especies
-Capacidad para transferir material genético y rutas de difusión potencial
-Métodos para detectar el organismo en el medio ambiente y para detectar la transferencia del ácido nucleico donado
-Potencialidad del organismo para afectar relaciones ecosistémicas

b.Un resumen de la evaluación de riesgo sobre los efectos en la conservación y el uso sostenible de la diversidad biológica, incluido sobre los animales domésticos y sobre la salud humana
c.Cualquier método o plan de contingencia
d.Método para la prevención o mitigación de accidentes

Revisión de la Solicitud

La Autoridad Nacional Designada de la Parte Receptora revisará el contenido de la solicitud y si la encuentra completa, dentro de los XXX días siguientes a la notificación, se lo comunicará por escrito a la Autoridad Nacional Designada de la Parte Originaria.

En caso de que la solicitud se encuentre incompleta, la Autoridad Nacional Designada de la Parte Receptora podrá solicitar, dentro del término señalado anteriormente, la información faltante, caso en el cual se suspenderán los términos aquí previstos hasta tanto se aporte la información solicitada.

Posibilidades de Respuesta

- La respuesta de la Autoridad Nacional Designada de la Parte Receptora respecto de la solicitud de un movimiento transfronterizo adoptará una de las formas siguientes:

a)Una decisión firme de:

i- Permitir el movimiento transfronterizo
ii- Negar el movimiento transfronterizo, en cuyo caso la Parte Originaria únicamente podrá, por intermedio de su Autoridad Nacional Designada, solicitar a la Parte Receptora llevar a cabo la evaluación de riesgo con el fin de revisar su decisión. En este caso la Parte receptora podrá exigir el cubrimiento de los costos parciales o totales de la evaluación.

b)Una respuesta provisional en la que:

i- Se informa la necesidad de llevar a cabo una evaluación de riesgo
ii- Se solicita información adicional

- En caso de que la Autoridad Nacional Designada de la Parte Receptora decida llevar cabo la evaluación de riesgo, cesarán de correr los términos estipulados por el artículo (Obligaciones de la Parte Receptora)
- Una vez efectuada la evaluación de riesgo la Autoridad Nacional Designada de la Parte Receptora podrá:

  a) Permitir el movimiento transfronterizo
  b) Permitir el movimiento transfronterizo sujeto a determinadas condiciones
  c) Negar el movimiento transfronterizo en cuyo caso no procederá recurso alguno

- La Parte en Tránsito podrá, con la debida justificación, objetar o condicionar el paso del OVM por su territorio

Obligaciones de la Parte Receptora

- La Autoridad Nacional Designada de la Parte receptora deberá dentro de los XXX días siguientes a la notificación, informar a la Autoridad Nacional Designada de la Parte Originaria de su decisión de acuerdo con el artículo (Posibilidades de Respuesta)
- Cada Parte Receptora comunicará a la Secretaría su respeusta a más tardar XXX días después de su pronunciamiento a la Autoridad Nacional Designada del País Originario

Obligaciones de la Parte Originaria

Cada Parte Originaria deberá:

a)Proveeer toda la información necesaria según lo dispuesto en el artículo (Notificación)
b) Aplicar las disposiciones legislativas y/o administrativas adecuadas para comunicar las respuestas de la Parte Receptora a las personas naturales y jurídicas interesadas en su territorio.
c) Acatar las condiciones establecidas en la respuesta de la Parte Receptora a más tardar XXX días después de la fecha de recepción de dicha comunicación
d)Tomar las medidas legislativas o administrativas adecuadas para asegurarse que el movimiento transfronterizo de OVM cumpla lo establecido en:

i. La respuesta de la Parte Receptora
ii. Lo dispuesto en el artículo (Manejo Transporte y Empaque)

e) Asesorar y ayudar, a solicitud la Autoridad Nacional Designada del país receptor para obtener información adicional sobre decisiones de otras Autoridades Nacionales Designadas relativas al OVM objeto del movimiento transfronterizo

AUTORIDADES NACIONALES DESIGNADAS

1. Cada Parte designará una autoridad nacional que estará facultada para actuar en nombre de esa Parte y para desempeñar las funciones administrativas requeridas para la aplicación del presente Protocolo
2. Las Partes procurarán que las Autoridades Nacionales Designadas cuenten con recursos suficientes para desempeñar eficazmente su labor.
3. Cada Parte, a más tardar en la fecha de entrada en vigor del presente Protocolo para esa Parte, comunicará a la Secretaría del Convenio sobre Diversidad Biológica el nombre y la dirección de su Autoridad Nacional Designada y deberá mantener esta información actualizada
4. La Secretaría comunicará sin demora a las Partes las notificaciones que reciba en aplicación del inciso anterior y cualquier cambio en la información relativa a las Autoridades Nacionales Designadas

EVALUACION DE RIESGOS

1. Cada país deberá definir internamente cómo será el mecanismo institucional para realizar las evaluaciones de riesgo y de emitir concepto técnico sobre las solicitudes de movimiento transfronterizo de conformidad con su legislación interna.

2. Para llevar a cabo la evaluación de riesgos, el país receptor deberá, entre otros:

   a) Tener en cuenta la información suministrada por el País Originario
   b) Considerar los efectos reales y/o potenciales sobre la salud humana, el medio ambiente, la producción agropecuaria incluido el equilibrio poblacional de los organismos relacionados
   c)Asegurarse que los procesos para la evaluación y gestión de riesgos de todo tipo de microorganismos se hagan en condiciones contenidas

GESTION DE RIESGOS

- Las estrategias de gestión de riesgos deberán:

  a) Corresponder a los resultados de la evaluación de la que habla el artículo (Evaluación de Riesgos)
  b) Establecerse tanto para utilizaciones confinadas como para contenidas y liberaciones
  c) Contener una descripción sobre el tipo y clase de contención y confinamiento del organismo en estudio
  d) Incluir el diseño de procedimientos y métodos para minimizar el riesgo en el manejo y uso del organismo en estudio

MANEJO, TRANSPORTE Y EMPAQUE

1. La Secretaría de la CDB deberá cooperar con la Organización Aduanera Mundial (WCO) para asignar un código de identificación universal para los productos objeto de este Protocolo
2. Cada Parte que realice un movimiento transfronterizo de un OVM de conformidad con el artículo (CFP) deberá asegurarse que dicho producto esté debidamente envasado, empacado, embalado y etiquetado, incluyendo su correspondiente Hoja Informativa de Seguridad (HIS) la cual deberá contener lo especificado en el Anexo 2
3. Las Partes deberán asegurarse que el movimiento transfronterizo de los OVMs desde su territorio estén sujetos a requerimientos de envasado, empacado, embalado y etiquetado no menores a los exigidos por su legislación nacional
4. La información contenida en la HIS deberá, en la medida de lo posible, estar en el idioma de la Parte Receptora

CLEARING HOUSE MECHANISM

1. El Mecanismo para la facilitación del intercambio de información y cooperación del Protocolo será el establecido por la Convención de Biodiversidad en su artículo 18 parágrafo 3.

2. Este mecanismo deberá incluir, entre otra[3], la siguiente información:

   a.Información sobre las medidas adoptadas por la legislación nacional de los países
   b.Información sobre decisiones adoptadas por los países en relación con el movimiento transfronterizo de OVMs
   c.Información sobre movimientos accidentales/ no intencionales de OVMs , incluidos los planes de contingencia o mitigación utilizados a que haya lugar
   d. Información relativa a la evaluación y gestión apropiadas de los riesgos
   e.Información sobre la aplicación del CFP, incluidos procedimientos simplificados y acuerdos bilaterales, multilaterales y regionales
   f.Información actualizada sobre las Autoridades Nacionales Designadas para efectos de este Protocolo

FORTALECIMIENTO DE LA CAPACIDAD NACIONAL

Elementos que deben incluirse en el artículo sobre fortalecimiento de la capacidad nacional:

- El fortalecimiento de la capacidad nacional es un requisito indispensable para la efectiva implementación del Protocolo

[3] En inglés *inter allia*

- Se entiende por Fortalecimiento de la Capacidad[4] la creación y/o el mejoramiento, cuando proceda, de los recursos institucionales o humanos, de acuerdo con las necesidades y prioridades identificadas por cada Parte, para:

  a. El manejo e intercambio efectivo de la información relacionada con el cumplimiento de este Protocolo
  b. La evaluación de riesgo
  c. La gestión del riesgo
  d. El establecimiento y adecuación de legislación nacional para la aplicación del Protocolo

- El fortalecimiento de la capacidad nacional deberá hacerse, entre otros, mediante:

  a.Recursos financieros nuevos y adicionales
  b.Capacitación y asistencia técnica
  c.Transferencia de tecnología relacionada con el ámbito de este Protocolo

[4] En inglés Capacity Building

REPUBLICA DE COLOMBIA
MINISTERIO DEL MEDIO AMBIENTE

ANEXOS DEL PROTOCOLO

ANEXO I: CONTENIDO DE LA INFORMACION REQUERIDA EN LA SOLICITUD DE CFP

1. Información relativa al organismo

1.1 Características del Organismo parental

a. Nombre o identidad del organismo (clasificación taxonómica, características fenotípicas y genotípicas)
b. Patogenicidad, toxicidad, alergenicidad frente a los humanos, y de existir, frente a otras especies
c.Habitat natural y orígen geográfico del organismo (su distribución y función sobre el medio ambiente)
d.Mecanismos que utiliza el organismo para sobrevivir, multiplicarse y difundirse (en el medio ambiente)
e. Medios de transferencia de material genético a otros organismos
f, Centros de Origen del organismo

1.2 Características del Vector

a. Nombre o identidad del organismo (clasificación taxonómica, características fenotípicas y genotípicas)
b. Patogenicidad, toxicidad, alergenicidad frente a los humanos, y de existir, frente a otras especies
c.Habitat natural y origen geográfico del organismo (su distribución y función sobre el medio ambiente?)
d. Mecanismos que utiliza el organismo para sobrevivir, multiplicarse y difundirse (en el medio ambiente?)
e. Medios de transferencia de material genético a otros organismos
f. Frecuencia de movilización o capacidad del vector para transferirse a otros organismos
g. Factores que podrían influir en la capacidad del vector para establecerse en otros huéspedes
h.Estado en que se encuentra (plásmido completo, parcial o desarmado)

1.3 Características del Organismo Huésped

a. Nombre o identidad del organismo (clasificación taxonómica, características fenotípicas y genotípicas)
b. Patogenicidad, toxicidad, alergenicidad frente a los humanos, y de existir, frente a otras especies
c.Mecanismo de supervivencia, persistencia y competitividad y difusión en el medio ambiente u otras interacciones pertinentes
d.Capacidad para transferir material genético y rutas de difusión potencial

e. Métodos para detectar el organismo en el medio ambiente y para detectar la transferencia del ácido nucleico donado
f.Potencialidad del organismo para afectar relaciones ecosistémicas
g.Caracterización del producto o los productos del gen o los genes insertados y, según proceda, de la estabilidad de la modificación
h.Actividad/manifestación del inserto

2. Información relativa a la utilización prevista

2.1 Condiciones confinadas

a-el número o volumen de los organismos que se van a utilizar
b-la escala de operación
c-las medidas de confinamiento propuestas, incluida la verificación y validación de su funcionamiento
d-información sobre control de desechos
e-información pertinente sobre utilizaciones previas
f-Medidas para la protección del personal
g-Medidas para controlar accidentes e imprevistos
h.Descripción sobre métodos y procedimientos de bioseguridad

2.2. Liberaciones intencionales

a-el propósito y la escala de liberación
b-la descripción y la ubicación geográfica de la liberación
c-el método y la frecuencia de la liberación
d-medidas para el control de desechos
e-información pertinente sobre utilizaciones previas
f-proximidad a fuentes de agua o a zonas residenciales
g.planes para el control de los accidentes y acontecimientos imprevistos/ desastres

3.Información pertinente procedente de cualesquiera liberaciones anteriores
4.Evaluaciones de riesgo realizadas sobre el OVM en cuestión
5. Nombre y dirección de la organización solicitante, entendiendose como tal la persona natural o jurídica interesada en el movimiento transfronterizo

ANEXO 2: HOJA INFORMATIVA DE SEGURIDAD (HIS)

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OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

CUBA

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CUBAN PROPOSAL ON THE POSSIBLE CONTENT OF THE ITEMS AGREED DURING THE SECOND MEETING OF THE AD-HOC GROUP FOR THE BIOSAFETY PROTOCOL

NATIONAL AUTHORITY

1.- Each State Party under its constitutional procedures should designate one or more national authorities. When more than one authority be designed, it should assign a specific field for the application of biotechnology. .

2.- The designed national authorities should fulfill, as a minimum, the following responsibilities:

a) To establish appropriate procedures to demand risk assessment of the release proposal of Living Modified Organisms which are likely to have adverse effect on biological diversity.

b) To examine the mechanisms to study and to evaluate risk assessment with the objective of guaranteeing a safe application of Living Modified Organisms to human health and environment.

c) To designate an examination body for risk assessment for all Living Modified Organisms release proposal into the environment.

ch) To establish mechanisms to facilitate data recording processing and diffusion about local conditions of areas where environment release will be done.

d) To check the right observance of established security conditions as a result of risk evaluation.

e) To establish appropriate procedures of control or mitigation, to finish release and eliminate wastes.

f) To guarantee the necessary confidence of commercial data.

g) To establish mechanisms to inform local communities about the Living Modified Organisms release, given appropriate educational materials.

h) To establish mechanisms for information exchange between countries and to develop national data bases.

i) To present pertinent information to competent international organizations about any negative or unforeseen repercussion on public health or environment related to Living Modified Organism release.

j) To keep a Registry of all activities related to Living Modified Organisms.

k) To receive and to arrange, to present and to evaluate all notification about transboundary movement of Living Modified Organisms.

l) The rest established by the present Protocol.

m) Any other assigned by their corresponding Governments.

CAPACITY-BUILDING.

1.- The Parties in this Protocol shall create the necessary capacity at local and national levels in correspondence to their possibilities, with the aim to achieve the following objectives:

a) To strengthen their endogenous capacities to facilitate the implementation of this Protocol and other instruments regarding safety in biotechnology and to develop the corresponding national legislation..

b) To identify any risk related to activities of development, use, production and release of Living Modified Organisms and to dispense the means for risk assessment and control to take proper decisions.

c) To guarantee safety when Living Modified Organisms are transferred to each country.

ch) To strengthen the development of policies, facilities, information systems and training in sciences related to safety in biotechnology, including evaluation and risk management techniques, as well as security procedures.

d) To increase technical knowledge and competence, facilities and resources to evaluate and control risks related to the use of Living Modified Organisms.

2.- The Parties will participate in the creation of capacities at regional level in order to jointly take advantage of the experience accumulated in the survey of risk assessment and in management strategies, contributing with detailed guidelines on national mechanisms of control.

3.- The parties will be able to strengthen their national or regional capacities using the financial mechanism, at the request of States Parties that consider it necessary, after assessment by the Secretariat, and intend some of its resources to facilitate technical cooperation, distribute reports and pertinent documents, hold practical courses and training meetings, as well as carrying out other connected activities for the benefit of the Parties being developing countries.

RISK ASSESMENT AND MANAGEMENT

1.- The Parties shall inspect the risk study and assessment mechanisms they have in order to determine if they are appropriate to provide for safe application of Living Modified Organisms both for human health and the environment.

2.- The Parties shall adopt the national legislation and ordinance to guarantee that any release of Living Modified Organisms be submitted to a process to assess any possible risks associated to this release and propose the corresponding control measures. The applied national standards

should be flexible and able to be adapted concerning up-to-date scientific information.

3.- The Parties should assess risks basing themselves on sound scientific principles and have them effected by scientifically competent bodies which are independent from the researcher or author of the release proposal.

4.- The national authority or authorities appointed by the Parties should create inspecting bodies at national level having required scientific and multidisciplinarian competence.

5.- The Parties should perform risk assessment in each process phase, "step by step", from laboratory research to release in the environment on a small or large scale, and concentrate preferably on the characteristics of the final product which human beings, animals and environment will be exposed to.

6.- The Parties shall take as standard the "case by case" assessment until they have acquired enough experience and the knowledge required to make classifications and generalizations.

7.- The Parties, in their national legislation, shall take into account that the type of risk management to be applied depends on each particular Living Modified Organisms. The adequate risk management measures shall be determined by risk assessment, employed organisms and way of release. The risk management measure should correspond to confirmed risks. If risk assessment exposes that foreseen application of a Living Modified Organism is not acceptable, further risk management measures should be taken and assessed.

RESPONSIBILITIES AND COMPENSATION FOR DAMAGE

1.- The Parties shall cooperate to adopt appropriate norms and procedures related to the responsibility and the compensation for the resulting damage of Living Modified Organisms release and transboundary movements.

2.- The Parties shall establish, in their national law, mechanisms of responsibilities and compensation, including environment rehabilitation for resulting damage of Genetically Modified Organisms release and transboundary movement.

3.- The Parties, in one of their meeting, shall adopt the norms and procedures to establish a global regimen of adequate responsibilities and compensation, including environmental rehabilitation, for the resulting damage from Living Modified Organisms release and transboundary movement.

ADVANCE INFORMED AGREEMENT

1.- It is established an advance informed agreement procedure on Living Modified Organisms subject to international trade which may have adverse effects on human health and the environment.

2.-The Parties that take provisions to prohibit or limit severely the use and manipulation of a living modified organism to protect health and environment shall notify the International Registry the measures adopted.

3.- The Living Modified Organism prohibited or severely limited for health or environmental reasons shall be submitted to advance informed agreement.

4.- The applid information and advance informed agreement shall meet the following objectives:

a) Help countries know in advance the characteristics of Living Modified Organisms being potentially dangerous and coming from other countries.

b) Create a decision-making process by the countries on future importation of Living Modified Organisms.

c) Foster this decision to other countries and obtain an official decision from importing countries.

d) Provide information on control measures intended to prohibit or restrict a Living Modified Organisms partially or rigorously.

3.- In their first meeting , the Parties will establish the scope, the documents and the mechanisms for the information and previous consent procedure and the criteria to select the Living Modified Organisms which would be included in the previous fundamented consent procedure.

TRANSBOUNDERY MOVEMENT OF LIVING MODIFIED ORGANISMS

1.- The Parties shall adopt pertinent legislation to secure the exporter and the importer provide the documents established by the International Registry on Living Modified Organisms before commercializing it as a product or as part of it.

2.- The Parties exporting a Living Modified Organism on which no field tests were allowed in the country shall communicate the reasons and all the information concerning this to any other country where they intend to export it.

3.- In order to keep safety levels during transportation, reception, and storage, the Parties shall adopt internationally harmonized and recognized procedures and practices which provide for adequate classification, bottling, and labeling.

4.- The Parties taking part in the commerce of Living Modified Organism shall take into account international conventions, agreements and recommendations on classification, bottling, labeling and documentation established by appropriate international organizations related to transport, particularly , the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO), International Rules of Transport and Dangerous Goods by Road (RID) and the International Airway Transport Association (IATA).

5.- The Parties shall consider as illegal traffic of Living Modified Organism, all transboundary movement that occur:

- without notification to all States concerned pursuant to the provisions of this Protocol,
- without the consent of a State concerned pursuant to the provisions of this Protocol,
- with the consent of the States concerned through falsification , false declarations or fraud, and
- in a manner not consistent with the advance information.

6 - The Parties shall adopt the pertinent measures to guarantee a rational environmental management of Living Modified Organisms to which this Article refers to and shall establish pertinent coordination with the States concerned.

7.- Rules regarding advance informed agreement and those concerning transboundary movement of Living Modified Organisms, in this Article, will be applied "mutatis mutandi" to the international commerce of these organisms on one hand , with or through a State not Party.

INTERNATIONAL REGISTRY ON GENETICALLY MODIFIED ORGANISMS

1.- It is established an International Registry on Living Modified Organisms which will be a scientific instrument to record and share data used to assess risks implied by Living Modified Organisms for public health and the environment. This Registry will work closely with the Global Environmental Monitoring System (GEMS) and other UNEP bodies intended to information exchange such as INFOTERRA and the Programme for Environmental Assessment. This Registry will have the following objectives:

a) Become a global network intended to information exchange on Living Modified Organisms.

b) Elaborate data profiles on Living Modified Organisms. Administer a data bank with all aspects related to Living Modified Organisms, including information concerning national policies and regulations applied to these.

c) Watch the fulfillment of guidelines elaborated for information exchange on Living Modifies Organisms subject to international trade.

ch) Provide assistance to developing countries for the establishment of their own national records. Facilitate attainment of the existing information on production, distribution, and elimination of Living Modified Organisms.

d) Offer training in fields related to control of stated risks and with scientific data use.

e) Foster scientific research. Issue scientific and technical publications on genetic handling and its end products as well as bulletins intended to provide information on Living Modified Organisms.

f) Provide consulting services.

g) Detect environmental changes associated to Living Modified Organisms, determine their causes, and communicate research results.

h) Identify the gaps in knowledge on the effects of Living Modified Organisms. Elaborate statements on environmental problems related to these.

2.- In the Parties' first meeting, the Registry functions, structure, and location procedures for information exchange and its functional ordinance will be established.

TECHNICAL AND SCIENTIFIC COOPERATION

1.- The Parties shall promote international technical and scientific cooperation in the field of handling and use of Living Modified Organisms, where necessary, through the appropriate international and national institutions.

2.- The Parties shall promote technical and scientific cooperation with other Parties, in particular developing countries, in implementing national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national capacity , by means of human resource development and the creation of institutions.

3.- Taking specially into account the needs of the developing countries, the Parties shall cooperate in promoting scientific-technical cooperation led to facilitate participation in this Protocol and its enforcement.

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

5.- At their first meeting, the Parties shall start deliberations on the means to fulfill the obligations of Paragraphs 1-4 of the present Article, including work plan elaboration in which special attention will be paid to the needs and circumstances of developing countries. The states and regional economic integration organizations not being Parties in the Protocol will be encouraged to participate in the activities specified in such plans

INFORMATION EXCHANGE

1.- The Parties shall cooperate according to their national laws, regulations, and practices and taking particularly into account the needs of the developing countries in order to foster, directly or through the International Registry of Living Modified Organisms and other competent bodies, the research, development, and information exchange on:

a) Most convenient technologies to improve risk confinement, assessment and, management.

b) Useful generic research for risk assessment and management.

c) The transboundary movement of Living Modified Organism and the approvals conferred for trading products having Living Modified Organisms as well as those being prohibited, approved or obtained recently.

d) Adopted legislation on biotechnology safety and national biosafety mechanisms.

e) Living Modified Organism releases and the unexpected or adverse effects on human health and the environment which have taken place due to them.

f) Technical, scientifc, and socio-economic research results, as well as the statistics available on the effects on human health and the environment.

g) Training and study programs and specialized, autochthonous and traditional knowledge.

h) The supervision of Living Modified Organism releases after its commercial use.

i) Groups of experts and advisory bodies.

PUBLIC AWARENESS

1.- The Parties shall stipulate public participation by allowing access to information on which decisions are based and shall cooperate to favor public awareness on any possible effects for the environment and health in general that Living Modified Organisms release may produce..

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 to modern biotechnology.

ANNEX I
INFORMATION REQUIRED IN THE NOTIFICATION

I.- GENERAL INFORMATION.

A.- Name and address of the notifier.

B.- Information on personnel and training.

1- Name of person(s) responsible for planning and carrying out the release including those responsible for supervision, monitoring and safety, in particular, name and qualifications of the responsible scientist;
2- Information on training and qualifications of personnel involved in carrying out the release.

II. INFORMATION RELATING TO THE GMO.

A.- Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):

1. scientific name;
2. taxonomy;
3. other names(usual name, strain name, cultivar name, etc.);
4. phenotypic and genetic markers;
5. degree of relatedness between donor and recipient or between parental organisms;
6. description of identification and detection techniques;
7. sensitivity, reability (in quantitative terms) and specificity of detection and identification techniques;
8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts;
9. potential for genetic transfer and exchange with other organisms:
10. verification of the genetic stability of the organisms and factors affecting it;
11. pathological, ecological and physiological traits:

a) classification of hazard according to existing rules concerning the protection of human health and/or the environment;
b) generation time in natural ecosystems, sexual and asexual reproductive cycle:
c) information on survival, including seasonability and the ability to form survival structure e.g.: seeds, spores or sclerotia;
d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (porviruses). Ability to colonize other organisms;
e) antibiotic resistance, and potential use of these antibiotics in human and domestic organisms of prophylaxis and therapy;
f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. nature of indigenous vectors:

a) sequence;
b) frequency of mobilization;
c) specificity;
d) presence of genes which confer resistance.

13. History of previous genetic modifications.

B.- Characteristic of the vector:

1.- nature and source of the vector;
2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO;
3. frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;
4. information on the degree to which the vectors is limited to the DNA required to perform the intended function.

C.- Characteristic of the modified organism: 1. Information relating to the genetic modification:

a) methods used for the modification;
b) methods used to construc and introduce the insert(s) into the recipient or to delete a sequence;
c) description of the insert and/or vector construction;
d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;
e) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
b) structure and mouth of any vector and/or donor nucleic acid remaining in the final construction of the modified organisms;
c) stability of the organism in terms of genetic traits;
d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;
e) activity of the expressed protein(s);
f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;
g) sensitivity, reability (in quantitative terms) and specificity of detection and identification techniques;
h) history of previous releases or uses of the GMO;
i) health considerations:

- toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;
product hazards;
- comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
- capacity for colonization;
- if the organism is pathogenic to humans who are immunocompetent:
  - diseases caused and mechanism of pathogenicity including invasivens and virulence,
  - communicability,
  - infective dose,
  - host range, possibility of alteration,
  - possibility of survival outside of human host,
  - presence of vectors or means of dissemination,
  - biological stability,
  - antibiotic-resistance patterns,
  - allergenicity,
  - availability of appropriate therapies.

III.- INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT.

A. Information on the release:

1. description of the proposed deliberated, including e purpose(s) and foreseen products;

2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases;

3. preparation of the site previous to the release;

4. size of the site;

5. method(s) to be used for the releases;

7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities);

8. worker protection measures taken during the release;

9. post-release treatment of the site;

10. techniques foreseen for elimination or inactivation of the GMOs at the end the experiment;

11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B.- Information on the environment (both on the site and the wider environment):

1. geographical location and grid reference of the site(s) (in case of notifications under Part C the site(s) of release will be the foreseen areas of use of the product);

2. physical or biological proximity to humans and other significant biota;

3. proximity to significant biotypes or protected areas;

4. size of local population;

5. economic activities of local populations which are based on the natural resource of the area;

6. distance to closest areas protected for drinking water and/or environmental purpose;

7. climatic characteristic of the region(s) likely to be affected;

8. geographical, geological and pedological characteristics;

9. flora and fauna, including crops, livestock and migratory species;

10. description of target and non-target ecosystems likely to be affected;

11. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release;

12. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT.

A.- Characteristic affecting survival, multiplication and dissemination:

1. biological features which affect survival, multiplication and dispersal;
2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.);
3. sensitivity to specific agents.

B.- Interactions with the environment:

1. predicted habitat of the GMOs;
2. studies of the behavior and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses;
3. genetic transfer capability:

a) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
b) post-release transfer of genetic material from indigenous organisms to the GMOs;

4. likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal of genetic material, Methods to verify genetic stability;

6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.;
7. description of ecosystems to which the GMOs could be disseminated.

C. Potential environmental impact:

1. potential for excessive population increase in the environment;
2. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
3. identification and description of the target organisms;
4. anticipated mechanism and result of interaction between the released GMOs and the target organism;
5. identification and description of non-target organisms which may be effected unwittingly;
6. likelihood of post-release shifts in biological interactions or in host range;
7. known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;
8. known or predicted involvement in biogeochemical processes;
9. other potentially significant interactions with the environment.

V.- INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS.

A. Monitoring techniques:

1. methods for tracking the GMOs, and for monitoring their effects;
2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques;
3. techniques for detecting transfer of the donated genetic material to other organisms;
4. duration and frequency of the monitoring.

B. Release Control.

1.- Methods and procedures to avoid or minimize the dissemination of GMOs out of the release place or the zone foreseen for their use.
2.- Methods or procedures to protect the already mentioned place from non-authorized people's entrance.
3.- Methods and procedures to prevent other organisms from penetrating in that place.

C. Refuse Treatment.

1.- Type of resume produced.
2. Foreseen refuse volume.
3. Possible risks.
4.- Proposed treatment description.

D. Action plans in case of emergencies.

1. GMO control methods and procedures in case of unexpected dissemination.
2. Decontamination methods for affected zones, for instance, GMO eradication.

3. Elimination or sanitation methods for plants, animal soil, etc. exposed to the organisms during dissemination or thereafter.
4. Isolation methods for the zone affected by dissemination.
5. Protection plans for human health and the environment in case an undesirable effect is produced.

ANNEX II

FURTHER INFORMATION REQUIRED IN CASE OF COMMERCIALITY NOTIFICATION

A) Besides the information specified in Annex II, the following shall be notified in the product commerciality notification:

1. Product name and that of the GMOs it contains.

2. Manufacturer or distributor's name and address in the country of origin.

3. Product specificity, exact product conditions, including, when pertinent, the environmental or geographic zone type for which the product is appropriate.

4. Foreseen use type: industry, agriculture and specialized activities, public consumption in general.

B) Besides the information presented in Item A, the following shall be provided, when pertinent, in conformity with Chapter _____ of the Present Protocol.

1. Measures to be adopted in case of non-intentional release or undue use.

2. Specific introductions or recommendations for storage and handling.

3. Estimate production or importation in the country.

4. Propose packing. It should be adequate so as to avoid non-intentional release of GMOs during storage or further phases.

5. Proposed labeling. It should include, at least summarizedly, the information referred to in Items A.1; A.2; A.3; B.1 and B.2

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OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
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13 to 17 October 1997

EUROPEAN COMMUNITY

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EUROPEAN COMMUNITY

SECTION A: items on which Governments have been invited to propose legal texts, and related items

Article 1 Objective

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

Article 2 Scope

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

2. This protocol shall not apply to :

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

- requirements for transport operations

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

Article 3 Competent authority/ies, focal point/s

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

2. Each Party shall also notify relevant data concerning its designated competent authority/ies and/or focal point/s to the Secretariat for inclusion in the Database provided for in Article 12 [on information exchange]. Each Party shall also immediately notify the Secretariat of any subsequent changes.

Article 4. General provisions

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

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

or disguised restrictions on international trade.

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

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

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

Article 5 Notification in case of intentional transboundary movement

For the intentional transboundary movement of LMOs, the exporter shall notify in advance the Party of import in writing of that movement and shall only proceed with such movement in compliance with the Articles 6 to 8.Information to be provided in the notification is specified in Annex IV.

Article 6 Acknowledgement of receipt

The Party of import shall within 30 days of the date of receipt of the notification acknowledge to the notifier the date of receipt of the notification.

Article 7 Procedures

1. The Party of import shall within the period referred to in Article 6 [30 days of the date of receipt of the notification] inform the notifier to proceed according to:

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

- or the procedure provided for in Article 8.

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

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

Article 8 AIA

1. The Party of import shall within the period referred to in Article 6 [30 days of the date of receipt of the notification] communicate to the exporter:

1.1 that, unless it has not, with justifications, asked for additional information, imposed conditions or refused permission for the notified movement within 150 days after the date of receipt of the notification, the movement may proceed;

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

2. The Party of import may inform the notifier with justification that this period [150 days] is extended by a defined period no longer than 60 days.

When calculating the periods referred to in paragraph 1, the number of days for which the Party of import is waiting for additional information which it has requested from the notifier shall not be taken into account.

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

Article 9: Simplified procedures

1. Without prejudice to Article 7 (2), a Party of import can with justification specify, in advance, to other Parties cases:

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

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

2 Information to be provided in the notification is specified in Annex V.

Article 10 Safeguard clause

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

Article 11 Unintentional transboundary movement

1. In the case that an unintentional transboundary movement of LMOs is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, the Party from which the unintentional movement originates shall

ensure that any affected Party/ies and non-Party/ies receives, as soon as possible, all relevant information concerning the unintentional transboundary movement and risks to the conservation and sustainable use of biological diversity, taking also into account risks to human health, and their management.

2. Information to be provided is specified in Annex VI.

Article 12 Information exchange

1. A Database for international information exchange shall be established and administered by the Secretariat. Without prejudice to Article 13 [on confidentiality of data], the Database shall contain and provide access to information relevant to the implementation of the protocol.

2. Without prejudice to Article 13 [on confidentiality of data], each Party shall provide that the Secretariat is informed, for inclusion in the Database, of:

- relevant data of designated competent authorities and focal points;

- the text of any decision on a notification of a intentional transboundary movement and the summary of the risk assessment;

- a summary of any notified unintentional transboundary movements which are likely to have significant adverse effects in another Party or non Party on the conservation and sustainable use of biological diversity, taking also into account risks to human health;

- the text of decisions taken pursuant to Article 10 [safeguard clause];

- general description of products consisting of or containing LMOs having received consent by a Party or Parties for placing on the market

- information concerning its biosafety regulatory framework on LMOs.

- a summary of any methods and plans for monitoring of LMOs.

3. Without prejudice to Article 13, the information shall be accessible to the public.

4. 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

Article 13 Confidentiality of data

1. Competent authorities, focal points and the Secretariat shall not divulge any confidential information received under the protocol and have the obligation to protect intellectual property rights relating to the data received.

2. The notifier may indicate the information submitted under the procedures of this protocol that

ensure that any affected Party/ies and non-Party/ies receives, as soon as possible, all relevant information concerning the unintentional transboundary movement and risks to the conservation and sustainable use of biological diversity, taking also into account risks to human health, and their management.

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- a summary of any methods and plans for monitoring of LMOs.

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Article 13 Confidentiality of data

1. Competent authorities, focal points and the Secretariat shall not divulge any confidential information received under the protocol and have the obligation to protect intellectual property rights relating to the data received.

2. The notifier may indicate the information submitted under the procedures of this protocol that

should be treated as confidential. Verifiable justification must be given in such cases.

3. The competent authority or focal points shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions.

4. Without prejudice to Article 13(5), in no case may the following information be kept confidential:

- the general description of the LMO or LMOs, name and address of the notifier, purpose of the movement;

- a summary of the risk assessment of effects on the conservation and sustainable use of biological diversity, taking also into account human health;

- any methods and plans for emergency response;

5. If, for whatever reasons including in case the competent authority and notifier disagree, a notifier withdraws a notification, the confidentiality of all the information supplied must be respected by the competent authorities and focal points.

Article 14 Risk assessment

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

- the characteristics of the organisms involved, including any introduced sequences or modified traits;

- the characteristics of the intended application;

- the characteristics of the potential receiving environment;

- and the interaction between these.

2. The risk assessment referred to in paragraph 1 shall, as appropriate, be based on the information and principles set out in Annex VII.

Monitoring and compliance

As regards monitoring:

Individual parties should report on the implementation of their commitments. The reporting should set out the measures taken by Parties to implement the Protocol. In this area as in others, relevant provisions of the CBD (e.g. Art.26) or decisions adopted by the CoP (e.g. Decision II/17) should be fully exploited before adding new requirements. All reports should be made available to the COP.

As regards compliance:

We consider that the provisions of the Protocol should be of such a normative character that a

procedure to review individual implementation and to help Parties to fulfil their commitments will be justified.

The process should be simple, co-operative and transparent and should be guided by the need of all Parties to co-operate in good faith and participate fully. Therefore it should be non-judicial, advisory and as transparent as possible.

This process could operate through a standing body composed of a limited number of experts nominated by Parties on basis of equal geographical distribution.

This process should result in friendly settlement of differences with a view to helping Parties finding themselves in difficulty to observe their obligations under the Protocol. The methods of friendly settlement could take the form of practical guidance and assistance, the result being the prevention of disputes.

SECTION B: items to be addressed by the Secretariat

financial issues:

The financial mechanism defined for the purposes of the Convention, as well as the entity or entities entrusted with its operation, shall serve as the financial mechanism and entity or entities for the purpose of the Protocol.

institutional framework:

The secretariat established by Article 24 of the Convention shall serve as the secretariat of the Protocol.

relationship with other international agreements:

The issue of the relationship with other international agreements should as far as possible be referred to in the context of Article 22 of the Convention.

settlement of disputes:

The provisions of Article 27 of the Convention shall apply to this Protocol.

review:

The Protocol should provide adequate, flexible procedures to allow adaptation to scientific and technical progress.

As regards the amendment of the Protocol, appropriate provision is already contained in Article 29 of the Convention.

The Protocol should be reviewed periodically as necessary.

Annexes to the Protocol

Annex I: Lists of and/or criteria for LMOs, genes/traits and activities with LMOs to which the Protocol shall not apply.

Annex II: relevant information on LMOs [in relation to Article 4(4)]

Annex(es) III: Cases of explicit consent [in relation to Article 7(2)]

Annex IV: Information requirements for notifications

Annex V: Information requirements for simplified procedures

Annex VI: Information requirements for unintentional transboundary movement

Annex VII: Risk assessment

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INDIA

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LEGAL TEXT OF CERTAIN ELEMENTS OF THE BIOSAFETY PROTOCOL BEING DEVELOPED UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY - INDIA

(1) Advanced Informed Agreement

Definition

"Advance informed agreement" means an agreement by the competent authority of the State of import to the transfer of any living modified organisms or products thereof based on the information supplied by the competent authority of the State of export with the understanding that the information is accurate and complete."

(i) A Party shall permit the export of living modified organisms or products thereof only when it confirms that the advance informed agreement of the State of import has been obtained based on the necessary information that the State of import has received in accordance with the provisions of (2) and Annexure I.

(ii) The competent authority of the State of export shall require the exporter to submit, inter alia, information on:

(a) The living modified organism:

- its taxonomy, and reproductive behavior;
- if genetically modified, information on the donor, recipient and vector organisms, the genes introduced, including marker genes, stability of the introduced genes and risks of transfer of those to other organisms, methods of managing unintended release, and methods of use;

(b) The product of living modified organisms:

- information on the living modified organisms, methods of using it, whether it is a novel chemical, or one which occurs in nature, the living modified organism which produced it as referred in (a) above, and management methods in case of accidents.

(iii) The competent authority of the State of import/export shall provide information concerning its laws, regulation, guidelines, legal and administrative procedures and other requirements related to the safe development, handling and use of living modified organisms and products thereof.

(2) Notification procedures

(i) The State of export shall notify, or shall require the exporter to notify in writing, through the channel of the competent authority of the State of export, the competent authority of the States concerned of any proposed transboundary transfer of living modified organisms or products thereof. Such application shall contain the declarations and information specified in Annex.I,

written in a language acceptable to the State of import. Only one notification needs to be sent to each of the States concerned and to the Clearing house.

(ii) The States of import shall respond to the notification in writing, consenting to the transfer with or without conditions, denying permission for the transfer, or requesting additional information. The States of import shall submit any final decision to the competent authority of the State of export and to the Clearing House.

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

(iv) If, at any time before, during or after the transboundary transfer, the exporter becomes aware of relevant new information on the living modified organism or the product in question which could have significant consequences for the associated risks, the competent authorities of the State concerned and the Clearing House shall be informed immediately on being aware but in any case not later than 15 days from being aware.

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

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

(vii) No transboundary transfer of living modified organisms or products thereof shall be allowed by the State of export unless risk assessment has been undertaken that these organisms or products are adequately and effectively tested for the safety in the various anticipated conditions in the State of import.

(viii) Every State shall take legal measures that the transboundary transfer originating from it be covered by insurance, bond or other guarantee.

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

(3) **Risk assessment and management**

(i) Each Party shall ensure that, in accordance with the provisions of this Protocol , assessments

prior to the use, transfer and release of living modified organisms or products thereof are undertaken as regards the risks or possible adverse impacts to human and animal health in their respective territories as well as in the territories of States of import.

(ii) Such assessments shall identify the risks associated with the living modified organism in question or the product thereof and specify actions to be taken in response. The risk assessment documentation to be submitted to the competent authorities of the States concerned shall contain, as a minimum, the information described in Annexure 2.

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

(iv) Each Party shall ensure that, in accordance with the provisions of this Protocol , appropriate management of the risks identified is undertaken until such risks have been avoided or reduced to an acceptable level - The risk management set out in Annex 3 shall be employed as a minimum.

(v) Without prejudice to paragraph (iv) above, each contracting party shall ensure genomic and trait stability in the environment. To this end any living modified organism shall undergo appropriate observation.

(4) Accidents and emergency measures

(i) Parties shall take the necessary measures to ensure that the competent authorities of the State(s) concerned are informed immediately in the event of an accident. The information shall include, inter alia, the circumstances of the accident, tkc identify and numbers of quantities of the living modified organisms released, other facts necessary to assess the effects of the accident on human and animal health, the environment and biological diversity, and the emergency measures taken or needed to be taken.

(ii) The States concerned shall, where information is provided under paragraph (i) above, ensure that in any emergency.-the appropriate measures are taken, including immediate alerting of any other State which could be affected by the accident.

(5) Labelling, packaging, and transportation

The parties shall ensure that products in transboundary transfer particularly food products incorporating living modified organisms or products thereof, are clearly labelled, safely packed and transported in accordance with guidelines.

(6) Competent authorities / focal points

(i) To facilitate the implementation of this Protocol, each Party shall :

a. Designate or establish a competent authority which shall receive notification and communicate decisions on living modified organisms and products thereof in accordance the advance informed agreement procedures set out in (1), (2) and Annex I.

b. Inform the Secretariat and the Clearing House within 90 days of the date of the entry into force of this Protocol the name of the agency designated as their competent authority.

(ii) Parties shall ensure that appropriate legal, institutional, and administrative frameworks are in place at the national level within two years after the date of ratification or accession.

(7) **Information sharing / Clearing House mechanism**

(i) The Clearing House mechanism under the CBD shall function as the Clearing House mechanism to provide the Parties and, as appropriate the Secretariat, with timely advice and information relating to the implementation of this Protocol.

(ii) Each Party shall ensure that timely information pertaining to biosafety is provided to the Clearing House.

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

(8) Capacity building

(i) The Parties shall take effective measures to develop and strengthen human resources and institutional capacities in biotechnology and biosafety, particularly in the developing countries.

(ii) According to the specific needs of Parties, different legions and sub-regions, activities for training avid capacity building for the safe handling and management of living modified organisms or products thereof shall be undertaken with financial assistance provided through the financial mechanisms under the Convention on Biological Diversity (CBD).

(9) **Public awareness and participation**

(i) The Parties shall promote and encourage understanding of the importance of safety in use, handling and management of living modified organisms and their products.

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

Annex 1
Information required in order to obtain advance informed agreement

The exporter of living modified organisms or products thereof shall provide the competent authorities of the States concerned with the following information in order to obtain advance informed agreement.

1. Names and addresses of the exporter and the importer

2. A complete risk assessment report on the living modified organism or the product thereof in accordance with the risk assessment parameters as stated in Annex 2 of the Protocol.

3 - Number or quantity of organisms or products to be transferred or volume of culture and physical form.

4 . The step reached in the testing and observation of the living modified organism or the product thereof according to the legal or administrative requirements of the State of export.

5 - The applicable laws, procedures and guidelines of the State of export.

6. Any requirements to manage risk and to ensure safe handling and use, and methods for safe disposal and appropriate emergency procedures in case of accidents.

7. Intended dates of transfer

8. Intended means of transport

9. Information relating to insurance.

10. Declaration by the exporter that the information is correct.

Annex 2
Risk assessment parameters

The user shall carry out an assessment prior to the use and release of living modified organisms or products thereof as regards the risks to human and animal health. Biological diversity, the environment and the socioeconomic welfare of societies. This assessment shall take the following parameters into consideration including any other parameter deemed to be relevant:

1. **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 allogenicity and/or toxicity of biochemical and metabolic products;

(s) Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

2. **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) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;

(e) Potential for pathogenicity and virulence;

(f) Natural and host range of vectors;

(g) Natural habitat and geographic distribution of natural and potential hosts;

(h) Potential impacts on human and animal health and the environment;

(i) Measures for counteracting adverse impacts;

(j) Potential to survive and multiply in the environment, or to form genetic recombinants;

(k) Genetic stability of vector(s), such as hypermutability.

3. **Characteristics of living modified 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;

(c) Purpose of the modification and intended use in relation to need or benefit;

(d) Method of modification, and in case of transgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism;

(e) Whether introduced gene(s) integrated or extrachromosomal;

(f) Number of insert(s) and its/their structures, for example, the copy number whether in tandem or other types of repeats;

(g) Product(s) of the transferred gene(s), levels of expression and methods for measuring expression;

(h) Stability of the introduced gene(s) in terms of expression and integration;

(i) Biochemical and metabolic differences of living modified organisms compared with the unmodified organism;

(j) Probability of vertical or horizontal gene transfer to other species;

(k) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous ciruses, plasmids and bacteria;

(l) Allgenicities, toxicities, pathogenicities and unintended effects;

(m) Autecology of the living modified organism compared with that of the unmodified organism;

(n) Susceptibility of the living modified organism to discuss and pests compared with the unmodified organism;

(o) Detailed information on past uses including results on all experiments leading to previous releases.

4. Characteristics of sesuscitated organisms and gene(s) and fossil DNA sequences.

5. 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.

6. 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 organism;

(d) 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 pathogenes, alltegenicity, 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.

7. Socio-economic considerations.

Annex 3
Risk management schemes

The user shall employ the following risk management schemes and procedures from the development, through all stages of testing of the living modified organism or the product thereof, to its intended use or commercialization.

1. **Imported products of living modified organisms used for human or animal health (e.g. antibodies, drugs and hormones);**

   (a) observation to ensure that changes in food habitats, nutrition and other factors that could conceivably modify the expected impacts are insignificant;

   (b) such observation can be limited in scope when it is shown that adequate trials on the specific products have been made on human or animals, as appropriate, in areas other than the State of import;

2. **Imported microbial living modified organisms for human and animal health.**

   Besides the limited observation specified in 1, experiments shall be carried out to evaluate viability and risks of reacquiring virulence or lending virulence to other micro organisms when in the body and in the environment, since some spilling is inevitable.

3. **Imported living modified organisms for contained use:**

(a) The products of living modified organisms will be treated as in 1;

(b) Experiments will be made in complete laboratory containment to determine: (i) longevity of the living modified organism in cases of unintended release in the premises and in the surrounding environment, and (ii) genetic transfer into other micro-organisms and implications thereof on human and animal health and the environment;

(c) Methods for counteracting adverse impacts resulting from unintended releases should be specified.

4. **Imported plant or microbial living modified organism for release:**

(a) The reports from releases in areas other than the State of import shall be thoroughly evaluated by a designated authority. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;

(b) If it is decided that the previous release mechanisms have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but otherwise kept at the same soil community, moisture, air temperature and plant and animal community conditions as the intended area of release;

(c) The observations will include the health of the living modified organism, the health of the organism within the area of limited release, and the biological diversity and the ecology of the area;

(d) Nationally approved limited field releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

5. Imported animal living modified organism for release:

(a) The reports from releases in areas other than the State of import shall be thoroughly evaluated by a designated authority. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;

(b) If it is decided that the regulations used in the previous release have been rigorous enough, then observations will be made in complete containment in the expected ambient climatic, nutritional and 'other environmental conditions to monitor physiological functions, adaptations and gene transfers;

(c) When the results have met the stated requirements, then a trial release may be authorized with adequate emergency plans put in place to deal with cases of escape.

6. General requirements:

(a) All trials, experiments or observations specified in all the above cases (1-5) are put in their logical sequence and shall be subjected to the hierarchical procedures of approval by the lower institutional and the higher national level bodies.

(b) Once approval from the appropriate designated authority is obtained at the completion of the final stage of the trials, experiments or observations, the living modified organism in question or the product thereof can be employed for its intended use. The appropriate designated authority shall notify its decision in writing to the competent authority.

(c) Whenever there is a need to dispose of the living modified organism or the product thereof upon the completion of every trial or experiment, it shall be made through complete incineration or other approved means of complete destruction.

(d) The release of living modified organisms or products thereof shall be monitored, appropriate and emergency plans to prevent escape and accident shall always be in place.

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CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

INDONESIA

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INDONESIAN INPUT TO THE PROTOCOL ON BIOSAFETY

BIOSAFETY AND CONVENTION ON BIOLOGICAL DIVERSITY

The fundamental principle of the Convention on Biological Diversity regarding the development and use of biotechnology are those of the precautionary principle, advance informed agreement, access to information and the overriding need for the assessment, regulation, control and management of risks arising from the use and release of genetically modified organisms (GMO) which adversely affect the conservation and sustainable use of biological diversity as well as risks to human health. This precautionary principle is accepted under the Convention in the preamble, articles 8(g), 8(h), 19(3) and 19(4).

In reviewing the implementation of Chapter 16 of Agenda 21 on "environmentally sound management of biotechnology", the Commission on Sustainable Development (1995) called for a balanced and objective approach to biotechnology, stressing while the benefits accrue from biotechnology.

Considering all the above principles, the following are important factors to consider in the development of International Protocol:

1. **Transboundary movement**. With regard to transboundary movement of living modified organisms, the importing party has to inform the neighboring countries on the kind of LMO, what precaution need to be taken where there is a possibility of unintentional spread of LMO. The needs of agriculture and industry will have to be considered separately, since in agriculture, there are considerable **genotype x environment interactions**.
2. **Risk assessment**. Risks assessment has to go hand-in-hand with the assessment of socio-economic impacts of the introduction of LMO. There should be balance between the risk of not using the technology and the socio-economic benefit of using the technology.
3. **Biosafety Information Focal Point**. There should be focal point for information related to all aspects of biosafety, including what LMOs are imported by the Parties as well as LMOs that do not accepted by Parties. The assessment procedures must be transparent and timely information should be provided to the public through the mass media. Information empowerment of the civil society is the best insurance against unfavorable risks. Consumer education is equally important.
4. **Capacity Building**. It is easy to develop biosafety regulations based upon the best available international experience. However, it will be difficult to implement the provisions of the biosafety protocol unless implementation structures are in place and an adequate number of trained personnel become available. Within the developing countries, capability of doing assessment and management of risks is minimal. Therefore, the exporting Parties have the obligation to also transfer the technology and help the human resource development to be able to do the risks assessment and management. Also, as part of the capacity building exercise, genetic enhancement centers should be set up in suitable institutions where novel genetic combinations can be produced for the use of breeders at the grassroots level who can then develop location-specific varieties.
5. **National Focal Point.** In addition to Biosafety Information Focal Point, every country should designate a National Focal Point with reference to biosafety policy and implementation

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JAPAN

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JAPANESE PROPOSAL FOR A PROTOCOL ON BIOSAFETY

1. Advance Informed Agreement

(1) General Provisions of the Advance Informed Agreement

(a) The Contracting Parties to the Protocol (hereinafter referred to as "Contracting Parties") shall establish national measures to implement of the Advance Informed Agreement (hereinafter referred to as "AIA") procedures which ensures that an Exporter intending to transfer beyond its national boundary living modified organisms (hereinafter referred to as "LMOs") resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity shall provide the competent authorities of the recipient Contracting Party with information on the transboundary transfer of the LMOs in question and receive the recipient Contracting Party's agreement in advance.

(b) The AIA procedures shall be initiated by the Exporter by submitting an application to the competent authority of the recipient Contracting party. The application shall be accompanied by information necessary for the AIA procedures.

(2) LMOs Subject to the AIA Procedures

(a) General

(i) All transboundary transfers of LMOs resulting from modern biotechnology, except those mentioned in (b) below, shall be within the scope of the application of the AIA procedures.

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

(iii) LMOs products which do not contain live cells shal also be excluded from the application of the AIA procedures.

(b) Exclusion from the Application of AIA Procedures

(i) The LMOs which are subject to any other international agreement related to transboundary transfer of LMOs shall be excluded from the application of the AIA procedures.

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

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

(3) Exemption from and Simplification of the AIA Procedures

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

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

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

(4) Information to be Provided

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

(b) The competent authorities of the recipient Contracting Party may requiest the Exporter to provide additional relevant information if necessary.

(c) The competent authorities of the exporting Contracting Party shall respond to inquiries from the recipient Contracting Party on the contents and the authenticity of the information provided by the Exporter.

(d) The competent authorities of the Contracting Parties shall not make undisclosed information containing intellectual property rights available to third parties.

(5) Period within which the Competent Authorities to Reply to the Exporter

(a) The competent authorities of the recipient Contracting Party shall inform, in writing, without delay the Exporter of the receipt of the application, including its date.

(b) The competent authorities of the recipient Contracting Party shall reply to the Exporter within [ ] days from the date of receipt of the application. This timing of reply may be extended by any length of time specified by the competent authorities if risk assessment of AIA procedures require additional period, such as for conducting field trials in the recipient Contracting party or obtaining additional relevant information from the Exporter. Once it is decided to extend such timing the competent authorities shall inform the Exporter accordingly.

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

2. Risk Assessment Including Minimum National Standards

(1) General

(a) The Contracting Parties shall establish measures to undertake, within the AIA procedures, risk assessment, which serves as a mechanism providing the basis for the decisions of the competent authorities of the recipient Contracting Party whether to agree to the transboundary transfer of LMOs or not.

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

(2) Responsibility of Risk Assessment

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

(b) The competent authorities of the recipient Contracting Party may request assistance from the Exporter or the competent authorities of the exporting Contracting Party, who should respond to the request to the extent possible. Especially in cases where the competent authorities of the recipient Contracting Party do not have sufficient experiences with the LMOs in question.

(3) Bases for Decision Making on Risk Assessment

The competent authorities of the recipient Contracting Party should conduct risk assessment exclusively on the basis of scientific information provided in the process of the application by the Exporter and other scientific evidence.

3. Risk Management

(No text is necessary because this matter is already dealt with in Paragraph (g) of Article 8 of the Convention.)

4. Unintentional Transboundary Movements (and Emergency, Accidental Cases)

(No text is necessary because emergency procedures are already dealt with in Paragraphs 1(d) and 1(e) of Article 14 of the Convention.)

5. Handling, Transportation, Packaging and Transit Requirements

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

6. Competent Authorities/National Focal Points

(1) General

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

(2) Roles of the National Focal Point and of the Competent Authorities

(a) The national focal point shall perform the following tasks:

- to provide other Contracting Parties, through the Secretariat of the Protocol, with general information on the implementation of the Protocol at the national level including, in particular, information on competent authorities responsible for the AIA procedures and/or for LMOs;
- to collect information on the implementation of the protocol at its national level; and
- to assist communication between foreign, regional or international institutions established for the implementation of the Protocol on the one hand and the national competent authorities on the other.

(b) The competent authorities shall perform the following tasks:

- to establish national guidelines and/or regulations for the implementation of the AIA procedures including detailed criteria for risk assessment within their competence;
- to receive from exporters applications for the AIA procedures;
- to conduct risk assessment;
- to take a decision on result of the risk assessment;
- to inform the exporter with the result of the risk assessment; and
- to conduct, if necessary, additional trials, including field trail.

7. Information sharing

(1) Information to be submitted ot the Secretariat of the Protocol

(a) The Contracting Parties shall provide the Secretariat of the Protocol with the following information:

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

- names, addresses and telecommunication numbers of the national focal point and the competent authorities;
- national guidelines and/or regulations for the implementation of the Protocol, including information required for the AIA procedures and for risk assessment
- if any bilateral, regional and multinational agreements or arrangements as well as unilateral declarations on the exemption and/or the simplification of the AIA procedures.

(ii) Periodical report on the implementation of the AIA procedures, including statistics.

(b) The Secretariat of the Protocol shall circulate the information received pursuant to (1) above to all Contracting Parties.

(2) Information to be Made Available

The Contracting Parties are encouraged to make available to all interested parties, including other Contracting Parties, regional and international institutions as well as individuals information on the implementation of the Protocol, not included in (I) above.

8. Capacity Building

(This matter should not be dealt with in the Protocol.)

9. Public Awareness / Public Participation

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

10. Socio-Economic Consideration

(Socio-Economic conditions vary too much from state to state to be measured by a standardized scale. Therefore, this item should not be dealt with in the Protocol.)

11. Liability and Compensation

(Liability and compensation with respect to the implementation of the Protocol should be dealt with in the context of Paragraph 2 of the Article 14 of the Convention and not in the Protocol.)

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MADAGASCAR

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PROTOCOLE SUR LA PREVENTION DES RISQUES BIOTECHNOLOGIQUES

PROPOSITION D'ARTICLES PAR MADAGASCAR

(à la date du 31 juillet 1997)

1. AUTORITÉ NATIONALE COMPÉTENTE

L'autorité nationale compétente sera un poste gouvernemental désigné officiellement et non une personne. Il n'y aura qu'une seule autorité nationale compétente par pays.

Ce poste devrait se trouver au sein du Ministère (ou à défaut de l'agence) chargé de la coordination des activités nationales en matière de prévention des risques biotechnologiques dans le cadre de la Convention sur la Diversité Biologique.

L'autorité nationale compétente sera l'interlocuteur unique pouvant recevoir les demandes et les notifications émanant des autorités nationales compétentes extérieures. Elle communiquera les décisions sur les Organismes vivants modifiés (O.V.M) et les produits issus des OVM.en accord avec la procédure de consentement préalable en connaissance de cause du Protocole.

La définition des tâches confiées à l'autorité nationale compétente est laissée à l'appréciation de chaque pays.

L'autorité nationale compétente entre en vigueur dès la date de la signature du protocole.

II. ACCORD PRÉALABLE EN CONNAISSANCE DE CAUSE

L'accord préalable en connaissance de cause est un moyen de faire connaître officiellement les OVM et les produits qui devront faire l'objet d'introduction dans un pays déterminé.

L'accord préalable est destiné à lancer un processus de prise de décision concernant l'importation future d'OVM et les produits qui en sont issus. Il a pour objet de promouvoir le partage de responsabilités entre pays exportateur et pays importateur, en ce qui concerne la protection de la santé, de la biodiversité, de l'environnement, du bien être socio-économique contre les effets néfastes des OVM.

Les OVM ou les produits issus des OVM ne peuvent être introduits dans un pays sans l'accord préalable de l'Etat importateur basé sur les différentes informations nécessaires reçues.

L'exportateur devra fournir officiellement à l'autorité compétente du pays importateur les informations concernant les OVM ou les produits issus d'OVM concernés faisant l'objet d'introduction, de transfert, suivant une liste annexée au Protocole (taxonomie, méthode de manipulation, et mode d'utilisation. etc.).

L'autorité nationale compétente de l'État importateur devra fournir à l'autorité nationale compétente du pays exportateur les informations nécessaires relatives aux lois, règlements, procédures légales et administratives existants et appliqués dans le pays.

L'accord préalable peut couvrir les importations sans restrictions et les importations limitées.

III. MOUVEMENTS TRANSFRONTIÊRES ET PROCÉDURES DE NOTIFICATION

La procédure doit être générale, qu'il s'agisse d'une première introduction ou d'une réintroduction d'OVM ou de leurs produits.

L'Etat exportateur doit notifier par écrit toutes les informations concernant tout mouvement transfrontière d'OVM ou des produits qui sont issus.

Le consentement du pays importateur doit être explicite, notifié par écrit dans la langue officielle de ce pays.

Toute notification est adressée à l'exportateur par l'autorité nationale compétente du pays d'importation, qui décide toujours en dernier ressort et qui informe le Centre d'échange de ses décisions.

Le Protocole devra contenir une disposition pour préserver le caractère confidentiel de l'information.

La notification des décisions prises par le pays importateur ou de transit est faite par écrit dans un délai déterminé d'un commun accord entre exportateur et importateur.

Les décisions, concernent soit le consentement pour le transfert avec ou sans condition, soit des demandes d'informations additionnelles soit l'interdiction de transfert.

L'exportateur (organisme public, société, université, centre de recherche ou agent de l'exportateur) opérant dans le pays d'importation, peut présenter une demande de transfert d'OVM. La notification est adressée à l'autorité nationale compétente.

IV. TRAFIC ILLICITE ET POUVOIR DE DESTRUCTION

Le trafic illicite concerne le transfert transfrontière d'OVM ou de produits issus d'OVM, qui n'a pas obtenu de notification ni un accord préalable en connaissance de cause.

Le trafic illicite concerne également tout cas de falsification d'usage de faux, de fraude, ou d'un accord préalable non conforme aux documents soumis, ou enfin de libération intentionnelle contraire au Protocole et aux principes du droit international.

En cas de trafic illicite, le pays d'importation a le droit de détruire les OVM ou les produits issus des OVM, dès l'arrivée dans un de ses territoires douaniers.

Le pays, d'importation appliquera la législation nationale existante qui prévient ou qui punit le trafic illicite et susceptible de s'appliquer au Protocole.

V. EVALUATION ET GESTION DES RISQUES

- **Evaluation des risques**

Le Protouole, qui est un instrument international juridiquement contraignant, devra fixer les principes généraux relatifs à la décision d'importer ou non des OVM et leurs produits, en fonction des risques prévisibles dus à leur introduction leur transfert, leur utilisation et leur libération (intentionnelle ou non).

L'évaluation des risques biotechnologiques dus aux OVM et leurs produits doit se faire selon des méthodes scientifiques et techniques standardisées, mais adaptables à différents cas et suivant plusieurs étapes successives.

L'évaluation des risques porte sur l'identification des effets néfastes possibles des transferts sur la santé humaine et animale, l'environnement, la diversité biologique et le bien être socio-économique.

L'évaluation des risques se fait en fonction des caractéristiques de l'OVM, des modifications génétiques introduites et en prenant en considération la diversité génétique du pays,

Le Protocole devra déterminer les responsabilités respectives de la Partie exportatrice et de la Partie importatrice en matière d'évaluation des risques.

- **Gestion des risques.**

Chaque partie s'assurera que la gestion des risques identifiées soit entreprise de telle façon que ces risques soient évités ou réduits à un degré acceptable (y compris le traitement des déchets issus de l'utilisation d'OVM).

Une période d'observation devra être prévu en rapport avec le cycle de vie de l'OVM ou sa période de reproduction, avant tout emploi prévu.

Des dispositions seront prises pour que la Partie exportatrice puisse apporter un appui à la Partie importatrice afin de lui permettre d'évaluer les risques de façon appropriée et de porter un jugement en connaissance de cause sur l'innocuité de l'OVM.

VI. IMPACTS SOCIO-ÉCONOMIQUES

Les Partie s'accordent sur le fait que les impacts socio-économiques de l'introduction des OVM et de leurs produits soient pris en compte pendant l'évaluation et la gestion des risques. Ces études se feront durant une période d'observations dont la durée est déterminée d'un commun accord entre les Parties, importatrice et exportatrice.

VII. CENTRE D'ÉCHANGE ET ÉCHANGE D'INFORMATIONS

L'échange d'information est distinct de l'obligation de communiquer des renseignements à l'occasion de mouvements transfrontières.

Les informations à communiquer au Centre d'échange concernent la mise en oeuvre du Protocole sur la prévention des risques biotechnologiques.

Ce Centre d'échange sur les risques biotechnologiques fera partie intégrante du Centre d'échange de la Convention sur la diversité biologique.

Le Centre d'échange, en relation avec les banques de données internationales et les Centres des pays Parties, sert d'organisme d'échange d'information, d'appui à l'application du Protocole et de coopération scientifique et technique entre les Parties.

Le Centre d'échange pour la biosécurité assistera les Parties en tant que de besoin, notamment dans les cas suivants:

* préparation et traitement des rapports dévaluation des risques, et d'études d'impacts sur la santé humaine et animale, sur l'environnement, sur la biodiversité, sur le bien être socio-économique, en fournissant des données scientifiques et techniques sur les OVM et sur les risques potentiels dus à leur introduction;
* appui à l'élaboration de texte législatifs réglementaires
* assistance en cas d'accident de situation d'urgence;
* mise en place de programmes et de procédures de gestion des risques;
* élaboration de normes minimales
* élaboration de dossiers avant accord préalable
* règlement des litiges entre les parties

VIII. RENFORCEMENT DES CAPACITÉS

La prévention de risques biotechnologiques constitue un domaine nouveau pour beaucoup de pays, qui nécessite pour eux un renforcement des capacités humaines, institutionnelles et financières.

Le Protocole devra prévoir des dispositions concernant le développement et le renforcement des ressources humaines à différents niveaux : scientifiques, décideurs, personnels d'exécution techniques, de divers organismes politiques, publics et privés.

Le Protocole devra prévoir le développement et le renforcement des institutions nationales en fonction des besoins identifiés par les pays pour les différentes activités notamment pour l'évaluation et la gestion des risques, le contrôle des OVM à l'arrivée, au moment de leur libération, et durant la période d'observation.

Le Secrétariat, en collaboration avec le C'entre d'échange international et les Centres d'échange nationaux, mettra en place des programmes de formation, pour permettre le renforcement des capacités nationales en matière de biosécurité. Il recherchera à cet effet les fonds nécessaires à la mise en oeuvre de ces programmes destinés à permettre une gestion saine des OVM et de leurs produits

La coopération internationale sera sollicitée pour la mise en place du système d'échange d'information, l'élaboration de lignes directrices pour le suivi des activités mise en place en vue d'une gestion saine des risques biotechnologiques.

UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

MALAYSIA

/...

PROTOCOL ON BIOSAFETY - THE GOVERNMENT OF MALAYSIA

Title

Protocol on Biosafety

Preamble

The Preamble should contain the following elements:

a) The reference to Article 19(3) and 19(4) of the Convention on Biological Diversity.

b) The precautionary principle as stipulated under Principle 15 of the Rio Declaration and the Convention on Biological Diversity (CBD) : Where there are threats of serious or irreversible damage/significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.

c) The element of Advance Informed Agreement (AIA) as stipulated under Art. 19(3) of the CBD. AIA means the prior informed consent, with such conditions as appropriate, by the receiving country through the competent authority, of any transfer, handling or use of living modified organisms (LMOs), based on required information that are accurate, complete and current supplied to it under this protocol.

d) Reference to Art 8(g) which speaks about the establishment or maintenance of the means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

e) Recalling the following elements of the Preamble of the CBD :

* that special provision is required to meet the needs of developing countries, including the provision of new and additional financial resources and access to relevant technologies.

* reaffirmation that States have sovereign rights over their own biological resources.

* awareness of the general lack of information and knowledge regarding safety in biotechnology and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures.

Article 1. Objective

The objective of this protocol is to ensure the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effect on the

environment, in particular, the conservation and sustainable use of biological diversity, socio-economic imperatives, and the risks to agriculture and human health.

Article 2. Use of Terms

"advance informed agreement" the prior informed consent and agreement, with such conditions as appropriate, by the receiving country Party, through the national competent authority, regarding any intended transfer, handling or use of LMOs to or within the receiving country Party by the intending country Party, based on required information which is accurate, complete and current supplied by the intending country Party and/or person or entity under the intending country Party's jurisdiction, in advance of the intended activities.

"biosafety" the safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effect on the environment, in particular the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health.

"centres of genetic diversity" the place or region where the source of diversity is located.

"Country of origin of genetic resources" the country which possesses those genetic resources in in-situ conditions.

"competent authority" the competent authority designated by parties to be the national competent authority in respect of the implementation of this protocol.

"contained use" any operation involving organisms which are controlled by physical barriers or a combination of physical and/or chemical and/or biological barriers which limit their contact with, or their impacts on, the potentially receiving environment, which includes humans.

"deliberate release" any release of LMOs that is not a contained use, including any intentional introduction of LMOs into the environment and/or the marketplace.

"living modified organisms" organisms, other than human or human embryo, produced through genetic modification and whose genetic make-up is unlikely to occur in nature, including any genetic material intended for use to produce

	genetically modified organisms, and products derived therefrom, including genetically modified organisms which have been deregulated in any country.
"modern biotechnology"	a set of enabling techniques for bringing about specific man-made changes in the genetic material of organisms.
"risk"	the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences will occur.
"risk assessment"	the measures to estimate what harm might be caused, how likely it would occur and the scale of the estimated damage to the receiving country Party and its environment, in particular the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health.
"risk management"	the strategies and measures to ensure that the transfer, handling and use of LMOs are safe, in accordance with Article 7.
"transfer"	includes the intentional transboundary movement of LMOs and the release of LMOs.
"unintended release"	any release which is not deliberate.
"user"	any person responsible for the development, production, use, handling, testing, marketing, transfer, release or distribution of LMOs but shall not include any member of the general public in the receiving country Party who purchases and/or uses an LMO.

Article 3. National Competent Authorities

1. The Parties shall establish or designate a National Competent Authority (NCA) to serve as the agency to handle any enquiries and proposals for any transfer, handling or use of LMOs pursuant to this protocol.

2. The Parties shall inform the Secretariat within three months of the entry into force of this protocol for them which agency they have designated as their competent authority. If there are any changes regarding the designation made by them under paragraph one above, the Parties shall inform the Secretariat within one month of that decision.

3. The National Competent Authority of each Party shall be the authoritative/decision-making body regarding any intended transfer, handling or use LMOs to or within the receiving country.

4. Each Party shall operate the Advance Informed Agreement procedure under Article 5 through the National Competent Authorities designated or established by every Party.

5. The National Competent Authority of the receiving country Party may impose such conditions and/or national procedures it deems fit regarding the transfer, handling or use of the LMO by the intending Party in order to protect its environment, in particular the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health.

6. The National Competent Authority of the receiving country Party may take into consideration any matter of national interest, including social and ethical matters in carrying out its responsibilities through the National Competent Authority. The National Competent Authority shall in particular be responsible for :

   a) receiving all required information, including the risk assessment supplied by the intending country Party or person or entity under its jurisdiction, through the National Competent Authority, prior to such transfer, handling or use.

   b) receiving prior notification regarding any intended transfer, handling or use to or within the receiving country Party.

   c) making decisions on the transfer, handling or use of the LMO to or within the receiving country.

   d) subject to the receiving country Party's capabilities and capacities, undertaking its own risk assessment and giving its own risk assessment decisions.

Article 4. Exchange of Information

Subject to the national laws, regulations and procedures of each Party, and without prejudice to the obligation to provide information under the AIA procedure under Article 5, the Parties shall facilitate through a clearing-house mechanism and/or national focal points of each Party, the exchange of information, from all publicly available resources, and from existing international agencies, organizations and regional networks, relevant to safety in biotechnology and the transfer, handling or use of LMOs and its impacts thereof, taking into account the special needs of developing countries. In facilitating such exchange of information, patents and other intellectual property rights must be supportive of and must not run counter to this protocol's objective.

Article 5. Advance Informed Agreement

1. Each Party shall apply the Advance Informed Agreement procedure with respect to all living modified organisms defined in Article 2 of this protocol.

2. No transfer, handling or use of LMOs to or within any receiving country Party shall be allowed without the advance informed agreement of the receiving country Party in

accordance with the Advance Informed Agreement procedures defined below.

Notification

1. Any Party who intends to transfer, handle or use any LMO to or within any receiving country Party shall give prior notice to, through its National Competent Authority, the National Competent Authority of the receiving country Party, by application in writing of its intention to do so.

2. Each Party shall ensure that any individual person or entity under its jurisdiction who intends to undertake any transfer, handling or use of LMOs to or within any receiving country Party shall give prior notice to the National Competent of the receiving country Party by application in writing, of its intention to do so. Such notification shall be done through the National Competent Authority exercising jurisdiction over such individual person or entity. However the notification may be made directly to the National Competent Authority of the receiving country Party provided the Party exercising jurisdiction over that individual person or entity ensures, through its national legislation, that all the conditions satisfying the provisions of this protocol are fulfilled, and that such Party shall be responsible and liable for the individual person or entity's actions regarding the or transfer, handling or use of LMOs to or within the receiving country Party.

Information

1. The intending country Party shall ensure that the application above contains the declarations and information stated below :

   a. Name and address of entity or person intending the transfer or export;
   b. Name and address of intended user;

   c. Origin, name and taxanomic status of recepient organism;

   d. Full description of all traits introduced or modified and characteristics of the organism, including prescribed and desired ecological and other parameters;

   e. Purpose of the genetic modification;

   f. The results of the risk assessment carried out by the applicant including a summary of the risks to the environment, in particular the conservation and sustainable use of biological diversity, socio-economic imperatives, and the risks to agriculture and human health, and the risk management measures and strategics applicable in respect of the receiving country Party;

   g. Previous experiences or any results of testing under real conditions, with growing plants, animals and living soil organisms , in different soil types and and under different water conditions, prior to the release of the LMO;

   h. The risk assessment undertaken and the risk management scheme formulated by the applicant and endorsed by the NCA of the applicant, in respect of the

receiving country;

i. Intended dates of transfer, handling or use;

j. Number of organisms to be transferred or volume of culture and physical state;

k. Any relevant requirements to ensure safe handling, storage, subsequent transfer and use of the LMO;

l. Methods for safe disposal and suitable procedures in case of accidents;

m. Intended use of the organism, including possible products derived therefrom, including ecological conditions and socio-economic impacts;

n. Intended location of the release or activity;

o. Relevant previous releases and the impacts on the environment, including socio-economic human health impacts such releases;

p. Information on experimentation, field trials, situation in the region of origin and genetic diversity of the LMO, where applicable;

q. The relevant laws, regulations, procedures or guidelines concerning the safe transfer, handling and use of the LMO in the applicant's country;

r. The use or release of the LMO that has been prohibited, severely restricted or withdrawn in another country or in the applicant's country;

s. Conditions of contained use and waste disposal procedures;

2. The National Competent Authority of the intending country Party shall attest the accuracy of the information stated above.

Responses

1. The Parties hereby agree that the receiving country Party has the right to make its own decisions on the application referred above in any manner it deems fit.

2. No intending country Party shall transfer, handle or use LMOs to or within a receiving country Party without first obtaining the receiving Party's consent. Any Party exercising jurisdiction over an individual person or entity shall ensure that no such person or entity shall transfer, handle or use LMOs to or within the receiving country Party without first obtaining the receiving Party's consent, through the receiving Party's National Competent Authority.

3. Upon receipt of the application by the National Competent Authority of the receiving country party, the receiving country Party shall provide an acknowledgement to the National Competent Authority of the intending country Party within 14 days. Thereafter, the receiving country Party may within ..... working days (the relevant time period) but

subject always to the right of the receiving Party's right at any time to extend the relevant time period for such periods it deems fit :

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

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

c) reject the application, absolutely or provisionally, with or without conditions.

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

5. Notwithstanding paragraph 3 above, the receiving country Party shall be allowed as much time as is necessary to assess the information it has received from the intending countryParty 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.

Review

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

2. 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.

Article 6. Mechanisms for Risk Assessment

Objective

1. The objective of a risk assessment is to provide a basis to enable the receiving country Party to evaluate possible risk or likelihood of it occurring in the receiving country Party and its environment, as a result of the transfer, handling or use of the LMOs by the intending country party, in particular, to the conservation and sustainable use of biological diversity, socio-economic imperatives, and the risks to agriculture and human health.

Submission of Risk Assessment

1. Each Party who intends to undertake a transfer, handling or use of LMOs to or within the

receving Party shall ensure that a risk assessment report is prepared by it and submitted to the National Competent Authority of the receiving country Party.

2. Each Party shall ensure that any individual person or entity under its jurisdiction who intends to undertake a transfer, handling or use of any LMO to any receiving country, shall prepare a risk assessment is that such risk assessment is submitted to the National Competent Authority of the receiving Party. Such Party shall also ensure through its national laws that such individual person or entity submits the risk assessment through the intending Party's National Competent Authority. For the avoidance of doubt, the intending country Party shall also be reponsible over the risk assessment prepared by the individual person or entity under its jurisdiction.

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

4. The risk assessment shall be submitted prior to the transfer, handling or use of the LMO and shall be submitted together with the notification under the AIA procedure defined above.

Parameters of Risk Assessment

1. The risk assessment must be relevant to the environment of the receiving country.

2. It should cover expected probabilities of events occurring and the magnitude of their effects.

3. Risk assessment should not only be based solely on scientific data that would take into account the characteristics of the LMO and its possible adverse effect on the environment, but also other data to address its possible impacts on the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health.

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

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

6. The key parameters of the risk assessment are further defined in detail in Annex....

The Receiving Country Party

1. The risk assessment shall not be the only basis upon which the receiving country Party can make decisions on the proposed transfer, handling and use of LMOs.

2. The receiving country Party shall take into account other factors including without

limitation, social, socio-economic and ethical considerations, in making decisions regarding such transfer, handling or use.

3. Subject to the capacity and capability of the receiving country Party to do so, after considering the risk assessment, the receiving country Party may make its own risk assessment decisions on such transfer, handling or use of LMOs.

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

Article 7. Risk Management

1. For the avoidance of doubt, Article 8(g) of the Convention on Biological Diversity shall not preclude the obligation under this Article to formulate appropriate risk management strategies and measures as stated below.

2. The Party intending to undertake any transfer, handling or use of LMOs to or within the receiving country shall formulate appropriate risk management measures and strategies that may be implemented in the receiving country Party for the management of risks and harm associated with the transfer, handling and use of the LMO and the protection and mitigation of potential harm to the receiving country party, and incorporate such measures and strategies with the risk assessment under Article 6 above.

3. The intending country Party shall ensure that any individual person or entity under its jurisdiction who intends to undertake the transfer, handling or use of any LMO to or within the receiving country shall formulate appropriate risk management measures and strategies that may be implemented in the receiving Party for the management of risks and harm associated with the transfer, handling and use of the LMO and the protection and mitigation of potential harm to the receiving country Party and incorporate such measures and strategies in the risk assessment under Article 6 above.

4. The type of risk management to be employed shall depend on the LMOs and the activity in question and such risk management strategies and measures shall be commensurate with the risk assessment.

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

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

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

Article 10. Illegal Traffic/Unauthorized Transfer

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

   a) without notification pursuant to the provisions of this protocol to Parties under this protocol; or

   b) without the advance informed agreement pursuant to the provisions of this protocol of any Party concerned; or

   c) with advance informed agreement obtained from Parties concerned through falsification, misrepresentation or fraud ; or

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

   e) that results in deliberate transfer, release, handling or use of LMOs in contravention of this protocol and of general principles of international law,

   shall be deemed to be illegal traffic/unauthorized transfers.

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

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

Article 11. Handling, Transport, Packaging and Transit Requirements for LMOs

1. The intending country Party shall require that LMOs that are to be subject of a handling, transfer or use be packaged, labelled and transported in conformity with generally accepted and recognised international rules and standards in the field of packaging, labelling and transport, and that due account is take of relevant internationally recognised practices.

2. The intending country Party shall, where appropriate, take further precautionary measures when packaging and transporting any LMO to ensure that any risks or harm to other Parties, particularly to the receiving country, is prevented, mitigated or minimised.

3. The receiving Party shall have the right to impose such terms and conditions on the packaging, labelling and transportation of the LMO to or within the receiving country,

for the protection of its environment, in particular the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health and taking into account also such social and ethical matters it deems fit for national interest purposes .

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

Article 12. Capacity-building

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

2. The developed country Parties shall transfer relevant know-how on fair and most favourable terms including on concessional and preferential terms, in biotechnology and biosafety to developing country Parties.

3. The developed country Parties shall develop such appropriate facilities, training in science related to safety in biotechnology and in the use of risk assessment and risk management techniques for the benefit of developing country Parties and to assist developing country Parties to make their own risk assessment decisions.

4. The developed country Parties shall establish such measures to enhance the capacity of developing country Parties to acquire and/or develop relevant biotechnology, and its proper and safe management, and the building up of their local, technological and institutional competence, thereby contributing to the distribution of benefits from the potentials of biotechnology.

Article 13. Centres of Origin and Genetic Diversity

An abundance of biological diversity resides in developing countries, which are often also the centres of origin and genetic diversity. In view of the paucity of knowledge and experience in the behaviour of LMOs in their centres of origin and genetic diversity, a separate section dedicated to the release of LMOs into their centres of origin and genetic diversity is warranted. The release of LMOs into their centres of origin and genetic diversity could result in an increased likelihood of gene flow from these LMOs to their wild relatives as well as the loss of genetic diversity of these organisms in these regions. It is therefore imperative that more stringent risk assessment and risk management measures are imposed. The party intending to release LMOs into their centres of origin

and genetic diversity should undertake to financially and technically assist the receiving country Party towards the conservation of the wild relatives of these LMOs.

Article 14. Social and Ethical Considerations

The risk assessment and risk management scheme provided by the intending country Party under Articles 6 and 7 may not be the only factors that a receiving country Party may take into account in coming to a decision, on the transfer, handling or use of LMOs to or within the receiving country Party. If and when considered appropriate by the receiving country, consideration should be given to the social and ethical aspects and sensitivities of the culture and religion prevailing in such countries. If a receiving country Party exercises its right to take into account social and ethical considerations in making its decisions, the other Party cannot appeal if the receiving country decides to prohibit the transfer, handling or use of the LMO, whether absolutely or conditionally to or within the receiving country Party.

Article 15. Participation in Biotechnology Research Activities

Measures should be undertaken to provide for developing country Parties that provide genetic resources, to participate in biotechnology reasearch undertaken in respect of the genetic resources and for the promotion and advance priority access to the results and equitable sharing of benefits arising from biotechnologies based upon genetic resources provided by those countries.

Article 16. Liability and Compensation

The following issues be addressed at the next meeting in the context of liability and compensation :

- Illegal transport and damages resulting from such actions
- Harm to a third party resulting from intentional/unintentional movement /transfer and options for protection or redress
- Unintentional movement/unintended harm and options for redress/compensation
- Duration of liability
- Time limit for compensation
- Civil and/or State liability
- Liability and responsibility with regard to emergency procedures

Article 17. Monitoring and Compliance

Monitoring and compliance should be seen in two perspectives :

f) General monitoring and compliance of the implementation of the commitments under the protocol.

g) Monitoring of the specific cases of transfers, handling and use of LMOs.

General Monitoring

Individual Parties should report on the general implementation of their commitments, subject to their respective capacities and capabilities of countries, especially developing countries. The reports could be processed through the Conference of Parties to the protocol.

The provisions of the protocol will be sufficiently normative in character to justify establishing a procedure for reviewing the implementation of commitments by individual parties. It should therefore establish its own procedures for review of implementation of commitments and that being so, procedures under other international instruments should not apply. The procedure should be co-operative and conciliatory, advisory and transparent. The process should be such that it prevents disputes; it should encourage friendly settlement of disputes and could serve as practical guidance to Parties in difficulty. The report should, inter alia, incorporate the operation and compliance by parties of the AIA and notification procedures.

The Convention on Biological Diversity established its own procedures for review of implementation of commitments and compliance aspects in the form of reports (Article 26) and the settlement of disputes mechanism (Article 27). The protocol being an international instrument that could legally stand on its own is not prohibited from establishing its own procedures to ensure compliance of commitments under the protocol.

There is a need to address the relationship between this procedure for review of implementation commitments and the possible review system established under the AIA procedure in Article 5.

Specific Cases

The monitoring of risks on specific transfers, releases, handling and use must also be built into this mechanism. This is especially in light of new information or scientific findings which may surface at any stage after approval, particularly where the LMO has already been transferred or released to or within the receiving country or is already being handled or used within the receiving country. The Party or person or entity under its jurisdiction is under the continuous duty to supply relevant information or new scientific findings to the receiving Party and is not absolved from this responsibility after the relevant approval had been given.

The receiving country should be informed immediately in the event of any risks that had not been known before regarding the transfer, release, handling or use of the LMO.

Monitoring can also be carried by the receiving Party and is often used to verify assumptions made in a risk assessment and should be used to evaluate whether the risk-management strategies and measures proposed are appropriate and effective.

Article 18. Biosafety Information Network

1. Parties shall endeavour to co-operate with existing international agencies, organizations, mechanisms and regional networks for the dissemination of biosafety-related information and standards applicable in other countries, including those about national biosafety mechanisms, and approvals given for the transfer, handling and use of LMOs in other countries and for the marketing of products containing LMOs and such other relevant information under Article 4.

Article 19. Public Awareness, Education and Participation

1. Subject to relevant national legislation, Parties shall endeavour, and shall procure the industry and researchers in this regard, to disclose or make available information on biotechnology, safety in biotechnology and the results and impacts of any releases or use of any LMO thereof to the public. Acceptance of biotechnology products will be enhanced if the information is disclosed, in particular to the community where any transfer, handling, release or use will occur.

2. Parties shall promote and facilitate, in accordance with national legislation and within their respective capacities, the development and implementation of educational, both formal and informal, and public awareness programmes on biosafety.

Article 20. Financial Mechanism

The protocol shall establish a fund for the purposes of providing financial resources to the developing country Parties in the implementation the provisions of the protocol, and in particular to implement capacity-building measures for the benefit of developing countries and for meeting contingencies in relation to biosafety.

Other Clauses

Settlement of Disputes
Relationship With Other International Agreements
Amendment
Signature
Accession
Right to Vote
Entry into Force

UNEP

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CONVENTION ON
BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING
GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

MEXICO

/...

PROYECTO DE PROTOCOLO SOBRE BIOSEGURIDAD EN EL MARCO DEL CONVENIO SOBRE LA DIVERSIDAD BIOLOGICA

PROPUESTA DE MEXICO

PREÁMBULO

Reafirmando los principios de la Declaración de Río sobre el Medio Ambiente y el Desarrollo de 1992, de la Organización de Naciones Unidas,

Reafirmando asimismo el Principio 12 de la Declaración de Río sobre Medio Ambiente y Desarrollo,

Reafirmando la cooperación internacional que debe existir para el tratamiento de los problemas ambientales,

Subrayando la importancia que tiene el respeto a los intereses de todos y proteger el medio ambiente, la conservación y uso sostenible de la biodiversidad, así como la salud humana,

Las partes convienen en el siguiente Protocolo sobre Bioseguridad en el marco del Convenio sobre la Diversidad Biológica, bajo los siguientes artículos,

ARTÍCULO 1.
PRINCIPIOS

1.1 Las Partes reafirman y se comprometen a observar todos los Principios establecidos en la Declaración de Río de Janeiro de 1992, y en particular, los siguientes:

Principio 13. Los Estados deberán desarrollar la legislación nacional relativa a la responsabilidad y la indemnización respecto de las víctimas de la contaminación y otros daños ambientales. Los Estados deberán cooperar asimismo, de manera expedita y más decidida en la elaboración de nuevas leyes internacionales sobre responsabilidad e indemnización por los efectos adversos de los daños ambientales, causados por las actividades realizadas dentro de su jurisdicción o bajo su control, o en zonas situadas fuera de su jurisdicción.

Principio 15. Con el fin de proteger el medio ambiente, los Estados deberán aplicar ampliamente el criterio de precaución conforme a sus capacidades. Cuando haya peligro de daño grave o irreversible, la falta de certeza científica absoluta no deberá utilizarse como razón para postergar la adopción de medidas eficaces en función de los costos para impedir la degradación del medio ambiente.

1.2 Además de los principios de la Declaración de Río las partes deberán observar, en particular, los artículos 3°, 8° g, 14° y 19° del Convenio sobre la Diversidad Biológica.

ARTÍCULO 2.
OBJETIVO

El objetivo del presente Protocolo es establecer los procedimientos adecuados, incluido en particular el consentimiento fundamentado previo, en la esfera de transferencia, manipulación y utilización de cualesquiera organismos vivos manipulados (OVMs) resultantes de la biotecnología.

ARTÍCULO 3.
USO DE TÉRMINOS Y DEFINICIONES

Se propone aquí un listado de términos que deberán definirse posteriormente

Biotecnología (definición de la CDB)
Manipulación Genética
Movimiento transfronterizo
Organismos vivos manipulados (OVMs)
Autoridad competente
Impacto adverso
Medidas de mitigación
Monitoreo
Impacto ambiental transfronterizo
Daño (en la salud humana, socioeconómico, a la biodiversidad, en el medio ambiente, etc.)
Compensación (económico-financiera, restitución, etc.)
Tránsito
País/Estado de tránsito

ARTÍCULO 4.
AMBITO DE APLICACION DEL PROTOCOLO

El protocolo se aplicará *inter alia* al movimiento transfronterizo, manejo y utilización de los OVM's obtenidos por técnicas de biotecnología.

ARTÍCULO 5.
DESIGNACIÓN DEL PUNTO FOCAL

Cada Parte designará a una oficina nacional, que será responsable de las acciones administrativas que este Protocolo requiera y que deberá contar con el apoyo gubernamental. Al momento de la ratificación del presente Protocolo se deberá notificar el nombre del Punto Focal.

ARTÍCULO 6.
PROCEDIMIENTO DE CONSENTIMIENTO FUNDAMENTADO PREVIO PARA EL MOVIMIENTO TRANSFRONTERIZO, MANEJO Y UTILIZACIÓN DE OVMs.

6.1 Para realizar un un movimiento transfronterizo, la parte exportadora deberá someter, ante la autoridad competente del país importador y antes de realizar el embarque del producto, una solicitud en el formato oficial utilizado por el país importador, con toda la información requerida por la Autoridad Competente y de acuerdo con la legislación nacional vigente en el país importador.

6.2 La Parte que efectúa la exportación deberá obtener los permisos necesarios de los países Parte o no Parte por los cuales deban de transitar los OMVs, así como asumir la responsabilidad en caso de liberación accidental en esos países.

6.3 Deberá darse una de las respuestas siguientes:

a. Consentimiento explícito para el movimiento transfronterizo.
b. Consentimiento condicionado a la importación con ciertas medidas de bioseguridad que señale la Autoridad Competente.
c. Respuesta intermedia que permita, ya sea dar un mayor plazo a los comités evaluadores para dar una respuesta apropiada, o bien solicitar a la parte exportadora mayor información y/o datos experimentales y de la prohibición.
d. Prohibición del movimiento transfronterizo.

6.4 No se podrá realizar el movimiento transfronterizo sino hasta obtener la respuesta oficial.

6.5 La respuesta oficial positiva deberá ser acompañada de la información sobre las reglamentaciones y normas que indiquen a la parte exportadora, paso a paso, los requisitos para la importación, así como la base de la decisión tomada. Si no hay una respuesta explícita significa que la importación está prohibida.

6.6 La parte exportadora deberá someter una nueva solicitud para importaciones subsecuentes aun cuando la Autoridad Competente haya dado una autorización positiva a la importación de un OVM específico.

6.7 Las reglamentaciones aplicadas a las importaciones deberán ser idénticas a las aplicadas a los OVMs producidos nacionalmente.

ARTÍCULO 7.
EVALUACIÓN Y MANEJO DE RIESGOS

Las decisiones tomadas por la autoridad competente con respecto a una solicitud de entrada al país de un OVM incluidas sus partes, productos, subproductos y sus derivados que pudieran tener efectos adversos sobre la conservación y el uso sostenible de la biodiversidad, o sobre la salud humana, deberán estar basadas en los principios científicos, en las características del OVM en cuestión, en las características de la aplicación propuesta, así como las características particulares del medio ambiente receptor. Deberá hacerse especial énfasis en los países de alta diversidad biológica, que sean centro de origen y/o presenten un alto grado de endemismos.

ARTÍCULO 8.
RESPONSABILIDAD Y COMPENSACIÓN CIVIL

El exportador será responsable y deberá compensar íntegramente por cualquier daño que se derive del movimiento transfronterizo de OVMs conforme a las disposiciones del presente Protocolo.

ARTÍCULO 9.
MOVIMIENTO TRANSFRONTERIZO ILÍCITO DE OVMs

En caso de daño como resultado de tráfico ilícito de OVMs, dará origen a la responsabilidad y compensación. No existirá ningún tipo de exoneración.

ARTÍCULO 10.
MOVIMIENTO TRANSFRONTERIZO NO INTENCIONAL DE OVMs

En caso de un movimiento no intencional de OVMs, se resolverá conforme a las reglas de la responsabilidad internacional del Estado por daños al medio ambiente de otros Estados o a cualquier zona situada fuera de toda jurisdicción nacional.

ARTÍCULO 11.
REQUISITOS DE TRANSPORTE Y EMPAQUE DE OVMs

Los movimientos transfronterizos de OVMs deberán realizarse de conformidad con y en cumplimiento de las leyes nacionales y los procedimientos administrativos del país receptor y/o el de tránsito. Se promoverá el desarrollo de métodos y procedimientos básicos internacionales, de empaque y transportación de OVMs, tomando asimismo en consideración las necesidades de los países en desarrollo y los de las economías en transición.

ARTÍCULO 12.
INTERCAMBIO DE INFORMACIÓN

Las partes contratantes facilitarán, a través del Mecanismo de Facilitación (Clearing House Mechanism) el intercambio de información de las fuentes públicamente disponibles incluyendo el intercambio de resultados de las investigaciones técnicas, científicas, ambientales y legales necesarias para implementar este protocolo así como las legislaciones nacionales, los reglamentos y normas a seguir por los países importadores, teniendo en cuenta las necesidades especiales de los países en desarrollo y de los países con economías en transición.

ARTÍCULO 13.
CONFIDENCIALIDAD

Las partes mantendrán en la medida de lo posible y según proceda, durante las evaluaciones y el manejo de riesgos la confidencialidad de la información protegida por secretos industriales con la debida atención hacia la conservación y uso sostenible de la biodiversidad, así como hacia los posibles efectos adversos sobre la salud humana.

ARTÍCULO 14.
CREACIÓN DE CAPACIDAD TÉCNICA Y JURÍDICA

Las partes promoverán programas de entrenamiento, cooperación e intercambio técnico y científico para el manejo adecuado de los OVMs, así como la cooperación necesaria para la elaboración de las leyes nacionales, para lograr que los países, en particular los países en desarrollo con alta diversidad biológica, que sean centro de origen y/o presenten un alto grado de endemismos, alcancen los objetivos de este Protocolo. Asimismo, promoverán la cooperación internacional y la creación de mecanismos financieros para obtener recursos nuevos y

adicionales, que hagan posible la realización de programas de cooperación incluyendo el desarrollo de personal debidamente capacitado.

ARTÍCULO 15.
ELABORACIÓN DE LEYES NACIONALES

Las partes deberán elaborar leyes nacionales para regular la transferencia, manipulación y utilización de cualesquiera OVMs resultantes de la biotecnología.

ARTÍCULO 16.
INFORMES

16.1 Las partes presentarán a la Instancia que funja como Secretaría del Protocolo, con la periodicidad que la Conferencia de las Partes decida, los informes sobre las medidas que se hayan adoptado para la aplicación de las disposiciones del presente Protocolo y sobre la eficacia de esas medidas para el logro de sus objetivos.

16.2 Los informes deberán incluir referencias a las medidas adoptadas en caso de impactos adversos así como a las acciones de mitigación que se hayan tomado.

16.3 La Secretaría pondrá a disposición de las Partes dicha información.

ARTÍCULO 17.
PERCEPCIÓN Y PARTICIPACIÓN PÚBLICAS

17.1 Las Partes tomarán las medidas adecuadas para asegurar que el público tenga acceso apropiado a la información relativa a la instrumentación de este Protocolo, respetando la información comercial confidencial.

17.2 Las Partes promoverán y facilitarán, de acuerdo a su legislación nacional y a sus respectivas capacidades, el desarrollo de programas educativos de sensibilización pública sobre seguridad en Biotecnología.

ARTÍCULO 18.
MOVIMIENTO TRANSFRONTERIZO DE ESTADOS NO PARTE HACIA ESTADOS PARTE DEL PROTOCOLO

De conformidad con la legislación nacional de cada Parte Contratante se regulará cualquier movimiento transfronterizo de OVMs sus partes, productos, subproductos y derivados resultantes de la biotecnología, provenientes de la jurisdicción de Estados no Partes.

ARTÍCULO 19.
SOLUCIÓN DE CONTROVERSIAS

La solución de controversias se realizará de acuerdo a lo dispuesto en el Artículo 27 del Convenio sobre la Diversidad Biológica.

ARTÍCULO 20.
RELACION CON OTROS CONVENIOS INTERNACIONALES

Las disposiciones de este Protocolo no afectarán los derechos y obligaciones de toda Parte Contratante derivados de cualquier acuerdo internacional, excepto cuando el ejercicio de esos derechos y el cumplimiento de esas obligaciones pueda causar graves daños a la diversidad biológica o ponerla en peligro

ARTÍCULO 21.
RELACIÓN CON EL CONVENIO SOBRE LA DIVERSIDAD BIOLÓGICA

El Presente Protocolo estará subordinado a las disposiciones del Convenio sobre la Diversidad Biológica.

ARTÍCULO 22.
ADOPCIÓN, ENMIENDAS Y ENTRADA EN VIGOR DE ANEXOS AL PROTOCOLO

ARTÍCULO 23.
DERECHO DE VOTO

ARTÍCULO 24.
FIRMA

ARTÍCULO 25.
RATIFICACIÓN, ACEPTACIÓN, APROBACIÓN O ADHESIÓN

ARTÍCULO 26.
ENTRADA EN VIGOR Y APLICACIÓN PROVISIONAL

ARTÍCULO 27.
RESERVAS

No se permite hacer reservas a este protocolo.

ARTÍCULO 28.
DENUNCIA

ARTÍCULO 29.
DEPOSITARIO

ARTÍCULO 30.
TEXTOS AUTÉNTICOS

Los textos árabe, chino, español, francés, inglés y ruso del presente convenio son igualmente válidos.

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CONVENTION ON BIOLOGICAL DIVERSITY

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NORWAY

/...

SUBMISSION BY NORWAY TO THE SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY - LEGAL TEXTS ON ELEMENTS IDENTIFIED BY BSWG2

Designation of Competent Authority/ies and Focal Point

To ensure an effective functioning of this Protocol, each Party shall:

1. Designate or establish one or more competent authority(ies) and one focal point.

The competent authority/ies shall be responsible for procedures related to Advance Informed Agreement (AIA), notification and information exchange. The competent authority in the State of import shall also be responsible for procedures related to risk assessment and risk management.

The focal point, which preferably shall be identical to the competent authority/ies, shall function as the contact point for the Protocol. The focal point shall be responsible for receiving and submitting information provided for in Articles xx.

2. Inform the Secretariat as soon as possible and no later than the date of the entry into force of the Protocol for the Party in question, which agencies have been designated as its focal point/competent authority(ies). Each Party shall within one month of the date of decision, inform the Secretariat of any changes regarding the designation made by it.

3. The Secretariat shall forthwith inform the Parties of notifications received under paragraph 2. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1 and 2 above for inclusion in the Database provided for in Article xx on information exchange.

Risk assessment

1. Each Party shall require any natural or legal person under its jurisdiction to submit an application to the competent authority for approval before undertaking a release into the environment. Parties shall undertake measures for contained use in accordance with Annex IV (to be developed).

2. Each Party shall carry out, or shall require any natural or legal person under its jurisdiction providing an LMO to carry out, a risk assessment in accordance with the provisions of Annex I before any release of an LMO into the environment. The aim of the risk assessment is to evaluate possible adverse effects on human health or conservation and sustainable use of biological diversity.

3. The State of export shall provide or shall require the exporter to provide, the State of import, information on the risk assessment as required by Annex I, and other relevant information, in order for the State of import to conduct its own risk assessment. The State of import shall in its assessment particularly take into account the characteristics of the receiving environment.

4. The risk assessment shal take due account of possible effects to the environment of neighboring states or effects to the environment outside national jurisdictions or to global commons.

Risk management

1. The Parties shall base their risk management decisions on a risk assessment as appropriate to the LMO in question. Examples of appropriate risk management measures to be applied are contained in Annex II.

2. The Parties shall aim at phasing out, or shall require the producers to phase out, antibiotic resistence marker genes in living modified organisms by the year 2002.

Advance Informed Agreement Procedure

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

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

3. The State of import shall promptly acknowledge to the exporter the date of receipt of the notification. The competent authority in the State of import shall be obliged to respond to the State of export within 90 days after the date of acknowledging the receipt of the notification.

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

(a) consenting to the intended movement with or without conditions;
(b) deny 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.

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

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

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

Simple notification with regard to subsequent imports of living modified organisms

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

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

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

Confidentiality of data

Parties receiving notifications and information regarding intentional transboundary movements shall take account of the need to protect intellectual proprietary rights and confidentiality of data received. The notifier may indicate the information in the notification, the disclosure of which might harm his competitive position, that shall therefore be treated as confidential. The data referred to in Annex III shall, however, not be regarded as confidential.

Transit requirements

1. The State of export shall require the exporter to notify either through the channel of the competent authority in the State of export, or by providing a copy to this authority, the State of transit of the first intended transit movement of a specific LMO for a specified use or puspose. In these cases, the State of export shall supply the information included in Annex III to the State of transit. The State of transit shall promptly acknowledge the receipt of the notification to the notifier. It may subsequently respond to the notifier in writing, within 30 days:
(a) consenting to the transit movement with or without conditions;
(b) denying permission for the movement, or
(c) provide an interim response, that may contain a statement to import with or without specified conditions or prohibiting import during the interim period. This may include a statement that a final decision is under consideration and/or a request for further information and/or extended period of time to respond.

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

Unintentional transboundary movements

1. The Parties shall apply Article 14(1) of the Convention.

2. In the case that an unintentional transboundary movement of LMOs is likely to have adverse effects on the conservation and sustainable use of biological diversity or human health, the Party from which the unintentional movement originates, shall immediately provide any affected Party/ies with all information relating to the unintentional transboundary movement. This information shall include:
(a) circumstances of the unintentional movement;
(b) the identity and quantities released;
(c) an assessment of the risks to the conservation and sustainable use of biological diversity and/or human health;
(d) emergency measures taken or needed to be taken;
(e) any available information regarding the handling of the organisms and related risk management measures to be applied.

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

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

5. The affected Party(ies) may ask for consultations between the concerned states.

Minimum national regulations for biosafety

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

2. The national regulations shall as a minimum fulfil the requirements set out in this Protocol with regard to the safe transfer, handling and use of LMOs.

Capacity-building

Each Party shall strengthen and/or develop human resources and institutional capacities in order to facilitate an effective implementation of this Protocol. Such measures shall aim to ensure:
- that Parties develop and strengthen their capacities to implement this protocol
- the development of national legislation related to safe transfer, handling and use of LMOs
- the development of procedures for risk assessment and risk management of LMOs.

Information exchange

1. A Database for information exchange shall be established and administered by the Secretariat. Without prejudice to the provisions in this Protocol concerning confidentiality of data, the Database shall contain and provide access to information relevant for the implementation of this Protocol.

2. Each Party shall provide information to the Secretariat for inclusion in the Database of:
- designated competent authority/ies and focal point
- information about national legislation for the implementation of the Protocol
- decisions made under the AIA procedure and related risk assessments
- declarations on simple notifications with regard to subsequent movements of LMOs
- information on research and cooperation in biotechnology
- the amount of LMOs exported, category, characteristics, states of import etc.
- information on accidental/unintended movements
- any other relevant information

3. This information shall be accessible to the public.

Packaging, labelling and transport requirements

1. Each Party shall:

(a) ensure that LMOs exported from their territories are subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export.
(b) require that living modified organisms be accompanied by a movement document from the point at which the transfer commences to the point of use.
(c) ensure that all LMOs to be exported are clearly labelled as such.
The labelling shall inform that the movement contains a living modified organism. The labelling shall also inform about the type of living modified organism and the names and addresses of the exporter and importer.

2. Ensure that LMOs to be exported are packaged and transported in accordance with international rules and standards in the field of packaging and transport, particularly in accordance with the UN Recommendations on Transport of Dangerous Goods. The Parties shall aim at developing standards with regard to packaging and transport practices under the Protocol.

Public awareness and participation

1. The Parties shall ensure that adequate information on the safe transfer, handling and use of LMOs is provided to the public in accordance with Article 13 of the Convention.

2. The Parties shall apply Article 14(1) of the Convention with regard to public participation.

Consultations on Liability

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

Annex I

Elements to consider in a risk assessment

INFORMATION RELATING TO THE LMO:

Characteristics of the organism from which the LMO is derived:

The relevant biological, physiological and genetic and environmental characteristics of the recipient/parental/host organism include, as appropriate:

- ### the name and identity of the organism;
- ### Pathogenicity, toxicity and allergenicity (in the case of micro-organisms, it should be noted that there are internationally accepted classification lists for human pathogens. Similar lists exist at national level for plant and animal pathogens in some countries);
- ### the natural habitat and the geographic origin of the organism, its distribution and its role in the environment;
- ### mechanisms by which the organism survives, multiplies and disseminates in the environment;
- ### means for transfer of genetic material to other organisms.

Characteristics of the organism(s) from which nucleic acids are obtained (the donor):

The relevant characteristics include, in particular, pathogenicity, toxicity and allergenicity.

Characteristics of the vector:

- ### identity, origin, natural habitat, and the relevant safety characteristics of the vector;
- ### the frequency at which the vector is mobilized or can transfer itself to other organisms;
- ### factors which would influence the ability of the vector to become established in other hosts.

Characteristics of the inserted (the insert) or deleted nucleic acid:

- ### functions coded by the inserted or deleted nucleic acid, including any residual vector;
- ### information on the expression of the inserted or deleted nucleic acid and the activity of the gene product(s).

Characteristics of the LMO:

The LMO should be compared with the organism from which it is derived, examining, where relevant the following points:

- ### pathogenecity, toxicity and allergenicity to humans and other organisms (in the case of micro-organisms it should be noted that there are internationally accepted classification lists for human pathogens. Similar lists exist at national level for plant and animal pathogens in some countries);

survival, persistence, competitive abilities and dissemination in the environment or other relevant interactions;
capacity to transfer genetic material and the ways in which this might occur;
methods for detecting the organism in the environment and for detecting the transfer of the donated nucleic acid;
functions which might affect its ecological range;
characterization of the product(s) of the inserted gene(s) and, where appropriate, the stability of the modification.

INFORMATION RELATING TO THE INTENDED USE

The amount of information required will vary with the characteristics of the organism and the intended use, frequency and the scale of the use. In the context of biosafety it is also relevant to compere the intended use of the LMO with traditional use of similar not modified organisms to detect whether new use, in new geographical or climatic regions, changed farming, forestry or aquaculture practice etc. will have any possible effect on biodiversity.

For contained uses, this shall include:

number or volume of organisms to be used;
scale of the operation;
proposed containment measures, including verification of their functioning;
training and supervision of personnel carrying out the work;
plans for waste management;
plans for safety of the health of personnel;
plans for handling accidents and unexpected events;
relevant information from previous uses.

For deliberate releases, this shall include:

purpose and scale of the release;
geographical description and location of the release;
proximity to residences and human activities;
method and frequency of release;
training and supervision of personnel carrying out the work;
likelihood of transboundary movement;
time and duration of the release;
expected environmental conditions during the release;
proposed risk-management measures including verification of their functioning;
subsequent treatment of the site and plans for waste management;
plans for handling accidents and unexpected events/disasters;
relevant information from any previous releases.

- new or changed use or practice compared to similar not modified organisms;
- long-term and secondary effects on conservation and sustainable use of biological diversity or human health

CHARACTERISTICS OF THE POTENTIAL RECEIVING ENVIRONMENT

The potential for an organism to cause harm is related to the environments into which it may be released, its interaction with other organisms and its intended or unintended use. Relevant information shall include.

- ### the geographical location of the site, the identity and any special features of the receiving environments that expose them to damage;
- ### the proximity of the site to humans and to significant biota;
- ### 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;
- ### the potential of any organism in the potential receiving environment to receive genes from the released organism.

Annex II

Examples of risk management measures for releases of LMOs

General precautions

- Appropriate information and training is provided for those involved in handling the organisms;
- Monitoring procedures are applied in such a way that appropriate measures can be taken in case of unexpected effects during or after the release;
- The dissemination of the released organisms and/or gene flow from the released organisms are controlled;
- Controlling access to the release site.

For plants

- Applying reproducvtive isolation, by:
  - spatial separation;
  - temporal separation: use of plants that will flower either earlier or later than plants of nearby reproductively compatible species;
  - biological prevention of flowering (e.g. by omitting vernalisation);
  - removal of the male or female reproductive structures;
  - bagging of flowers
  - making use of sterility.
- Controlling the persistence or reproductive structures structures such as propagules or seeds.
- Destroying volunteer plants after harvest; control of volunteers nay be necessary during longer periods, depending on the species.

For animals

- Confining by appropriate means such as fences, filters, islands, ponds;
- Applying reproductive isolation by using sterile animals;

- Isolation from feral animals of the same species.

- Controlling the persistence or dispersal of reproductive structures such as larvae or eggs.

For micro-organisms

- Using organisms with impaired ability to grow or persist in the environment;

- Minimizing gene transfer by:

  - Using organisms that do not contain known self-transmissible mobilizable or transposable genetic elements;

  - ensuring that introduced traits are stably located on the chromosome.

These measures will often not be applicable once an LMO, such as a modified crop plant, is a result of testing during research and development, it has been shown that the risks are acceptable low.

Annex III

Information to be supplied by the State of export under the Advance Informed Agreement Procedure

- name and address of exporting company/institution
- name and address of receiving company/institution
- origin, name and taxonomic status of recipient organism
- description of all traits introduced or modified and characteristics of the organism
- purpose of the genetic modification
- the risk assessment carried out by the exporter on possible adverse effects on human health and the conservation and sustainable use of biological diversity, including as far as possible the conditions in the State of import. Taking particularly into account releases in centres of origin for the LMO, the State of export shall also evaluate whether the LMO in question may establish viable populations or may hydridise with local species in the receiving environment.
- intended dates of transfer
- number of organisms to be transferred or volume or culture and physical state
- any relevant requirements to ensure safe handling, storage, subsequent transport and use
- intended dates of transfer/movement/release/activity
- methods for safe disposal and contingency plans in case of accidents/unintended movements
- intended use of the organism
- information on experiences with previous releases and the impacts on conservation and sustainable use of biological diversity human health of such releases
- intended labelling of the LMO

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OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

PERU

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PROPUESTA PERUANA PARA EL DESARROLLO Y ELABORACIÓN DE UN PROTOCOLO DE BIOSEGURIDAD DE CONFORMIDAD CON LA DECISIÓN II / 5 DE LA CONFERENCIA DE LAS PARTES DEL CONVENIO SOBRE LA DIVERSIDAD BIOLÓGICA

AUTORIDAD(ES) COMPETENTE(S)

La Autoridad(es) Competente(s) será(n) designada(s) por el Estado y tendrá(n) como funciones:

a) Aceptar o denegar las solicitudes de los países exportadores para la introducción, liberación y comercialización de organismos vivos modificados y los productos resultantes de la biotecnología moderna, acorde con el procedimiento del Consentimiento Informado Previo.
b) Suspención de autorización concedida en los casos que la autoridad nacional competente haya comprobado fehacientemente que la importación de dicho OVM o producto haya ocasionado daño o que se haya producido cambio de uso de la autorizaciòn concedida.
c) Autorizar la utilización confinada así como la liberación voluntaria con fines de investigación en los supuestos previstos en la legislación nacional e internacional sobre la materia.
d) Mantener informada a la oficina Punto Focal nacional o regional cuando éste último exista.

De igual modo será competente para:

e) Adoptar criterios sobre evaluación de riesgo, que aseguren que los productos introducidos, liberados y comercializados no produzcan daños a la salud de las plantas, animales y seres humanos y al ambiente en general.

PUNTO FOCAL NACIONAL O REGIONAL.

1.- El Punto focal regional cuando éste exista, será designado por las partes y por consenso.

2.- El punto focal regional cuando exista, deberá representar regiones ecológicas comunes a las partes.

3.- El punto focal nacional o regional cuando éste exista, será el responsable de recibir y enviar información de los movimientos voluntarios e involuntarios de OVM, accidentes ocurridos debido a movimiento transfronterizos de OVM, así como toda información relacionada con la bioseguridad nacional, regional y mundial manteniendo estrecha comunicación con la secretaría y la Conferencia de las Partes.

PROCEDIMIENTOS PARA EL MOVIMIENTO TRANSFRONTERIZO DE OVM ACORDADO

1.- El sujeto exportador deberá notificar a través de su Autoridad Nacional Competente su intención de exportación por escrito, a la Autoridad Nacional Competente del país importador.

Dicha solicitud deberá contener la declaración e información requerida de acuerdo con el Procedimiento del Consentimiento Informado Previo, en el idioma aceptado por el país importador. Cada una de las partes involucradas deberán recibir copia del documento.
De existir puertos de embarque intermedios (países transito), deberán estos ser igualmente notificados solicitando su consentimiento.

2.- La solicitud de exportación deberá estar acompañada de documentos que indiquen:
   a) Clara descripción de las características del OVM o producto que se pretende exportar.
   b) Evaluación de los riesgos para la salud humana y el medio ambiente que puedan derivarse de la importación y uso del organismo o producto.
   c) Las condiciones de manipuleo y liberación de los mismos.
   d) Datos que indiquen resultado de otras liberaciones realizadas en su país de origen y en otros países,
   e) Autorizaciones o denegaciones previas de importación.

3- La Autoridad Nacional Competente analizará la información entregada por el país exportador, pudiendo solicitar información adicional de considerarlo necesario, manteniendo reserva respecto a aquella información que el solicitante la catalogue como confidencial. Luego de un lapso de tiempo prudencial, (establecido en la normatividad interna del país importador), autorizará o denegará la solicitud.

4.- Ningún movimiento transfronterizo de OVM o productos derivados de ellos, deberá ser permitido sin el Consentimiento Informado Previo del estado importador.

5- El Estado importador, deberán responder por escrito a través de la Autoridad Nacional Competente la aceptación, denegaciòn o requiriendo información adicional para la importación, igualmente los países de transito deberán manifestar su conformidad por escrito, indicando ambos si existiesen condiciones particulares para tal transferencia.
Las respuestas escritas, serán enviadas a todas las partes interesadas.

6- En caso de que se deniegue la importación, el país exportador podrá solicitar la revisión del caso siempre y cuando cuente con información relevante no presentada en la primera solicitud de exportación

7- Cada solicitud y análisis de la misma es independiente de si existe una aceptación previa sobre el mismo OVM o productos derivados de ellos, en el país importador u otro país parte.

8- Se concede la importación de un OVM o producto para un uso específico , en caso de cambio de uso, deberá solicitarse a la Autoridad nacional Competente una nueva Autorización por nuevo uso.

9.- Cuando un país parte tenga conocimiento de una liberación deliberada o no intencionada o cualquier accidente que ocurra en un país vecino y que suponga un riesgo para la bioseguridad de su territorio, deberá informar a las Autoridades Nacionales Competentes de las partes que participan en el movimiento transfronterizo acordado de su preocupación. Igualmente deberá informar del hecho a las instancias internacionales respectivas, dejando constancia de su preocupación por el riesgo.

PROCEDIMIENTOS PARA LA EVALUACIÓN Y GESTIÓN DE RIESGOS

1.- La evaluación de los riesgos que implique el movimiento transfronterizo, el manipuleo y la liberación de OVM o productos derivados de ellos, serán realizada por la autoridad nacional competente del país importador en concordancia al procedimiento del Consentimiento Informado Previo y bajo las disposiciones de la ley nacional y sus procedimientos internos.

2.- La autoridad competente podrá para tal fin:
   a) Solicitar al exportador y al responsable de la liberación voluntaria que proporcione información relevante al tipo de organismo o producto a importarse y que se especifica en el anexo correspondiente.
   b) Consultar a otras instituciones públicas y privadas, o personas calificadas en esta materia sobre el riesgo de la liberación propuesta.
   c) Proporcionar libre acceso público, a la información del proyecto de liberación voluntaria.
   d) Realizar cuantas pruebas e inspecciones sean necesarias.
   e) Solicitar la observación del OVM al menos durante un periodo proporcional a su ciclo vital o tiempo de generación, antes de utilizarlo en su forma prevista.

3.- Analizados los documentos y datos aportados y en su caso, los resultados de las consultas e informaciones adicionales practicadas así como las observaciones realizadas, se resolverá sobre la liberación solicitada, autorizándola o denegándola según se cumplan o no los requisitos de riesgo establecidos. La resolución que autorice la liberación impondrá, en su caso, las condiciones necesarias para su realización.

ESTÁNDARES MÍNIMOS NACIONALES

1.- La legislación y normatividad interna de cada estado parte y los estándares mínimos nacionales que en ellas se prevea para el uso, comercialización u movimiento transfronterizo de OVM, será establecida en concordancia con los acuerdos estipulados en el presente protocolo, asegurando los marcos jurídicos, institucionales y administrativos adecuados para la seguridad de la transferencia, la manipulación y la utilización de OVM.

CONSENTIMIENTO INFORMADO PREVIO

1.- El presente protocolo asume que el único procedimiento válido para la importación de OVM o productos derivados de ellos, es el del Consentimiento Informado Previo.

2.- Son criterios básicos para el Consentimiento Informado Previo el que:
   a) La parte exportadora podrá ingresar el o los organismos modificados o productos derivados de ellos, solo cuando el consentimiento del estado importador ha sido obtenido por adelantado, luego de la presentación por escrito a través de su autoridad competente, de una solicitud en el idioma oficial adjuntando además la información requerida por el estado importador.

3.- La Autoridad Competente del país importador requerirá que el exportador remita la "Ficha de Origen" del OVM o Producto Derivado de éste en donde se consigne la información sobre:

a) El organismo vivo modificado:

Su taxonomía, ecología y comportamiento reproductivo.

Información sobre el organismo donante del gen o genes, el receptor de dichos genes, el organismo vector, los genes introducidos incluyendo los genes marcadores, estabilidad de los genes introducidos y riesgos de transferencia de ellos a otros organismos, métodos de manejo de las liberaciones no intencionadas y métodos de uso.

b) El producto de organismos vivos modificados:

Información sobre los métodos de uso, si es un producto nuevo o ya existente en la naturaleza, el organismo vivo modificado que lo produjo indicando la informac<ión referida en a) y las consideraciones a tener en cuenta en caso de accidentes.

4. La autoridad competente del estado del importador proveerá información al exportador a través de la autoridad competente del estado exportador concerniente a sus leyes, regulaciones, lineamientos, procedimientos legales y administrativos y otros requerimientos relacionados con el desarrollo seguro, manipuleo y uso de los organismos vivos modificados o productos derivados de ellos.

ETIQUETADO, EMPAQUE Y TRANSPORTE

1.- Todo movimiento transfronterizo de un OVM o producto derivado de éste deberá ser cubierto por un seguro aceptado por las partes involucradas.

2.- Para el traslado de OVM o productos derivados de ellos, deben tomarse las debidas precauciones a fin de minimizar riesgos durante su transporte, aduanaje y recepción.

3.- Las partes deberán asegurarse que los productos de exportación que sean OVM o productos derivados de ellos, se encuentren claramente etiquetados, al menos en tres idiomas oficiales, siendo uno de ellos el idioma del país importador.

4.- El etiquetado deberá cumplir las siguientes especificaciones:

a) Estar ubicado en lugar claramente visible.

b) Tener un tamaño estándar y simbología internacionalmente aceptada.

c) Indicar en tres idiomas, (idioma oficial del país exportador, idioma oficial del país importador y un tercer idioma oficial), que el paquete contiene un OVM o producto derivado y que debe ser manipulado cuidadosamente.

5.- Los OVM o productos derivados de ellos, cuyo consumo humano o animal no hayan sido aún aprobado, deberán ser empacados y etiquetados indicando que tal OVM se encuentra en proceso de evaluación y que por ello se encuentra aislado.

REQUERIMIENTOS DE TRANSITO

1.- Todo OVM o los productos derivados de ellos podrán encontrarse de tránsito entre el país exportador e importador, siempre y cuando medie una aceptación por escrito aceptando tal condición.

2.- Deberá cumplirse todos los requisitos de etiquetado, empaque y transporte.

3.- La documentación provista para el transporte de los OVM deberá especificar los cuidados necesarios durante el transito de los mismos.

MOVIMIENTO TRANSFRONTERIZO NO INTENCIONAL POR CULPA O NEGLIGENCIA

1.- Las partes deberán tomar previsiones dentro de sus territorios, durante las liberaciones, a fin de minimizar la ocurrencia de movimientos transfronterizos no intencionales.

2.- La parte que tome conocimiento de la ocurrencia de un movimiento transfronterizo no intencionado de un OVM, deberá informar de inmediato a las autoridades nacionales competentes de las partes involucradas sobre tal hecho a fin de que se tomen las acciones pertinentes. Para ello la parte informante deberá proporcionar datos sobre el tipo de OVM, número o volumen de que se trate, y de ser el caso, proporcionar o solicitar la **ficha de origen** del organismo en mención.

MOVIMIENTO TRANSFRONTERIZO INTENCIONAL (DOLOSO)

3.- La Autoridad Nacional Competente del pais que se vea afectado por la presencia de un OVM no autorizado a su ingreso, informará a las instancias internacionales a fin de delindar responsabilidad y esclarecer si se trata de una liberación no intencionada o una liberación dolosa, sin perjuicio de evaluar la posibilidad de ejercitar las acciones pertinentes que provee el derecho internacional.

ACCIDENTES Y CASOS DE EMERGENCIA

1.- En caso de ocurrencia de un accidente, la compañia aseguradora, en coordinación con la(s) Autoridad(es) Nacional(es) Competente(s), tomarán inmediata acción a fin de evitar los posibles efectos negativos de los OVM o productos derivados de ellos, sobre el medio ambiente o la salud humana.

2.- En caso de ocurrencia de un accidente durante el movimiento transfronterizo o liberación de un OVM, se informará de inmediato sobre tal hecho a las autoridades competentes de las partes involucradas, proporcionando de inmediato la Ficha de origen del OVM así como las recomendaciones sobre manejo del riesgo respectivos.

TRAFICO ILEGAL DE OVM

1.- Se denominará como trafico ilegal o ilícito de OVM a todo uso o comercialización de OVM o productos derivados de ellos, sin notificación acorde con el procedimiento de Consentimiento Informado Previo, o cuyo consentimiento se haya obtenido a través de falsificaciones, fraude o falsas representaciones.

2.- Cada parte deberá establecer legislaciones internas que prevean el trafico ilícito de OVM y en caso de detectarse esta actividad ilegal, deberá este ser destruido.

INTERCAMBIO DE INFORMACIÓN

1.- Las partes deberán facilitar el intercambio de información entre ellas y con la Secretaría y la Conferencia de las Partes, pudiendo esta información tener diferentes niveles de acceso.

2.- La autoridad nacional competente o el punto focal o regional de ser este el caso, será el encargado de sistematizar la información relacionada con:

a) Desarrollo, utilización y transferencia de los OVM o productos derivados de ellos.
b) Metodologías, técnicas, expertos, equipo, materiales y resultados de investigaciones relacionadas con la respuesta a las liberaciones no intencionadas de OVM que pudieran aprovecharse en casos de accidentes o situaciones de emergencia.
c) Liberación de OVM al mercado
d) Información sobre legislación nacional de los países partes.
e) Información referida sobre movimientos transfronterizos de los OVM.
f) Información de los mecanismos que adoptaran las partes para la implementación del protocolo.
g) Información sobre las estadísticas disponibles sobre los de la liberación de los OVM en la salud humana y el medio ambiente.
h) Información sobre las decisiones tomadas por los países partes en relación a movimientos de organismos vivos modificados.
i) Infamación sobre liberaciones domesticas de OVM
j) Información sobre OVM prohibidos, aprobados y recientemente desarrollados.
k) Información sobre monitoreo post-comercial de la liberación de OVM.
l) Relación de expertos en bioseguridad.

CREACIÓN DE CAPACIDAD

1.- Cada parte deberá ordenar su sistema interno a fin de reforzar las capacidades institucionales para cumplir con las obligaciones y mecanismos que emanan del presente protocolo y para ello deberán:

a) Designar recursos propios para el logro de tales fines.
b) Establecer mecanismos regionales y sub-regionales para la formación de recursos humanos y el reforzamiento de capacidades institucionales.
c) Los países en desarrollo gestionarán ante los países desarrollados la posibilidad de colaborar en el reforzamiento de las capacidades internas de los primeros para la identificación, planificación y ejecución de sus programas de creación de capacidad.

CONCIENCIA Y PARTICIPACIÓN PUBLICA

1.- Tanto el sector publico como el privado deberá participar activamente en la generación de conciencia y participación pública sobre las implicancias de la liberación de OVM y la utilización de productos derivados de ellos, a través de programas educativos a todo nivel de la sociedad organizada.

2.- Se debe considerar la opinión pública y en especial la del grupo humano que probablemente pueda verse afectado por la liberación de OVM o productos derivados de ellos, en la toma de decisiones sobre liberación o puesta en comercialización de estos.

Julio 1997

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CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

ST. KITTS AND NEVIS

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VIEW OF ST. KITTS AND NEVIS ON THE CONTENTS OF THE PROTOCOL ON BIOSAFETY

1. THE POSITION OF THE FEDERATION OF ST. KITTS AND NEVIS ON THE FOLLOWING IMPORTANT TERMS AND PROVISIONS ARE:

The definition of Advance Informed Agreement (AIA) as submitted by the FAO Draft International Code for Plant Bio technology as it affects the Corporation and Utilization of Plant Genetic Resources, should be adopted.

So too are the definitions for Living Modified Organisms (LMO's), Risk Assessment and Risk Management as submitted in Report of panel of Experts on Biosafety, Cairo 1995.

2. ADVANCE INFORMED AGREEMENT (AIA)

Transfer of LMO's should require specific consent from the importing Country. If implicit consent be allowed in the Protocol, whereby consent would be deemed to have been given in the absence of a response, the vulnerability of developing Countries to the potential hazards of LMO would be increased. Developing Countries generally lack adequate assessment facilities.

3. SOME IMPORTANT ITEMS THAT SHOULD BE INCLUDED

Provision for liability and compensation. Settlement of disputes and dissemination of relevant information should be included in the Protocol.

4. ONE OTHER ITEM

Capacity building should also be included in the Protocol.

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SOUTH AFRICA

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CONVENTION ON BIOLOGICAL DIVERSITY

PROTOCOL ON BIOSAFETY

SOUTH AFRICAN DRAFT TEXT

JULY 1997

Preamble

The preamble should be considered and negotiated at a later stage after the more important items of substance.

Article 1
Definitions

For the purpose of this Protocol:

Accident (=Accidental) is any incident involving unintended release of LMO's in the course of their contained use (including trial release) or transfer, and which may or may not lead to an immediate or delayed hazard to the conservation and sustainable use of biological diversity and/or to human or animal health.

Adverse effect is any negative impact (in the lono, and the short term) on the conservation and sustainable use of biological diversity, or on human or animal health.

Advance Informed Agreement (AIA) is a formal agreement between two States or between a State and a group of States belonging to a regional economic integration organisation, Party to the Protocol, in accordance ,with the principle that international exchange of LMO's should not proceed, without the informed agreement of, or contrary to the decision of, the competent authority in the recipient country (cf also PIC=Prior Informed Consent).

Competent authority is any governmental or intergovernmental authority possessing sufficient relevant scientific capacity, and designated by a Party to regulate biotechnology and biosafetv, to issue and receive notification and advanced informed agreement for transboundary transfer, and to execute the functions of issuing, and withdrawal of approval for handling and use of GM0's.

Contained use refers to any limited experimental, non-commercial operation or activity involving organisms which are controlled by physical barriers or a combination of physical

and/or chemical and/or biological barriers which limit or prevent their contact with, or their impacts on, the potentially receiving, environment and any, living species, which includes humans.

Deliberate release is any release of an LM10(s) with the intent of, and for the purpose of use other than contained use, including, trial release.

Familiarity means the knowledge of, and experience with an LMO, the potential receiving environment and interactions of that LMO ,with such an environment and any living species, which includes humans. '

Focal point is that institutional component of (or delegated by) a competent authority designated by the Party(ies), to receive and submit information on LMO'S, including their handling, use and transboundary movements, to the Secretariat *[of the Convention on Biological Diversity and/or the Protocol on Biosafety].*

Living Modified Organism (LMO) is a genetically modified organism (GMO) whose genetic material (inclusive of DNA and RNA) does not occur naturally by mating or natural recombination.

Release is any use of, or activity or incident involving an LMO(s), other than contained use.

Risk assessment is the use of scientific methods to identify and characterise the nature, likelihood of occurrence and potential magnitude of hazards, if any, with due regard to the precautionary principle.

Risk management is the implementation of measures in accordance, with minimum standard requirements to eliminate or minimize risks associated with the transfer or use of LMO's and mitigate the potential adverse effects of such transfer or use on the conservation of biological diversity and human or animal health.

Safe/safety means the conditions determined with reasonable certainty to have acceptable or negligible risk to biological diversity or human or animal health.

Safe transfer is transfer that completely eliminates any possibility of adverse effects on biological diversity or human or animal health.

Transboundary movement is any movement of LMO's, intentional or unintentional, and by any means including gene transfer, across one or more national boundaries.

Transfer is the movement of LMO's, aided by human intervention, between two or more geographically, distinct points.

Trial release is the deliberate release of LMO's into the environment in the open under conditions where the decree of dissemination of the LMO's is limited by, physical and/or chemical and/or biological which prevent the survival of such organisms in the environment.

Article 2
Objective

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

Article 3
Scope

To be developed at later stage

Article 4
General obligations

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

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

3. Subject to the provisions in Art 7.1, Parties shall not approve or allow the export of LMO's until such time as an advance informed agreement (AIA), with explicit consent, has been obtained in writing, from the State of import for that specific import.

4. Parties shall not approve or allow the export of any LMO's to those Parties which have prohibited the import of such organisms. Parties exercising their right to prohibit the import of LMO's shall inform the Secretariat and the Clearing House of their decision *[For the purpose of this Protocol, the Secretariat and Clearing, House of the Convention on Biological Diversiy will also fulfill those functions for the Protocol.]*

6. Parties shall cooperate among themselves in order to develop an environmentally sound risk management system for LMO'S.

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

   (a) Ensure safety in biotechnology, especially in the handling, use, release and transboundary transfer of LMO' s resulting from modern biotechnology.

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

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

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

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

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

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

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

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

Article 5
Designation of competent authority and national focal point

To facilitate the implementation of this Protocol, each Party shall:

1. Designate and/or establish a competent authority which shall receive notifications, conduct and/or evaluate risk assessments and communicate decisions on LMO's in accordance, with procedures stated in Articles 6 and 7.

2. Inform the Secretariat and the Clearing House within 90 days of the date of entry into force of this Protocol, which agency has been designated as competent authority for that Party .

3. Inform the Secretariat and the Clearing, House within 30 days of the date of decision, of any changes regarding the designation made by it in terms of paragraph 2 above.

Article 6
Advance Informed Agreement (AIA)

1. Subject to Article 7. 1, all initial transfers of LMO's to another country which is Party to this Protocol, will be subject to the AIA procedure.

2. In accordance with para.1, no transboundary transfer of LMO's shall be allowed without an AIA of the State of import. The Competent Authority of the State of export shall not allow the exporter to commence the transboundary transfer until it has received the AIA from the Competent Authority of the State of import.

3. The Competent Authority of the State of export shall supply the following information to the competent authority of the State of Import, prior to the first transfer of LMO's:

- name and address of exporting company/institution
- name and address of recieving company/institution
- origin, name and taxonomic status of relevant donor and recipient organisms and characteristics of recipient organisms
- centres of origin and diversity
- description of all traits introduced or modified
- purpose of the genetic modification and stability of introduced genetic material
- the result(s) of an appropriate risk assessments carried out, including a summary of risks to human health and the environment
- intended dates of transfer
- number of organisms, or volume and physical state of culture, to be transferred
- any relevant requirements to ensure safe handling, storage, subsequent transport and use
- methods for safe disposal and suitable procedures in case of accidents
- intended use of the organism
- information on similar previous releases
- any differences between the environment of the exporting country and the environment into which the organism is to be released.

4. The competent authority of the State of import shall respond in writing to the State of export within 60 days. A response may consist of either:

- explicit consent to import;
- consent to import only under specified conditions or
- an interim response, that may contain a statement to import with or without specified conditions or prohibiting import during the interim period, which may include for example a statement that a final decision is under consideration and/or a request for further information.

5. In cases where the Competent Authority of the State of import considers that the documentation provided by the Competent Authority of the State of export is not sufficient in order to determine the potential or anticipated adverse effects of an LMO, the Competent Authority of the State of import may request such additional information as it deems necessary for this purpose. The Competent Authority of the State of export, or the exporter, may require the Competent Authority of the State of import to enter into an agreement of confidentiality, regarding, such additional information requested by the Competent Authority of the State of import.

6. If at any time before, during or after the transboundary transfer, the Competent Authorities of the States concerned become aware of relevant new information on the LMO in question, which could have significant consequences for the associated risks, the competent authorities of the states concerned will be informed ,within 30 days and the terms of the AIA may be changed accordingly.

7. All Parties to this Protocol will, whenever it comes to their knowledge, ensure in the case of any unintended or deliberate release or any accident occurring during or subsequent to the transboundary transfer of living modified organisms, which are likely to present risk to the biological diversity, the environment or human and animal health in other States, that those states are immediately informed.

Article 7
Notification procedure

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

2. The Competent Authority of the State of export may, subject to the provisions of Article 6.1 and paras. 1 and 5, substitute or allow the exporter to substitute, an AIA with notification of intent to export LMO's to the recipient State of import.

3. Notification of intent to export LMO's in terms of para. 2 -, will contain the following information

- name and address of exporting company/institution
- name and address of receiving company/institution
- origin, name and taxonomic status of donor and recipient organisms
- information on previous exports of same LM0 to recipient State
- date of intended transfer, which will not be less than 30 days from the date of notification

4. If the Competent Authority of the State of export is not notified by the Competent Authority of the State of import of any objection or reservations to the intended transfer within 30 days of the date of notification of intent to transfer, subject to the provisions of Article 6.1, the State of import will be deemed to have given consent for the intended transfer.

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

Article 8
Illegal traffic

1. Any transboundary transfer of LMO's without appropriate notification to, or advance informed agreement of, all States concerned, pursuant to and in accordance with the provisions of this Protocol, shall be deemed to be illegal traffic.

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

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

Article 9
Transport, handling,, packaging and labelling

To be developed in accordance with existing, international UN recommendations and agreements

Article 10
Risk assessment / Risk management

To be developed at a later stage.

Article 11
Emergency procedure

To be developed at later stage.

Article 12
Socio-economic considerations

To be developed at later stage.

Article 13
Capacity building

To be developed at later stage.

Article 14
Clearing-house

The clearing house mechanism of the Convention on Biological Diversity will be the clearing house for this protocol. The functions of the clearing house will be to facilitate access to information regarding:

- national procedures for regulation, assessment and risk management
- scientific references necessary to the assessment and risk management
- database on experiments of organisms genetically modified and on commercial products thereof
- information on transboundary movement and on results of AIA
- dissemination of information on transboundary movement and use to Parties sharing ecosystems with, or bordering on, Parties importing or using, LMO's for the first time

Article 15
Liability and compensation

To be developed at later stage

Article 16
Monitoring and compliance

To be developed at later stage

Article 17
Public awareness

To be developed at later stage in accordance with Art. 13 of the CBD.

Article 18
Information exchange

To be developed at later stage in accordance with Art 17 and 19(4) of the Convention on Biological Diversity.

Article 19
Financial issues

To be developed at later stage

Article 21
Settlement of Disputes

To be developed at later stage in accordance with Art. 27 of CBD.

Article 22
Review and Amendment

To be developed at later stage in accordance with Art. 29 and 30 of CBD.

APPENDICES: *To be developed at later stage.*

UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

SRI LANKA

/...

Ministry of Forestry and Environment
Government of Sri Lanka

THE LEGAL TEXT PROPOSED BY SRI LANKA ON THE SELECTED ITEMS (C1 - D3) OF THE BIOSAFETY PROTOCOL

Article C1

ADVANCE INFORMED AGREEMENT (AIA)

1. Each Party shall apply the Advance Informed Agreement procedure with respect to all Living Modified Organisms (LMOs) and products thereof that come under its jurisdiction as defined in Annex 1 of this protocol.
2. No export or transfer of any LMOs or products thereof to any receiving Party shall be allowed without the Advance Informed Agreement of the receiving Party in accordance with the AIA procedures defined in Annex 2.
3. Any Party who intends to export or transfer any LMOs to any recipient Party shall notify the National Competent Authority or the accredited agency of the recipient Party through its own National Competent Authority or its accredited agency.
4. The exporter shall not commence the transboundary movement until it has received written confirmation that the applicant has received the AIA of the Party of Import.
5. No export of LMOs or products thereof shall be allowed by the State of Export unless risk assessment has been carried out with the said LMOs or products thereof by testing them adequately by scientifically accepted methods in the State of Export or State of Origin, as agreed to by the State of Import.
6. Every export of LMOs shall be covered by insurance, bond or other guarantee as may be required by the Parties concerned and/or as stipulated in the Biosafety protocol.
7. The Competent Authority of the Party of Import shall be obliged to respond to the Party of Export within a period of **six months**. A response may consist of any of the following:
    i. Explicit consent to import,
    ii. Explicit refusal to import,
    iii. Consent to import only under specified conditions,
    iv. An interim response that further information is needed for a final decision.

    Where the Party of Import considers that the documentation provided by the Party of Export is insufficient in order to assess the potential adverse effects of an LMO, the burden of proof of biosafety lies with the Party of Export.

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

9. The Parties shall take appropriate risk management decisions and measures based on the risk assessment to minimise the risks to acceptable levels as may be decided upon by the Competent Authority of the Importing Party (see annex 4).

Minimum National Regulations for Biosafety:

1. Each Party shall ensure that appropriate legal, institutional and administrative frameworks relating to safe research, manufacture, development, transfer, handling and use of LMOs are in place at the national level as early as possible and in any case well before the ratification of the International Biosafety Protocol. Such regulations shall include adequate provisions for both contained use and planned release into the fields.

2. The international biosafety protocol shall act as the minimum requirement for national regulations with regard to safe handling, transfer and use of LMOs.
3. An appropriately formulated Environmental Impact Assessment shall be carried out with each LMO introduced to the country as recommended by the national Competent Authority and approved by the same authority.

Article C2:

Risk Assessment (+management) including mechanisms and minimum national standards:

1. Each Party shall ensure that, in accordance with the provisions of the Biosafety Protocol, assessments prior to the transfer, release and use of LMOs or products thereof are undertaken as regards the risks or possible adverse impacts in their respective territories as well as in the territories of States of import, including the transboundary effects to human and animal health, the environment, biological diversity and the socio-economic welfare of societies.
2. Such assessments shall identify and characterise the risks associated with the LMOs in question or the products thereof and specify actions to be taken in response. The risk assessment documentation to be submitted to the Competent Authority of the States concerned shall contain, as minimum, the information described in Annex [ ].
3. Each Party shall ensure that appropriate decisions are taken based on the outcome of the risk assessment and on a case-by-case basis. If the assessment shows that risk cannot be avoided or reduced to an acceptable level, the States concerned shall refuse authorization to the development, use, release, import, export or transfer of such LMOs or product thereof.
4. Each Party shall ensure that, in accordance with the provisions of this Protocol, appropriate management of the risks identified is undertaken until such risks have been removed or reduced to acceptable levels.

Article C3:

Unintentional Transboundary Movements (including accidental and emergency cases):

1. The Parties shall ensure that in the case of an accident occurring during the transboundary movement of an LMO, or in the case of an accidental/unintended movement within their own territories which may have transboundary effects which are likely to present risks to human health and/or the environment in other Parties, such Parties are immediately informed.
2. In the event of an unintentional transboundary movement of LMOs and/or accident, the exporter or importer shall be required to inform immediately the competent authorities of the States concerned. The Information shall include, *inter alia*, circumstances of the accident, the identity and numbers or quantities of the living organisms released, other facts necessary to assess the effects of the accident on human and animal health, the environment, the biological diversity and the emergency measures taken or needed to be taken together with any available information regarding the handling of the organisms and information related to risk assessment and management.

Article C4:

Handling, Transportation, Packaging and Transit Requirements:

1. Parties shall require adequate packaging and labelling of LMOs at all times in order to maintain safety during transport, transit and handling.

Article C5:

Competent Authority (s)/Focal Point (s):

1. A National Competent Authority shall be designated for the implementation of the Biosafety Protocol as soon as possible.

2. Responsibilities of the designated National Competent Authority/Focal Point shall include, but are not limited to, the following:

i) to receive notification;
ii) to transmit information to other Parties and/or the Secretariat and the notifiers;
iii) to evaluate risk assessment;
iv) to take decisions about notifications under AIA;
v) to transmit decisions on AIA to the notifier and other relevant agencies;
vi) to serve as the focal point for handling inquiries and proposals regarding any intended transfer/transboundary movement/release which affects its country or any activity undertaken on LMOs within its national boundaries;
vii) to establish and impose such conditions as it deems appropriate regarding the movement of LMOs in order to protect its environment and human health;
viii)to undertake risk assessment and give risk management decisions;
ix) to be informed immediately in the event of an adverse effect of the transfer of the LMOs which could affect it.

3. The National Competent Authority shall be provided with adequate financial and technical assistance to establish and develop its infrastructure and human resources to carry out the responsibility assigned to it;

4 Each State shall inform the Biodiversity Convention Secretariat, the agency it has designated as National Competent Authority, as soon as the International Biosafety Protocol enters into force.

Article D1:

Information Sharing and Clearing-House (Confidentiality)

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

2. The Parties shall facilitate and encourage the collection and exchange of scientific, technical, environmental, socio-economic , commercial and legal information relevant to the implementation of the Protocol. Such information shall be transmitted to the Secretariat, the Biosafety Clearing House and other relevant bodies and parties as the case may be.
3. Information that could be shared include, but not limited to, the following:
    i) information relevant to proper risk assessment and risk management;
    ii) information on accidental/unintentional movement of LMOs which have adverse impact on the environment and human health;
    iii) information on LMOs released on the market;
    iv) information on national legislation in countries;
    v) information regarding transboundary movement of LMOs;
    vi) the number of LMOs exported/imported, categories, characteristics, etc.;
    vii) information available on effects on human health and environment;
    viii)information on decisions taken by countries in relation to movement of LMOs;
    ix) information on codes of practice and guidelines related to the transboundary movement of LMOs;
    x) information on the implementation of the AIA
    xi) information on domestic releases of LMOs;
    xii) information on prohibited, approved and newly developed LMOs;
    xiii)information on monitoring post-commercial release of LMOs;
    xiv)lists of experts and training workshops/programmes;
    xv) lists of advisory bodies.

4. An appropriate Biosafety Clearing House mechanism shall be established through the CBD clearing-house mechanism to provide the parties and, as appropriate the Secretariat, with timely advice and information relating to the implementation of the Biosafety protocol. This body shall be composed of recognised experts from developing and developed countries and shall be multidisciplinary. It shall report regularly to the meeting of the Parties on all aspects of its work and to the Secretariat regarding the implementation of procedures on notification and advance informed agreement.

5. The Biosafety Clearing House shall serve as a body for information exchange, monitoring of implementation, and scientific and technical co-operation among parties. It shall in particular:

    i) collect and disseminate to parties information concerning:
        - the development, use and transfer of LMOs and products thereof
        - methodologies. Techniques, experts, equipment, materials, available results relating to risk assessment and management

    ii) assist Parties, particularly developing countries, when requested, in any of the following or other appropriate matters:
        - preparing or evaluating risk assessment reports or impact statements;
        - developing or evaluating risk management schemes and appropriate monitoring programmes, procedures and standards;
        - preparing emergency plans and other safety measures;
        - transmitting requests for assistance and relevant information in the event of accidents;
        - providing information that may be relevant to the settlement of disputes.

6. Confidentiality and proprietary provisions shall not be excessive or broad so as to hinder information sharing among parties which would undermine the ability of the national competent authority to take informed decisions.

Article D2

Capacity Building

1. Each Party shall strengthen and/or develop human resources and institutional capacities in order to facilitate an effective implementation of the Protocol. Such capacity building shall aim to ensure:
    i) that Parties develop and strengthen their capacities to implement the Protocol;
    ii) that national legislation related to biosafety is developed;
    iii) that states involved in the transfer, handling and use of LMOs are aware of any associated risks and have the means to access and manage risks;
    iv) that states are able to achieve safety when certain LMOs are transferred into and/or to be used in their territories.

2. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety.,

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

4. Regional or sub-regional centres for training and capacity building regarding the safe management of LMOs or products thereof should be established, according to the specific needs of different regions and sub-regions.

Article D3

Public Awareness/Public Participation:

1. The Protocol shall include a provision on public participation on compliance with the Protocol.

2. The Parties shall ensure that adequate information on the safe transfer, handling and the use of LMOs is provided to the public.

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

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

Annex I

Definitions of:

1. Living Modified Organism (LMO)

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

2. Advance Informed Agreement (AIA)

For the purpose of the Biosafety Protocol, "Advance Informed Agreement" means an agreement by the Competent Authority of the State of Import to the transfer of any living modified organisms or products thereof to the State of Importt based on the information supplied by the State of Export with an assurance that the information is accurate and complete.

3. Risk Assessment

"Risk assessment" means the identification of potential harm of living modified organisms and products thereof in accordance with the criteria and procedure set out by the Biosafety Protocol and based on the charcteristics of the organism used. The characteristics of the site and the surrounding environment including socio-economic impacts and conditions of the release.

4. Risk Management

"Risk management" means any appropriate measure for the management of potential risk, including experimental design, post-release design, post-release monitoring including Environmental Impact Assessments, emergency plans and other measures indicated in the Protocol.

ANNEX 2

Advance Informed Agreement Procedure

1. **Notification**

Any Party who intends to export or transfer any LMO to any receiving Party shall notify, through its National Competent Authority or its accredited agency, the National Competent Authority of the receiving party, by application in writing of its intention to do so.

2. **Information:**

The exporter of LMOs or products thereof shall provide the Competent Authority of the recipient Party with the following information in order to obtain AIA in accordance with Article C1.

- Names and addresses of the exporter and the importer;
- A complete risk assessment report on the LMO or the products thereof in accordance with the risk assessment parameters as stated in Annex [ ] of the Protocol;
- Number, quantity, volume or of organism or products thereof to be transferred and their physical form;
- The safety standards reached in the testing and observation of the LMO or the products thereof according to the legal or administrative requirements of the Party of export;
- The applicable laws, procedures, guidelines of the Party of export;
- Any requirements to manage risks and to ensure safe handling and use, and methods for safe disposal and appropriate emergency procedures in case of accidents;
- Intended dates of transfer;
- Intended means of transport;
- Information relating to insurance, liabilities and compensation;
- Certification by the Competent Authority or the accredited agency of the Party of export that the information provided is correct.

Annex 3

Risk Assessment Parameters:

1. **Characteristics of the living modified organism and its parental organisms:**

i) Scientific name and taxonomy including strain, cultivar or variety;
ii) Natural and potential range of geographical distribution of the LMO and its parental organisms including information on their natural habitats, predators, prey, parasites, competitors, symbionts, commonsals and hosts;
iii) The description of the modifications made and traits introduced including methods using gene technology;
iv) The function of the genetic modifications and/or the new insert, including any marker genes;
v) Purpose of the modification and intended use in relation to need or benefit;
vi) Whether introduced genes integrated or extrachromosomal;

vii) Number of inserts and other structures, for example, the copy number whether in tandem or other types of repeats;
viii)Products of the transferred genes, levels of expression and methods for measuring expression;
ix) Stability of the introduced genes in terms of expression and integration;
x) Biochemical and metabolic differences of the LMO compared with those of the unmodified organisms;
xi) Nature, host range and the genetic stability of the vectors used;
xii) Probability of vertical or horizontal gene transfer to other species including wild and naturalised relatives;
xiii)Probability of inserts or transferred genes to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;
xiv)Allogenicities, toxicities, pathogenicities and any unintended effects;
xv) If pathogenic, their virulence, infectivity, invasiveness, toxicity and mode of transmission;
xvi)Host range of the LMO and mutability;
xvii)Ability to survive outside the human and animal hosts, any secondary hosts, resting and survival stages;
xviii)Information on appropriate therapies against pathogenicity, allergenicity and toxicity;
xix)Autecology of the LMO compared with that of the unmodified organism;
xx) Susceptibility of the LMO to diseases and pests as compared to that of the unmodified organism;
xxi)Detailed information on past uses including results on all experiments leading to previous releases;
xxii)Ability of the organism to survive and colonise the environment to which release in intended or otherwise.

2. **Environmental Considerations:**

Information on the LMO, the donor and recipient organisms as well as the vectors in relation to:

i) Factors affecting the survival, reproduction and spread of the LMO in the environment;
ii) Available techniques for detection, identification and monitoring of the LMO and transmission of genes from the LMO to other organisms;
iii) Known and predicted habitats/ecosystems of the LMO;
iv) Possible interactions between the LMO and other organisms in the ecosystem which might be affected by accidental release;
v) Possible involvement in biogeochemical processes;
vi) Effects on agriculture, the environment and human and animal health;
vii) Proposed risk management measures including verification of their functioning and availability of methods for decontamination of the landscape in case of accidental releases;
viii)Scale, method, frequency, time and duration of release;
ix) Likelihood of transboundary movement.

3. **Socio-economic Considerations:**

i) Possible threats to biological diversity, traditional farming and indigenous technologies and sustainable agriculture;
ii) Possible effects which are antagonistic to the social, cultural, ethical and religious values of communities from the use or release of the LMO or products thereof.

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CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Third Meeting
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SWITZERLAND

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Art. 1 Objectives

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

Art. 2 Scope

This Protocol applies to the transboundary movement of living modified organisms intended for deliberate release in the environment that may have adverse effect on the conservation and sustainable use of biological diversity in the importing Contracting Party, taking also into account the risks to human health.

Art. 3 Definitions

will be developed later

Art. 4 General obligations

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

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

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

Art. 5 Designation of National focal point

1. Each Contracting Party shall designate or establish one national focal point that is authorized to act on its behalf and to be responsible for the administrative functions required by this Protocol.

2. Each Contracting Party shall, no later than the date of entry into force of this Protocol, notify the name and address of its national focal point to the Secretariat for inclusion in the[Biosafety Clearing House] [International safety Database] [Database for international information

exchange]. Each Contracting Party shall also immediately notify the Secretariat of any further changes

3. Each Contracting Party shall ensure that its national focal point has sufficient resources to perform their tasks effectively.

Art. 6 Procedures for the first transboundary movement of living modified organisms

1. Each exporting Contracting Party shall, with respect to the export of living modified organisms within the scope of this Protocol:

a) take appropriate legislative and/or administrative measures to ensure compliance by exporters with importing Contracting Party responses under paragraph 4 of this Article;

b) assist, upon request and as appropriate, focal points in importing Contracting Parties in obtaining further information relating to decisions with respect to paragraph 4 of this Article.

2. Prior to the first shipment of a living modified organism, the exporter has to supply the national focal point in the importing Contracting Party with an application containing the information listed in Annex X.

3. The importing Contracting Party shall take appropriate legislative and/or administrative measures to ensure response to the application referred to in paragraph 2 of this Article in writing to the exporter and the Secretariat within [120] days of receiving the application.

4. This response shall consist of either:

a) A final decision to consent to importation with or without specified conditions, or to deny to importation;

b) An interim response which may include a statement that a final decision is under consideration and a request for further information and/or a request to the focal point of the exporting Contracting Party for assistance in assessing the application.

5. If the importing Contracting Party fails to transmit a final decision or an interim response within the period specified in paragraph 1 of this Article, the living modified organism concerned shall not be exported without the explicit consent of the importing Contracting Party.

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

Art. 7 Procedures for subsequent transboundary movement of living modified organisms

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

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

Art. 8 Risk assessment and risk management

1. Decisions implying risk assessment and risk management, in particular under paragraph 4 of Article 6, in regard to adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks for human health shall be based on up-to-date scientific data and experience and take account of the characteristics of the living modified organism involved, the characteristics of the intended application and the potential receiving environment.

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

Art. 9 Bilateral, multilateral and regional agreements

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

2. Contracting Parties shall notify the Secretariat of any bilateral, multilateral or regional agreements or arrangements referred to in paragraph 1 of this Article and those which they have entered into prior to the entry into force of this Protocol for them. The provisions of this Protocol shall not affect transboundary movements which take place pursuant to such agreements provided such agreements are compatible with the environmentally sound management of living modified organisms as required by this Protocol.

Art. 10 Unintentional transboundary movement

Each Contracting Party shall, whenever it comes to their knowledge, ensure that, in the case of an unintentional transboundary movement of living modified organisms which are likely to present risks to human health and the environment in other States, those States are immediately provided with all relevant information.

Art. 11 Transport, and packaging requirements

In order to maintain adequate safety levels during transport, each Contracting Party shall take appropriate measures to ensure that products containing living modified organisms are appropriately packed and labelled[1].

Art. 12 Exchange of information

1. Each Contracting Party shall facilitate the collection and exchange of all publicly available scientific, technical, environmental and legal information relevant to the implementation of this Protocol taking into account the special needs of developing country and the countries with economies in transition through a [Biosafety Clearing house[2]] [International Safety Database] [Database for international information exchange].

2. Without prejudice to Article 13, each Contracting Party shall ensure that following information is provided to the Secretariat for inclusion in the [Biosafety Clearing House] [International safety Database] [Database for international information exchange]:
- information on intentional movement having been subject to Advance Informed Agreement according to Art. 6 and related decision(s)
- information on unintentional movements according to Art.10.

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

Art. 13 Confidentiality

[This will be discussed and developed at a later stage]

Art. 14 Capacity building

The Contracting Parties shall, taking into account in particular the needs of developing countries and countries with economies in transition, cooperate in promoting technical assistance for the development of the infrastructure and necessary capacity to manage living modified organisms for the implementation of this Protocol. Contracting Parties with more advanced biosafety-regulating programs should provide technical assistance, including training to other Contracting Parties in developing infrastructure and capacity to manage living modified organisms within their countries.

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[1] Par. 52 UNEP ITG, WHO Laboratory Safety Manuel
[2] Art. 20 African proposal,

Art. 15 Public awareness and participation

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

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

Art. 16 Monitoring

Each Contracting Party shall at intervals to be determined by the meeting of the Contracting Parties, present to the other Contracting Parties, reports on measures which it has taken for the implementation of the provisions of this Protocol and their effectiveness in meeting the objectives of this Protocol[3]

Art. 17 Movement to and from Non-Contracting Parties

Art. 18 Settlement of disputes

Art.19 Assessment and review of procedures/annexes

Beginning in .... and at least every 5 years thereafter, the Contracting 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 Contracting Parties shall convene appropriate panel of experts and determine its composition and terms of references. Within one year of being convened, the panels will report their conclusions, through the Secretariat, to the Contracting Parties[4].

Art. 20 Meeting of the Contracting Parties

Art. 21 Duties of the secretariat

Art. 22 Financial provisions

Art. 23 Annexes

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[3] Art. 26 CBD
[4] Art. 5 Montreal Protocol

Art. 24 Amendment to the Protocol

Art. 25 Amendment to the Annexes

Art. 26 Relationship between the Protocol and the Convention on biological diversity and with other international agreements

Art. 27 Signature, ratification, acceptance or approval and accession

Art. 28: Entry into force

Art. 29: Reservations

Art. 30: Withdrawal

Art. 31: Depository

Art. 32: Authentic texts

Annex X: Information to be provided according to Art. 6 and Art. 7

- name and address of exporting user;
- name and address of importing user;
- origin, name and taxonomic status of recipient organisms;
- description of the traits introduced or modified and characteristics of the organism;
- summary of the assessment of risks to human health and the environment;
- intended dates of transfer;
- number of organisms to be transferred or volume of culture and physical form;
- any requirements to ensure safe handling, storage, subsequent transport and use;
- methods for safe disposal and suitable procedures in case of accidents;
- intended use of the organism;
- information on relevant previous releases.[5]

Annex XX.

To be developed

[5] par. 47 UNEP ITG

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CONVENTION ON
BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING
GROUP ON BIOSAFETY
Third Meeting
Montreal, Canada
13 to 17 October 1997

UNITED STATES OF AMERICA

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Submission of Legal Texts by the United States of America to the Secretariat of the Convention on Biological Diversity for Items to be Discussed at the Third Meeting of the Ad Hoc Working Group on Biosafety

Article on
Designated National Focal Point(s)

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

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

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

Article on
Information Sharing

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

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

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

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

Article on
Advance Informed Agreement

1. Scope. An LMO is subject to this Article where:

(a) The LMO has not been imported into the importing Party and the LMO is not being produced in the importing Party, and

(b) The LMO is one

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

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

(3) for which approval is in the process of being sought in the exporting Party;

(4) for which approval in the exporting Party would have been required had the LMO been intended for domestic commercialization or growth in the exporting Party but for which approval was not sought because the LMO was not intended for commercialization, field testing, or field growth in the exporting Party; or

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

2. Notification. Each exporting Party shall notify, or require a natural or legal person under its jurisdiction to notify, in writing, the importing Party through the importing Party's national focal point prior to the first export to the importing Party of an LMO that is subject to paragraph 1[1]. The notification need be sent to only one focal point in the importing Party concerned. The notification shall include the information contained in the annex to this protocol.

3. Confidentiality. The importing Party shall not divulge any confidential information received under this protocol and shall protect intellectual property rights relating to data so received and shall establish appropriate internal procedures for the protection of information so received.

The notifier should indicate any information submitted under the procedures of this protocol that it considers to be confidential and/or subject to intellectual property protection.

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[1] Paragraph 1 limits the scope of the article on advance informed agreement to those LMOs which may present risks to the conservation and sustainable use of biodiversity.

4. Advance Agreement. An importing Party shall respond to notification of intention to export to the importing Party an LMO that is subject to paragraph 1 as soon as possible but not later than x days after transmission of such notification.

The importing Party shall so respond to the notifier by (a) consenting to the import with or without conditions, (b) denying permission for the import, or (c) requesting additional relevant technical information.

When calculating the period referred to in this paragraph, the number of days for which the importing Party is waiting for additional information which it has requested from the notifier, shall not be taken into account.

5. Report. The importing Party's national focal point shall transmit its decision in writing to the notifier, to the exporting Party's national focal point(s), and to the central clearinghouse/database. The importing Party shall notify the aforementioned of any change in its decision.

6. Equal Treatment. The importing Party shall ensure that its decisions and actions with respect to the import of an LMO are not more restrictive than with regard to the same LMO produced domestically or imported from any other country.

Article on
Mutual Cooperation Agreements and
Voluntary Participation as an Importing Party

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

2. Any Party may notify the Secretariat at any time that the advance informed agreement provisions shall not apply with respect to imports to such Party.

Article on
Risk Assessment and Risk Management

1. Decisions by importing Parties regarding risk assessment and risk management in regard to potential adverse effects on the conservation and sustainable use of biodiversity should make use, as appropriate, of existing guidelines relevant to biosafety.

2. Decisions shall be based on scientific principles, and in this context, should take into account relevant technical experience.

3. Parties are encouraged to assist importing Parties with importing Parties' risk assessment and risk management decisions through the sharing of information and expertise.

Article on
Unintentional Transboundary Movement

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

2. Any Party receiving such information shall not divulge any confidential information received under this protocol and shall protect intellectual property rights relating to data so received. The notifier should indicate any information submitted under this protocol that it considers confidential and/or subject to intellectual property protection.

Article on
Handling, Transport and Packaging

Each Party shall promote, as appropriate, measures for the appropriate handling, transport, and packaging of LMOs subject to the Article on Advance Informed Agreement.

Article on
Capacity Building

1. The Parties support the aspiration of all importing Parties to perform their own risk assessments.

2. The Parties shall assist each other through information-sharing about LMOs, including through the provision of information to the centralized database.

3. The Parties shall promote technical and scientific cooperation, including the promotion of cooperation in the training of personnel and the exchange of experts, in order to strengthen the ability of importing states to perform risk assessments and to develop and implement risk management procedures.

Annex to the Protocol

Information Requirements for Notification under an AIA.

The notification shall include the following information:

a) the name and address of the importer;

b) the taxonomic name and common name of the recipient organism;

c) a description of the traits modified or introduced including the taxonomic status of the donor organism and the function of the introduced DNA (if known);

d) the characteristics of the LMO;

e) known and available assessments that may have been generated by the regulatory process with respect to the LMO;

f) any relevant requirements to ensure safe storage, transport, and use; and

g) any applicable methods for safe disposal and procedures for accidents.

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URUGUAY

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URUGUAY

En la 1a. Reunión del Grupo especial de Composición Abierta de Expertos en Seguridad de la Biotecnología , llevada a cabo en el marco del mandato emanado de la 2a. Conferencia de las Partes del Convenio de Diversidad Biológica, en la ciudad de Aarhus, Dinamarca, entre el 22 y 26 de julio de 1996, se dispuso que los gobiernos deberán enviar a la Secretaría los puntos de vista oficiales sobre los aspectos a incluir en el futuro Protocolo sobre Seguridad de la Biotecnología.

Esta Secretaría de Estado, conjuntamente con técnicos del Ministerio de Ganadería, Agricultura y Pesca y del Instituto Nacional de Investigaciones Agropecuarias, se abocaron al estudio de los distintos aspectos a tener en cuenta en relación a este tema.

En tal sentido, remitimos la propuesta a ser considerada como posición del Gobierno Uruguayo, estimando que el futuro Protocolo deberá contener, al menos, los siguientes elementos:

- Preámbulo
- Objetivos y alcance
- Definiciones de términos. (sin perjuicio de compartir las definiciones de términos contenidas en el glosario de las Directrices técnicas elaboradas por UNEP, deberán definirse otros términos que no se incluyen en las mismas).
- Designación de una autoridad nacional competente y un Punto Focal.
- Creación de capacidades.
- Procedimientos de información, notificación y acuerdo fundamentado previo, requiriendo el consentimiento del país importador antes del movimiento transfronterizo.
- Criterios para determinar el uso de AIP y/o notificación.
- Mecanismos para evaluación de riesgos.
- Mecanismos para gestión de riesgos.
- Requerimientos para manipulación, transporte y tránsito de organismos vivos modificados.
- Divulgación pública.
- Mecanismos de intercambio de información (Clearing-House).
- Resolución de disputas.
- Mecanismos financieros.
- Mecanismos institucionales.
- Introducción de enmiendas.
- Monitoreo y cumplimiento de las obligaciones del Protocolo.

Respecto al tema de la inclusión de cláusulas de Responsabilidad y Compensaciones, en principio no vemos razones "a priori" para oponernos a la inclusión de las mismas, dependiendo del alcance de su contenido; sin embargo creemos que la inclusión o no de dichos aspectos no debería ser obstáculo para alcanzar un acuerdo internacional en los plazos previstos. En todo caso, el tema en cuestión podría ser objeto de una negociación paralela, teniendo en cuenta los antecedentes de otros acuerdos internacionales.

Ministerio de Vivienda, Ordenamiento Territorial y Medio Ambiente
República Oriental del Uruguay.