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Second Meeting
Montreal, Canada
12 to 16 May 1997

# INDIVIDUAL GOVERNMENT SUBMISSIONS ON THE CONTENTS OF THE FUTURE PROTOCOL

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**AFRICAN REGION**

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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 1Error! Bookmark not defined.
## 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 use as human or animal vaccines:
   (a) Initial molecular, tissue culture, serological and other related studies in the laboratory in complete containment:
   (b) Trials with experimental animals under strict 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 escape and accident shall always be in place.

## 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 use as human or animal vaccines:
   (a) Initial molecular, tissue culture, serological and other related studies in the laboratory in complete containment:
   (b) Trials with experimental animals under strict 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 escape and accident shall always be in place.

UNEP

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# CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING
GROUP ON BIOSAFETY
Second Meeting
Montreal, Canada
12 to 16 May 1997

**AUSTRALIA**

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# NEGOTIATION OF A PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

## POSSIBLE ELEMENTS OF THE PROTOCOL

## SUBMISSION BY AUSTRALIA

1. This submission by Australia is in accordance with the terms of the invitation of the first meeting of the Ad Hoc Working Group on Biosafety (BSWG1), Aarhus, 22-26 July 1996, to Governments to submit their views, by 31 December 1996, on the possible contents of the proposed protocol on biosafety.

2. The submission provides comments on some of the possible elements of the protocol as identified in the Annex to the report of BSWG1. It focuses on those items identified in Part A of the annex, i.e. those items included in all proposals submitted during BSWG1.

3. The submission includes comments on the terms proposed for definition in the protocol, as listed in the appendix to the report of BSWG1, and the definitions contained in the document subsequently provided by the Secretariat *Glossary of Terms Relevant to a Biosafety Protocol* (26 September 1996, hereafter referred to as the *Glossary*).

4. In developing the submission, Australia has been guided by a number of key principles, reflecting the conditions set out by the Conference of the Parties regarding the scope of a protocol, in particular that the protocol should:

- specifically focus on transboundary movement of living modified organisms resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity;
- not exceed the scope of the Convention;
- not override or duplicate any other relevant international legal instrument;
- provide for a review mechanism; and
- be efficient and effective and seek to minimise negative impacts on biotechnology research and development

5. The submission is provided in the interests of advancing the negotiations on a biosafety protocol, in accordance with COP-2's decision II/5. It should be understood in the context of Australia's position, as stated at previous meetings, towards key possible elements of the protocol. The views contained in the submission are offered without prejudice to Australia's final position on the possible elements, structure and scope of the protocol. Australia reserves the right to submit further material and views on the protocol.

6. The term LMO used throughout this submission refers to the concept of "living modified organism resulting from modern biotechnology".

## COMMENTS ON SPECIFIC ITEMS INCLUDED IN ALL PROPOSALS

### A. Title

7. Australia suggests that the title of the protocol be considered at a later stage and that for the time being Protocol on Biosafety be used as a working title for the purpose of the negotiations.

### B. Preamble

8. Australia agrees on the need for a preamble. It should contain introductory language setting out the motivations of the parties in concluding the protocol. It should state the relationship between the protocol and the head agreement (i.e. the Convention) and reaffirm the principles of the head agreement. It could set out general guiding principles relevant to the protocol. These could be drawn largely from the language of COP-2 decision II/5. The preamble should not attempt to address issues more appropriately covered in the provisions of the protocol.

9. Australia considers negotiation of the preambular text would be best considered at a later stage of the negotiations. The BSWG should concentrate first on elaborating the text of the elements of the protocol, guided by the mandate as recorded in decision II/5 and taking into account the views expressed by countries in their submissions and the paper to be prepared by the Secretariat on the relationship with existing international agreements. The Working Group could then move to the text of the preamble.

### C. Use of terms/definitions

10. Australia considers it would be necessary to define in the protocol a number of terms used in the protocol, in order to avoid possible later confusion or disagreement in implementing the protocol arising from a lack of clear agreement over the meaning of these terms. The importance of clearly defined and agreed terms is demonstrated by difficulties in implementation being experienced by parties to other international environment agreements as a result of a lack of clear definitions. The terms to be listed in the biosafety protocol should be drawn from those listed in the appendix to the report of BSWG1 which the meeting agreed should be proposed for definition. All terms should be defined in a manner consistent with the Convention and to ensure coherence with the terms used in other relevant international agreements.

11. Issues needing to be considered include which of the terms in the appendix should be included in the protocol and at what stage of the negotiations should the process of defining them take place. It would seem desirable to arrive at early agreed definitions of at least some key terms in order that negotiators have a clear common understanding. These could be regarded as working definitions subject to later fine tuning and endorsement, to avoid the possibility of the BSWG getting bogged down too early in the negotiations in negotiating minute aspects of the terms. If, at the end of the negotiations, a particular term is not referred to in the protocol, that term should be deleted from the list of definitions.

12. Australia has developed definitions for some key terms. These are set out in Attachment A. The terms are drawn mainly from the appendix list.

### D. Advance informed agreement (AIA)

13. Australia considers the BSWG should be guided by the following general principles in considering an AIA procedure for the protocol. Any AIA procedure should:

- be designed to allow fully informed decisions by the importing country regarding the intended import of LMOs;
- ensure that final judgements in relation to risk assessment of the likely effects of LMOs in an importing state remain the responsibility of that country;
- operate effectively and efficiently, in order to minimise costs and timing delays;
- be consistent with the provisions of the World Trade Organisation (WTO) agreements;
- be implemented through existing institutional mechanisms where practical and appropriate.

14. Further consideration will need to be given to whether the following issues should be addressed in elaborating an AIA procedure, i.e. whether:

- all or only some LMOs that are to be covered by the protocol should be covered under AIA
- a positive or negative list approach should be adopted in determining coverage of LMOs under AIA
- the appropriate trigger mechanisms for determining whether an LMO would come under AIA should be specified.

D.1 Coverage

15. The negotiating mandate specifies that the protocol cover LMOs that may "have [an] adverse effect on the conservation and sustainable use of biological diversity" . It will therefore be necessary to establish criteria to enable judgments to be made as to whether an LMO constitutes a risk to biodiversity. Clearly, some kind of "sorting" mechanism will be required to deal with the likelihood that some LMOs will be regarded as posing no significant risk for biodiversity. In the interests of keeping the protocol simple and effective, the exclusion or exemption from AIA of LMOs which are widely accepted, on the available scientific knowledge and experience, as having no adverse effects on biodiversity should be considered. It would be important to ensure that categories of LMOs are not subjected to more rigorous, costly and time consuming AIA and/or risk assessment processes than necessary, recognising that different types of LMOs will pose different types and degrees of risk to biodiversity. For example, as UNEP's International Technical Guidelines for Safety in Biotechnology state, "it is generally anticipated that, in most cases, there will be low environmental risk from introducing into a similar environment ....well known crop plants after they have been modified by adding only one or a few genes, especially when compared with the risks of introducing entirely new or alien species".

16. In developing the protocol, an issue for consideration will be the development of lists or annexes of LMOs to be covered or exempted under AIA. There was considerable discussion at BSWG1 over criteria for determining the scope of coverage of such lists, in particular, whether the list(s) should identify LMOs which may have adverse effects on biodiversity and be covered by AIA (i.e. positive list approach), or whether they should

identify LMOs which are deemed not to, or unlikely to, have an adverse effect on biodiversity (i.e. negative list approach).

17. Whether to include lists and what form they should take is likely to be one of the key aspects of negotiations. It is apparent from preliminary discussions on this issue at BSWG1 that there are advantages and disadvantages to the various approaches. Further consideration of the various options is required before definitive views can be reached.

18. The BSWG should also take into account the dynamic, rapidly changing nature of modern biotechnology. Provision should be made in the protocol for the regular, frequent and easy updating of any lists of LMOs (whether "positive" or "negative") to take into account factors such as the development of new LMO products, changes in circumstances and availability of new information.

D.2 AIA Trigger Mechanism

19. Designing an appropriate mechanism for triggering application of an AIA procedure to a particular LMO will clearly be an important issue to consider. Some aspects requiring further consideration are: criteria for setting off the trigger (i.e. under what circumstances would the proposed import of an LMO activate the AIA procedure?); the role of risk assessment in making a judgement as to whether a proposed import would have an adverse impact on the environment; and the mechanism for operating the AIA procedure (i.e. how a notice of intent and consent to import scheme would operate).

D.2.1 Criteria

20. There are a number of factors whose suitability as criteria for the AIA trigger mechanism should be considered. These are: the intended use of the LMO in the receiving country; the nature of the introduced characteristic of the LMO; the type of receiving environment; the degree of familiarity/domestication (i.e. the history of cultivation) of the non-genetically modified species in the receiving environment; the type of reproductive mechanism of the LMO. Attachment B provides details of how these factors might operate to activate AIA. The trigger factors outlined in Attachment B have been formulated in relation to genetically modified plants. For other categories of LMOs (such as microorganisms or animals) different trigger factors may be appropriate.

21. Other factors may also be relevant to national authorities in that while they may not be a determinant of whether AIA should be activated, they could provide relevant information which could be taken into account in determining whether to consent to the import of an LMO into their country. Such factors could include the regulated status of the LMO in the exporting country, whether there are related species in the receiving environment and whether such species are pests.

22. Another aspect is whether imports of LMOs should be subjected to AIA on a shipment-by-shipment basis, or whether, having once obtained a clearance, subsequent imports of the LMO under similar conditions, could be exempted from AIA or given a lower and less comprehensive level of assessment.

23. Consideration could also be given to whether the protocol should provide for parties to conclude bilateral agreements in relation to the import/export of LMOs which could modify the application of the protocol to those parties.

D.2.2 Risk Assessment

24. Suitable mechanisms for risk assessment and risk management will be an important element underpinning the effective functioning of any AIA procedure under the protocol. However it does not automatically follow that the mechanisms themselves should form part of the protocol. It should be noted that national systems provide for a diverse range of regulatory measures for undertaking risk assessment and risk management. In addition a number of international guidelines exist, including the UNEP International Technical Guidelines on Safety in Biotechnology, which address risk assessment. As appropriate risk assessment and risk management mechanisms will vary from country to country, taking into account differences in the receiving environment, they should not form part of an international legally binding instrument.

25. However, the protocol could set out the following general guiding principles for the operation of risk assessment procedures for biosafety:

- risk assessment should be applied within a well-defined technical/scientific methodology for safety in biotechnology including a step-wise and case-by-case basis
- assessment should be made of the possible adverse effects from LMOs on the conservation and sustainable use of biological diversity
- risk assessment should be based on the characteristics of the organism, the genetic modification and the receiving environment
- special considerations should apply to risk assessment in centres of origin and areas with high genetic diversity.

26. One of the key issues for the BSWG will be identifying the respective responsibilities of the exporting party and the importing party for risk assessment. It could be appropriate for the protocol to include provisions requiring exporting parties to cooperate in facilitating the exchange of scientific knowledge.

27. Consideration could perhaps also be given to the protocol including a provision that exporting parties consider assisting in other ways the process of risk assessment in the importing party to help reach informed judgements as to the suitability and safety of an LMO, in terms of possible adverse effects on biodiversity, for import by another party. However, this should not be mandatory.

28. It should be noted that while some form of cooperation by exporting parties in the risk assessment and/or risk management processes may be appropriate, the decision whether to import an LMO or not should remain the sole responsibility of the importing party. A party should not be obliged to take responsibility for making a judgment or decision on import by another party.

D.2.3 AIA operating mechanism

29. It has been suggested that existing PIC procedures may provide a model for an AIA operating procedure for biosafety. It would be useful to examine the operation of these mechanisms to assess whether there are aspects which may be suitable for application to AIA. However, as the Secretariat's Background Paper to BSWG1 noted, there may be difficulties in trying to translate the existing PIC procedures into the LMO context. For example, the existing PIC models cover only cases where the exporting state has taken action to ban or

severely restrict particular chemicals or identified hazardous wastes in its own jurisdiction and it is the act of banning or imposing restrictions that automatically activates the PIC mechanism. In the case of LMOs other trigger mechanisms would seem to be more appropriate (see Criteria section, paragraph 20) because receiving environments vary between countries.

30. Further consideration would need to be given to operational matters such as:

- should the trigger be limited to the exporting country notifying the importing country of relevant details concerning the LMO it intends to export;
- would it be necessary for the protocol to require each party to designate a national authority and, if, so, what would be the functions of designated national authorities in relation to the transboundary movement of LMOs, including exports and imports;
- should details of the proposed export and the response of the importing country be forwarded to a clearing house type of agency for the information of other Parties;
- should there be a time limit on the AIA process whereby the importing party must make a decision on whether to approve the proposed import within a reasonable period of time;
- where an importing party does not give its agreement to the import of the LMO, what repercussions could such a refusal have for other potential importing Parties;
- whether provision should be made in the protocol for an exporter to request a review of a decision of the importing country on the import of an LMO.

31. The provision of information will be an integral part of any AIA procedure. Assuming that the submission to a importing party by an importer of a notice of intent to import would be the starting point in the process of determining whether AIA should apply, certain basic information would have to be provided in the notice of intent so that the importing party can determine its next steps. This information should cover the species of the LMO (scientific name), the introduced characteristic and the intended use. The importing party may subsequently seek further information so it can undertake any necessary risk assessment, e.g. information relating to the reproductive mechanism, details of the intended use and introduced characteristic(s) and details of any known releases in the exporting country. The exporting party would be expected to cooperate in the provision of this information, either directly or through the exporter as appropriate. The supply of information requested in the AIA procedure should not go beyond what is necessary and reasonable for undertaking risk assessment. The avoidance of onerous costs to exporters is a valid consideration.

32. Consideration would need to be given to the manner in which such information is conveyed (channels of communication) and to where the onus should be placed, i.e. with the exporter or the importer, for lodging the notice of intent to import and providing any other information relevant to AIA to the designated national authority. Consistent with the practice in international quarantine arrangements regarding plants, animals and their products, there would appear to be a strong case for the onus to rest with the importer, although the exporter would be required to cooperate in providing certain details to the importer. This would not rule out the option of direct liaison between designated national authorities, although there would seem to be no need for this to be specified in the protocol.

33. The BSWG could also consider the desirability of depositing relevant information in publicly accessible data bases, to enable other parties and interested bodies to be informed of proposed transfers of LMO. Account should be taken of the potential of existing data bases to fulfil this function. The potential for "clearing house" type mechanisms, including the Convention's Clearing House Mechanism, could also be considered.

34. The incorporation of a qualification protecting commercially sensitive information would seem to be essential. The need to protect from disclosure commercial-in-confidence information may also be relevant to information derived from academic research projects. Protection would also be consistent with the qualifications of Article 17.1 of the Convention (see following Section E), which have the effect of excluding confidential information held by a Contracting Party's public or private sectors from the obligations under this provision. At the same time it would be desirable that such protective measures are not exploited, e.g. not providing information which it would be appropriate to provide for the purpose of risk assessment.

## E. Information sharing

35. The exchange of information on LMOs will be essential to the effective operation in all countries of a transparent, scientifically based system for regulating the transboundary movement of LMOs. Apart from the need for basic information for AIA purposes of intended imports of LMOs (see Section D), parties will benefit from having broader access to information about LMOs, such as the development of new LMOs, details of any releases of LMOs in other countries, and risk assessment and risk management procedures in other countries. There could be situations not involving transboundary movements of LMOs where provision of information, or an exchange of information, although not required under AIA, could be desirable in order for a country to make an informed assessment of risk. For example, information about a planned domestic release of an LMO might be relevant to a neighbouring country in terms of assessing any potential threat to its own biodiversity.

36. The protocol could contribute to building the capacity necessary for its effective and efficient implementation by including a general commitment for parties to cooperate in making available information on LMOs. This would assist parties to build up their own information base. Parties could make information available to internationally accessible data bases. The Convention's Clearing House Mechanism and other clearing house type arrangements could also play a useful role in this regard.

37. Australia considers the provision and exchange of such information should be based on the existing obligations of the Convention. Article 17 provides for the general facilitation of exchange of information, including biotechnology, subject to certain qualifications. Under Article 17.1, the facilitation of information exchange is limited to information relevant to the conservation and sustainable use of biological diversity, and to information from publicly available sources. Article 17.2 refers to an exchange of indigenous and traditional knowledge and technology (i.e. technology being transferred pursuant to Article 16.1, which would include biotechnology). Article 19.4 of the Convention creates a bilateral obligation on a party to provide any available information on an LMO to another party prior to providing the LMO itself to that party. This provision would apply automatically to the protocol, in accordance with COP-2 decision II/5 and could be regarded as a minimum level of information sharing under the protocol. A relevant consideration flowing from this is what additional information, if any, might be required to be provided in order to achieve the objectives of the protocol.

38. While there is a clear need for the protocol to provide for publicly available information about releases into the environment to be made available, adequate protection from disclosure

of commercial-in-confidence information should also be provided (see Section D). Consideration will need to be given to the extent to which information sharing provisions could be extended to contained uses of LMOs, where much of the information is likely to be of a confidential nature.

39. The protocol should provide for parties to make available, through a centralised international data base, the following types of information, where known, in the case of domestic releases of LMOs:

- organisation proposing the release (including details of contact person)
- details of the parent organism (natural range, distribution in the member country, region of origin, use by humans, any known undesirable effects of parent organism on biodiversity and human health, reproductive mechanism, dispersal mechanism)
- the genetic modification and its effect (donor organism, genes inserted, phenotypic effect of the genetic modification)
- vector (method used for introducing the gene(s) into the organism, nature and origin of any vectors used, whether vector is present in the final construct)
- details of the release (if known) - the organism (parent species), location, timing, scale (number of organisms to be released, area of land), procedures for releasing the LMO, details of the physical site, measures to prevent spread of the LMO and/or gene beyond the release site, supervision arrangements and procedures to be used by personnel on the site, procedures to be used during the release to monitor spread of the introduced trait beyond the site and any other potential adverse effects
- procedures following release (if known) - procedures for removal of LMOs from the site, treatment of the site, monitoring of the site after removal of the LMO
- transport (procedures to be used for transport of the LMO to and from the release site)

## F. Relationship with other international agreements

40. The relationship between the protocol and other existing international agreements will be of critical importance and will need to be addressed in the protocol. The background document on existing international agreements which the Secretariat is to compile for the next meeting of the BSWG should assist participants in the negotiations to gauge the extent to which and ways in which these agreements may be applicable to the transfer of LMOs. The BSWG, in consultation with relevant organisations, could usefully identify the potential for these agreements to meet the objectives of the protocol, including the feasibility of modifying these agreements as appropriate to address the effects on biodiversity of LMOs.

41. Further consideration will also be required as to how the rights and obligations derived by any party from any existing international agreement might be affected by the protocol. In this regard the agreement reached at COP-2 (Annex to Decision II/5) that the protocol will, among other things, "not override or duplicate any other international legal instrument in this area" should be noted. For example, the outcome of negotiations on the protocol would need to ensure that the instrument does not derogate from the provisions of the Agreement Establishing the World Trade Organisation (WTO) or affect the rights and obligations of Members of the WTO.

42. One difficulty with negotiating a protocol dealing with the impact of LMOs on the conservation and sustainable use of biological diversity is determining how it should relate to existing agreements which deal, or may deal, directly or indirectly, with LMOs. Successive agreements could impose obligations which, whilst not inconsistent, apply to a particular subject in a different way. For example, a biosafety protocol could include a general obligation to notify the secretariat and other parties of the outbreak of a pest or disease resulting from the use of LMOs that adversely affect the conservation and sustainable use of biological diversity. Both the International Plant Protection Convention and Office International des Epizooties agreements contain requirements to notify their respective international authority on any new pest outbreak.

43. If the biosafety protocol is not to override existing international agreements, the ways in which it, or parts of it, could relate to other agreements include, but are not limited to, the following:

- It could seek only to fill "gaps" left by existing instruments by giving precedence to existing instruments, either generally or by referring to specific instruments;

- It could provide that the obligations imposed are additional to those of other agreements; or

- It could adopt or incorporate by reference parts of existing agreements.

44. Australia has undertaken a preliminary analysis of the capacity of a range of these agreements to meet the objectives of the biosafety protocol. This is set out in Attachment C and should be regarded as Australia's input to the background document which the Secretariat is to compile on existing international agreements, in accordance with paragraph 7 of the Progress Report Elaboration Of A Biosafety Protocol (UNEP/CBD/COP/3/27).

45. Australia has examined the following agreements: International Plant Protection Convention (IPPC); Office International des Epizooties (OIE); Codex Alimentarius; WHO Pharmaceutical Inspection Convention and Certification Scheme; and Agreement on the Application of Sanitary and Phytosanitary Measures (SPS).

46. This preliminary work suggests that these agreements could be interpreted as having some direct or indirect application to LMOs. But because the agreements have differing purposes and are not necessarily specifically concerned with potential risk to the environment, careful and more detailed analysis is required.

47. Furthermore, it should be noted that there are other international instruments that may also be relevant and applicable to LMOs. A number of these were identified in the Report of the Panel of Experts on Biosafety which met in Cairo from 1-5 May 1995 (see Annex II to Annex IV of document UNEP/CBD/COP/2/7).

48. It is also the case that there are many agreements aimed at the preservation or conservation of particular habitats, geographic locations, ecosystems and species of plant, animal and marine life which impose general obligations capable of applying to LMOs that could have an impact on the conservation and sustainable use of biological diversity. For example, the Ramsar Convention on Wetlands of International Importance (1971) imposes general obligations on parties to preserve wetlands and waterfowl, which would presumably cover the situation of a particular release of an LMO in a listed wetland which caused a change to the ecological character of that wetland.

49. This raises the question of how far one needs to go in assessing the operation of "other agreements" in analysing existing instruments "of relevance to the impact of LMOs resulting from modern biotechnology on the conservation and sustainable use of biological diversity". Do we need to examine all agreements that are relevant to the impact of LMOs? If not, where should the line be drawn?

## G. Institutional framework for the functioning of the protocol

50. The protocol should make provision for institutional arrangements for its implementation. These should be guided by the general principles of transparency, cost effectiveness and avoidance of the creation of unnecessary new institutions and mechanisms.

### Secretariat

51. There would not appear to be a particular case for the creation of a separate secretariat to service the protocol. The protocol should provide for this function to be performed by the Convention Secretariat. It should list the functions to be performed by the secretariat in a general and brief way, and there should be a general provision that parties to the protocol would contribute to the cost of secretariat services for the protocol.

### Conference of the Parties

52. The protocol would be required to have a decision making/governing body (a meeting of the parties). Australia considers the Convention's Conference of the Parties could serve concurrently as the meeting of the parties to the protocol. The differential voting procedure specified in Article 32.2 of the Convention limiting voting on decisions under any protocol to parties to the protocol would apply in this case.

53. Alternatively, the protocol could have its own meetings of a decision making/governing body. In this case the instrument would need to make provision for the creation of a separate meeting of parties to the Convention's Conference of the Parties. For reasons of administrative convenience and expense consideration could be given to scheduling its sessions immediately before or after those of the Convention. To minimise the possibility of confusion, it could be called something other than a Conference of the Parties, possibly a Meeting of the Parties. The new body could be given a list of functions, which could be based, among other things, on relevant provisions of Article 23 of the Convention.

### Subsidiary bodies

54. If a subsidiary body to provide scientific, technical and technological advice on biosafety is considered necessary, the protocol should provide that the Convention's Subsidiary Body on Scientific Technical and Technological Advice provide this function in a manner broadly similar to the provision of services to the Convention's COP. The cost of undertaking additional work should be met by the parties to the protocol. Representatives of countries not parties to the protocol should be enabled to participate in the work on biosafety of the SBSTTA (and meetings of the protocol), in accordance with Article 32.2 of the Convention.

## H. Settlement of disputes

55. At some stage, the BSWG will also need to focus on monitoring and enforcement mechanisms. The Convention contains a dispute resolution mechanism (Article 27) which is to apply to any protocol "except as otherwise provided in the protocol concerned."

## I. Amendment

56. Article 29 of the Convention applies to amendment of the Convention and protocols to the Convention. The protocol should therefore state that amendment shall take place in accordance with the provisions of Article 29. The amendment process should include provision for the simple amendment of any lists or annexes of LMOs given the dynamic nature of biotechnology developments.

## J. Final clauses

Provisional application

57. Consideration could be given to providing in the protocol for individual parties to be able to apply its terms provisionally (i.e. before it enters into force). Such a provision could be useful if delay were expected in entry into force. It would also allow states to move to begin meeting their commitments, if they so chose, when they faced long delays before joining the protocol because of domestic processes.

Entry into force

58. Article 36 of the Convention sets out the provisions for the entry into force of both the Convention and protocols to the Convention.

Adoption and amendment of annexes

59. Article 30 of the Convention sets out procedures for the adoption and amendment of annexes to the Convention and to protocols to the Convention. The amendment process should include provision for the simple amendment of any lists or annexes of LMOs given the dynamic nature of biotechnology developments.

Other issues

60. Other final provisions would include Signature, Consent to be Bound, Withdrawal, Authentic Texts, and Depositary.

# DEFINITIONS FOR KEY TERMS

**Living modified organisms (LMOs)**

Organisms or parts of organisms which are capable of propagation, in which the genetic material has been altered by techniques of modern biotechnology (that is, in a way that does not occur naturally by mutation, mating or natural recombination).

**Modern biotechnology**

The use of techniques such as recombinant DNA technology, molecular biology, cell or tissue culture, and cell fusion to modify the genetic material of organisms in ways that do not occur naturally by mutation, mating or natural recombination.

**Transboundary movement**

The transfer of LMOs across national boundaries.

**Competent authority**

See definition of designated national authority.

**Designated national authority**

A government authority designated by a Party to serve as the focal point and be responsible for communication between Parties and with any centralised data base or clearing house mechanism designated by the protocol in relation to any matter which is the subject of the protocol.

**Familiarity**

Knowledge of and experience with an LMO, an intended activity involving the LMO, and the potential receiving environment, which would enable a risk/safety assessment of that activity.

**Adverse effects**

Consequences of activities involving LMOs which are deleterious to the conservation and sustainable use of biological diversity. These effects may be direct or indirect, immediate or delayed.

**Contained use**

Any operation involving LMOs which are controlled by physical barriers or a combination of physical and biological barriers designed to prevent release of the LMOs into the open environment.

**Intended/deliberate release**

Intentional introduction of an LMO into the open environment, including for scientific or commercial purposes. This may take the form of a field trial or a general release.

**Field trial**

Introduction of an LMO into the environment with provisions for limiting the potential for uncontrolled dissemination or persistence of the LMO or its genetic material in the environment.

**General release**

Introduction of an LMO into the environment with no provisions for limiting the potential for uncontrolled dissemination or persistence of the LMO or its genetic material in the environment.

**Risk assessment**

The process of estimating what harm to the conservation and sustainable use of biological diversity might be caused by an LMO, how likely it would be to occur, and the extent of the harm, using scientific data and methodologies.

**Risk management**

The identification and implementation of the most appropriate measures to minimise identified risks.

**Biosafety**

The safe handling, transfer and use of LMOs which may have adverse effects on the conservation and sustainable use of biological diversity.

**Centre of origin**

The area in which a given taxonomic group of organisms originated and from which it has subsequently spread.

**Centre of genetic diversity**

A region where a particular taxonomic group of organisms exhibits greater genetic diversity than it does elsewhere.

**Accidental release**

Any incident involving an unintended release of LMOs in the course of their contained handling, transfer or use which could present a risk to the conservation and sustainable use of biological diversity.

**Open environment**

An environment in which containment of an LMO or its genetic material may not be possible.

ATTACHMENT B

# ADVANCE INFORMED AGREEMENT (AIA): RELEVANT TRIGGERING FACTORS

| FACTOR | AIA MAY BE REQUIRED | AIA MAY NOT BE REQUIRED |
|---|---|---|
| **Intended Use of LMO** | Released into the environment | Contained |
| **Introduced Characteristic of LMO** | Resistance<br>Tolerance<br>Fitness<br>Persistence<br>Pathogenicity | Quality<br>Performance |
| **Receiving Environment (RE)** | Centre of origin<br>Centre of genetic diversity | Exotic |
| **Familiarity in RE** | Limited | Extensive |
| **Reproductive Mechanism of LMO** | Outcrossing | Self-fertilising<br>Vegetative |
| [1]* **Regulated status of LMO in exporting country** | Regulated | Deregulated |

[1] * This factor *per se* may not determine the need for an AIA but may provide useful information which reinforces a decision based on consideration of the above factors

## EXPLANATORY COMMENTS RELATING TO AIA TRIGGER FACTORS

1. To operate efficiently and effectively any system of advance informed agreement (AIA) under the Biosafety Protocol would need to specify relevant criteria for triggering the AIA procedure.

2. One possibility for such a system would be to have a series of triggers which would alert companies or countries to the possible need for an AIA when importing or exporting certain categories of LMO.

3. Certain key factors relating to the LMO could serve as triggers for an AIA. Some of these factors are listed in the table above which also shows examples of the types of factors which may or may not trigger the need for an AIA.

4. In situations where the intention is to release the LMO into the environment, due consideration would need to be given to all the other listed factors relating to the LMO. The LMO would need to conform to certain specifications in relation to these other factors in order to avoid the need for an AIA.

5. The decision to require or waive an AIA should therefore not be based on the specification of a single factor but should only be made after consideration of the possible interactions between all factors. The factors should be considered simultaneously in making an overall assessment of whether an AIA procedure is required.

6. The comments below provide some background information which explains the rationale behind the proposed AIA triggering mechanism. The trigger factors discussed have been formulated in relation to genetically modified plants. For other categories of LMOs (such as microorganisms or animals) different trigger factors may be appropriate.

### INTENDED USE

7. Where an LMO is intended to be used under contained conditions, there would be less concern about the likelihood of the LMO posing a threat to biodiversity. Most instances of contained use will involve moderate to large-scale culture or fermentation of microorganisms such as bacteria or fungi for the production of pharmaceuticals, food or industrial chemicals. Obviously, the terms 'contained use' or 'containment' are difficult to define in absolute terms. For the purpose of negotiating the modalities of a Biosafety Protocol, there needs to be an internationally-acceptable standard for 'contained use'. The Good Industrial Large Scale Practice (GILSP) system developed by the OECD could constitute a basis for such a standard.

8. Where an LMO is intended to be released or introduced into the environment (the receiving environment), there is an obvious need to consider whether it is likely to present any threat to the conservation or sustainable use of biodiversity. An example of such a threat would be the large scale cultivation of an out-crossing genetically modified plant, containing a selectively-advantageous gene, in close proximity to a related pest species growing around the cultivated area.

9. Close proximity could be operationally defined as closer than the separation distance which is used by plant breeders and seed growers to ensure that cross pollination with related plants is minimized. If the trait that could pass to wild populations is of relatively low risk (e.g. some aspect of fruit quality) then a smaller separation distance might be acceptable than if the trait that might be passed was, say, herbicide resistance to a wild population which was

already exhibiting a tendency to weediness. In the latter case, a larger separation distance would be required. The outcrossing of a transgene which conferred a selective advantage (e.g. drought resistance or salt tolerance) to a related pest species could result in proliferation of the pest species under adverse conditions and displacement of important indigenous species.

10. The intended scale of release of the LMO is also a factor which could be considered in determining whether AIA is required or not.

## INTRODUCED CHARACTERISTIC

11. If the LMO to be released contains a novel gene (transgene) which endows it with some selective advantage in the receiving environment, there would be reasonable cause to scrutinise it for possible adverse effects on the conservation and sustainable use of biodiversity.

12. Such novel genes could include, for example, those which confer resistance or tolerance to herbicides or insecticides, or increased fitness or persistence (e.g. salt or drought resistant) in the receiving environment.

13. The nature of the reproductive system of the LMO (see below), and the presence of related pest species in the receiving environment, are major factors in determining whether the release of an LMO is likely to pose any threat to biodiversity.

14. In the case of an LMO containing a transgene which modulates the quality of the LMO or its products (such as fruit or seed), there might appear to be less cause for concern about any potential threats to biodiversity. Example of such LMOs are tomatoes in which ripening has been delayed, cereals in which the amino acid composition has been modified or ornamental plants in which flower colour has been altered.

15. Despite the apparently benign nature of these modified characteristics, there may be situations where outcrossing of the transgenes to related species in the receiving environment may pose some threat to biodiversity. For example, modified flower colour in related plant species may have an effect on the behaviour or persistence of insects which pollinate the normal species.

16. Any risks relating to the conservation and sustainable use of biodiversity could be realised if close relatives of the LMO inhabit the vicinity of the release site and are capable of cross breeding with the LMO. There may also be risks associated with the introduction, into a particular receiving environment, of an LMO which itself may be capable of becoming a pest, e.g. because of increased fitness resulting from the introduced trait. Factors such as these are primary considerations in risk assessment and risk management.

## RECEIVING ENVIRONMENT

17. The receiving environment is intended to mean not only the geographical area in which the LMO is to be propagated, domesticated or used in some particular way, but also includes the natural flora and fauna in the surrounding vicinity.

18. For many animals and plants, particularly agricultural varieties, there is an obvious centre of origin which is the geographical area from which a given taxonomic group of organisms has originated and spread.

19. Many authorities believe that the centre of origin is also the centre of genetic diversity for a particular taxon where it exhibits greater genetic diversity than it does anywhere else.

20. Obviously, if an LMO is introduced into the centre of origin of the parental organism there is a likelihood that it could have an impact on the conservation and sustainable use of biodiversity. The likelihood and nature of any potential impact on biodiversity would be determined by the novel characteristic in the LMO, the reproductive mechanism of the LMO and the proximity of related native species.

21. The introduction of an LMO into a region which is not a centre of origin for that particular species, is less likely to have an adverse effect on the natural biodiversity of the parental species. In this situation, a possible adverse impact which might occur would be the displacement of other native species by ecological competitiveness of the LMO itself. Alternatively, outcrossing of a selectively advantageous transgene to a related, but non-indigenous, weed species might increase the competitiveness of the weed and thereby threaten biodiversity. The objective of risk assessment, in this situation, would be to ensure that control of the related pest species is not compromised by the acquisition of a selectively-advantageous transgene, e.g. for herbicide resistance.

22. In this situation, there would be a need to examine the likelihood and consequences of transgene flow from the LMO to the pest species. These considerations would take into account such factors as the nature of the novel characteristic in the LMO, the reproductive mechanism and the proximity of the LMO and the related species.

## FAMILIARITY

23. Familiarity is generally defined as the accumulated knowledge and experience relating to an organism, its uses and the environment in which it is normally propagated or domesticated.

24. Familiarity with an LMO obviously increases with increased trialing and use of the LMO in the environment in which the natural counterpart (parent) of the LMO has been cultivated or domesticated for an extended period of time.

25. Increased familiarity does not necessarily mean increased safety. In certain instances it may indicate that some initially perceived risks were unfounded whereas others may be substantiated. Increased familiarity may also highlight risks which were not initially recognised or perceived.

26. There would be minimal familiarity in the situation where an LMO is introduced into a receiving environment in which the parental organism had not been previously cultivated or domesticated.

27. Such a situation is essentially analogous to the introduction of an alien species and a precautionary approach would be warranted.

## REPRODUCTIVE MECHANISM

28. The process or mechanism by which an LMO reproduces itself is a major factor in determining its likelihood of posing a threat to biodiversity. Different categories of organisms can have substantially different reproductive mechanisms.

29. Asexual reproduction involves the multiplication of an individual without the need for interaction (conjugation) with another individual of the same species. Asexual reproduction is

generally referred to as vegetative reproduction (in plants) or parthenogenesis (in animals, mainly insects).

30. Microorganisms such as bacteria, yeast and fungi normally reproduce asexually. They can also differentiate into reproductive forms, such as spores, which are able to survive adverse environmental conditions, and subsequently germinate, under appropriately conducive conditions, to ensure their survival.

31. LMOs which are microorganisms, such as bacteria which have been genetically modified to degrade xenobiotic compounds (bioremediation agents), could pose a threat to microbial biodiversity, under selectively advantageous conditions, by displacing endogenous beneficial microorganisms occupying the same ecological niche.

32. The following discussion and examples are largely based on the reproductive mechanisms of plants. Plants exemplify the diverse range of reproductive mechanisms found among living organisms. Plants also represent the major class of LMOs which have been developed, trialed and commercialised to date.

33. An LMO which reproduces asexually may pose a threat to biodiversity if its transgene confers increased fitness or tendency to weediness.

34. Sexual reproduction involves the fusion of gametes (sex cells; sperm/pollen and ova) from two individuals (male and female; donor and recipient) of the same species and consequent reassortment of the genes of both parents in the resultant offspring or progeny.

35. In plants, sexual reproduction may involve several distinct mechanisms. These may range from obligatorily self-fertilising plants (cleistogamous) to obligatorily out-crossing plants.

36. Obviously, an LMO which is cleistogamous poses no threat to a related species in the receiving environment since it is self fertilising and therefore cannot transmit its transgene. An LMO which is cleistogamous could present some threat to biodiversity in situations where the LMO itself has the capacity to become a weed. Establishment of the LMO in natural ecosystems may lead to displacement of important native species.

37. An LMO which is out-crossing may also pose a threat to biodiversity. If it is obligatorily out-crossing, such an LMO is capable (and likely) to transfer its transgene to any related species that may be present in the receiving environment. The LMO itself may also become a weed.

**REGULATED STATUS**

38. There are currently about 60 types of plant LMO in various phases of development in some 30 countries worldwide.

39. The majority of these are food, fibre or ornamental plant varieties. Relatively few of these have yet progressed through experimental and field-testing phases to commercialization.

40. The deregulation of an LMO generally means that it has been subjected to a sound scientifically-based risk assessment via a step-wise series of increasingly-sized field trials and has been considered safe to cultivate on a normal commercial scale. Risk assessment leading to deregulation involves very careful consideration of the receiving environment in which the LMO will be commercially cultivated.

41. A risk assessment based on a particular receiving environment cannot necessarily be assumed to be valid for a different receiving environment. In addition, there may be countries in which an LMO is deregulated without a proper risk assessment having been carried out. Hence the deregulation of a particular type of LMO, e.g. insect-resistant cotton, in one country should not be assumed to mean that it would be automatically deregulated in another country. Similarly, restrictions or bans in one country on a particular LMO should not automatically mean that the LMO should be treated in the same way in another country with a different receiving environment.

# LMOs AND EXISTING AGREEMENTS AND ARRANGEMENTS

1. This paper is submitted in accordance with the agreement of the first meeting of the Ad Hoc Group on Biosafety (BSWG1) that governments could contribute to the background document to be prepared by the secretariat on existing international agreements that may be relevant to a biosafety protocol.

2. The purpose of this paper is to examine a number of existing international agreements that may be relevant and applicable to the impact of LMOs resulting from modern biotechnology on the conservation and sustainable use of biological diversity. The extent to which and way in which existing international agreements may be applicable to the transfer, handling and use of LMOs resulting from modern biotechnology will clearly have a significant bearing on the identification of gaps in the existing legal framework.

3. Australia has examined the following agreements:

I. International Plant Protection Convention (IPPC);

II. Office International des Epizooties (OIE);

III. Codex Alimentarius;

IV. WHO Pharmaceutical Inspection Convention and Certification Scheme; and

V. Agreement on the Application of Sanitary and Phytosanitary measures (SPS).

4. This paper focuses on the coverage and institutional mechanisms of these agreements with a view to determining whether the agreements currently deal, or could be adapted to deal, with LMOs resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity. It should also be recognised that the coverage of these agreements may, over time, be expanded to accommodate developments in new technology, including modern biotechnology, that are relevant to achieving their objectives.

5. Furthermore, it should be noted that there are other international instruments that may also be relevant and applicable to LMOs' resulting from modern biotechnology. A number of these were identified in the Report of the Panel of Experts on Biosafety which met in Cairo from 1-5 May 1995 (see Annex II to Annex IV of document UNEP/CBD/COP/2/7).

6. The agreements listed in paragraph 3 above are concerned primarily with arrangements and mechanisms for controlling the transfer across national borders of pests and diseases. A number of these agreements provide:

- a mechanism to establish standards and norms in relation to the transfer of products across national boundaries;

- for international cooperation to share information in advance of transboundary movements;

- for international or regional reporting of adverse episodes or events; and

- a mechanism to ensure information is available about findings and actions taken in response to an adverse episode or event.

7. The approach taken to examining the specific agreements listed in paragraph 3 has been to concentrate on the following questions:

a. What is the objective of the international agreement?

b. To what extent, if any, does the international agreement cover LMOs resulting from modern biotechnology?

c. Is the international agreement currently being applied, or could it be applied, to the oversight of LMOs resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity?

d. What obligations or disciplines contained in the international agreement could be assessed as being relevant to the Terms of Reference for the Biosafety Protocol negotiations?

e. Is the international agreement currently being revised/renegotiated, or when will the next revision/renegotiation be undertaken? What is the expected timing for completing such revisions/renegotiations? Is it expected that the next revised text of the international agreement will address the impact of LMOs resulting from modern biotechnology on the conservation and sustainable use of biological diversity?

## I. International Plant Protection Convention (IPPC)

8. The primary objective of the IPPC is to protect plants and plant products from "pests", particularly by minimising the risk of the international spread of pests across national boundaries. It operates by requiring members to establish national plant protection organisations, enabling them to establish standards to regulate international trade in plants and plant products in order to provide protection against specific risks associated with "pests" (subject to certain requirements such as those specified in Article VI.2), requiring them to communicate relevant requirements to other parties and requiring them to cooperate with other members by exchanging information, reporting outbreaks of pests etc.

Current application to LMOs resulting from modern biotechnology

9. The IPPC does not specifically refer to LMOs resulting from modern biotechnology. It applies to "pests", which are defined as "any form of plant or animal life, or any pathogenic agent, injurious and potentially injurious to plants or plant products" (Article II.2). This definition, whilst developed before the advent of LMOs resulting from modern biotechnology, would appear to include LMOs resulting from modern biotechnology, but only in so far as they posed a threat to plant life. It would not cover LMOs resulting from modern biotechnology that threatened animal and other non-plant life.

Relevant obligations

10. The IPPC's concern is the spread of pests as a result of the transfer of goods across national boundaries, particularly associated with international trade in plants and plant products. It allows importing States to regulate the transfer of "pests" as defined in the Convention including those which are LMOs resulting from modern biotechnology. Each party to the Convention is required to develop and circulate to other parties its own phytosanitary standards to govern imports of plants and plant related material. These

standards entail the listing of prohibited plant materials and plant pest or disease organisms. The standards are published and distributed among IPPC parties.

11. The IPPC does not focus exclusively on the rights and obligations of importing States. The obligations of exporting states include the requirement that they prepare phytosanitary certificates (in the form annexed to the Convention), in which they must certify that the goods covered by the certificate are free from quarantine pests, practically free from other injurious pests and otherwise comply with the importing state's phytosanitary standards. "Quarantinable pests" means a pest of potential national economic importance to the country endangered thereby and not yet present there, or present but not widely distributed and being actively controlled (Article II.2). The exporting state would not, however, be under any obligation to determine whether any organism would constitute a "pest" in a particular importing country or assess the risk of release of pests in the importing country. The onus is on the importing state to determine which pests and diseases it wishes to control or exclude. The exporting state need only certify that the products comply with the requirements of the importing state.

12. For example, if, in the case of import of LMOs resulting from modern biotechnology, the importing country required additional information about the processes used in the genetic modification process, or did not wish to accept goods produced by particular processes or containing particular genetically modified material, it could include those requirements in its regulatory framework, provided they were relevant to the control of "pests". If those requirements satisfied other requirements of the IPPC they would have to be complied with by other member states. It would be possible for the importing state, subject to the requirements contained in the IPPC, to require that the description of the goods in the phytosanitary certificate include a reference to any genetic modification process or the use of genetically modified pest control agents.

13. Under the SPS Agreement, SPS measures which conform to international standards, guidelines or recommendations are deemed to be necessary to protect human, animal or plant life or health and are presumed to be consistent with the relevant provisions of that Agreement and of GATT 1994. "International standards, guidelines and recommendations" are defined to include, in relation to plant health, those developed under the auspices of the Secretariat of the IPPC . If parties to the SPS Agreement propose to impose import restrictions which deviate from those international standards, guidelines or recommendations, they are obliged to notify other members of the extent to which they deviate from them.

Possible Implications for the Biosafety Protocol Negotiations

14. It should be noted that in its application of the IPPC in Australia, the Australian Quarantine and Inspection Service (AQIS), does not treat genetically modified products differently from any other goods. The only relevant consideration in the imposition of conditions on proposed imports is the pest and disease status and risk of the products.

15. The IPPC has been in force for a considerable period of time and most parties would already have in place a regulatory framework and an administrative apparatus for its implementation (e.g. quarantine system). Could those mechanisms be adapted to cover LMOs resulting from modern biotechnology?

16. Do any countries address the question of LMOs resulting from modern biotechnology specifically in their quarantine/phytosanitary regulations?

17. The IPPC is currently in the process of being revised. Consideration could be given to whether and, if so, how an amended IPPC could specifically address the question of LMOs resulting from modern biotechnology.

## II. Office International des Epizooties/International Office of Epizootics (OIE)

18. The OIE was established by the International Agreement for the Creation at Paris of an International Office for dealing with Contagious Diseases of Animals (1924). Its primary objective is to limit the spread of diseases of animals. To advance this objective the Office coordinates research into contagious diseases, provides members with information about diseases and means of controlling them, develops standards for adoption by countries in their national import controls (International Animal Health Code), develops standards for diagnostic tests and vaccines, provides members with information about the regulatory framework for disease management of other members and assists developing countries to develop disease control infrastructure. Member States are obliged to notify the Office of outbreaks of various specified diseases. Up-to date information about diseases is disseminated in the weekly, monthly and annual publications. There are also plans to make information available by Internet.

Current application to LMOs resulting from modern biotechnology

19. At present, none of the diseases dealt with by the OIE is known to have been generated by LMOs resulting from modern biotechnology. However, if in the future such animal diseases did develop, the OIE would appear to provide an adequate mechanism, or could be adapted to provide an adequate mechanism, for limiting their international spread. The OIE, as currently constituted, could deal with those LMOs resulting from modern biotechnology which are associated with or relevant to diseases of animals and agents for management and eradication of diseases of animals. It would not appear to apply to LMOs resulting from modern biotechnology that related to plant life.

Relevant obligations

20. The notification provisions of the agreement apply to lists of specified diseases, which may be amended or augmented as required. If genetically engineered material posed a threat to animal health, the OIE could assist in minimising that threat by disseminating information about it internationally. It could, in principle, assist in controlling both the transfer and movement of LMOs resulting from modern biotechnology where they were relevant in some way to the control of listed diseases. The effectiveness of the OIE in combating the spread of disease is very much dependent on the exchange of information through the Office's central bureau.

21. The standards for import control developed by the OIE and which are contained in the International Animal Health Code are given specific recognition in the SPS Agreement. That agreement provides that in relation to animal health, and zoonoses, "the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics" are deemed to be necessary to protect animal life or health and are presumed to be consistent with the relevant provisions of that Agreement and of GATT 1994.

22. The OIE also works, in conjunction with aid agencies of member countries, to assist developing countries develop their disease control infrastructure. The experience of this capacity-building work could provide helpful guidance to the Open-ended Ad Hoc Working Group in its deliberations on capacity-building.

Possible Implications for the Biosafety Protocol Negotiations

23. Consideration should be given to whether any notification and information exchange mechanisms of a biosafety protocol would be subject to or would coexist with (and thereby duplicate) those of the OIE in so far as they dealt with LMOs resulting from modern biotechnology associated with diseases of animals. (This is a specific example of the more general problem of how the protocol should relate legally to other agreements, which is discussed below).

## III. Codex Alimentarius (CA)

24. The intention of Article 19.3 of the CBD and COP-2's decision suggest that a biosafety protocol would not address aspects of risks to human health. If, however, human health risks were to be addressed, Codex Alimentarius and the WHO Pharmaceutical Inspection Convention and Certification Scheme could be relevant. In any case, it is suggested that the mechanisms contained in these agreements could warrant examination as institutional models which may possibly be applicable to transboundary movement of LMOs resulting from modern biotechnology.

25. The Codex Alimentarius System is an international mechanism for the setting of food standards, codes, guidelines and recommendations. The standards are developed by a system of expert committees. Members of the CA Commission are not legally bound to adopt the standards nationally, but often are guided by the work of the CA in development of their national standards.

Current application to LMOs resulting from modern biotechnology

26. To date, Codex standards, guidelines or recommendations have not specifically addressed the use of LMOs resulting from modern biotechnology. There appears to be no reason why the standards developed by the CA Commission would not apply to LMOs resulting from modern biotechnology that are used in the production of food for human consumption. The standards are, however, developed with a focus on human health and not in relation to the conservation and sustainable use of biological diversity.

Relevant obligations

27. Members are not required to adopt Codex standards. The CA system does not purport to control the international movement of goods. Rather, it works to assist members to regulate food standards nationally, including the setting of any consequential import restrictions.

28. Under the SPS Agreement, SPS measures which conform to international standards, guidelines or recommendations are deemed to be necessary to protect human, animal or plant life or health and are presumed to be consistent with the relevant provisions of that Agreement and of GATT 1994. "International standards, guidelines and recommendations" are defined to include those established by the Codex Alimentarius Commission "relating to the food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice". If members of the SPS Agreement propose to impose import restrictions which deviate from those international standards, guidelines or recommendations, they are obliged to notify other members of the extent to which they deviate from them.

29. The question of whether Codex should deal with LMOs resulting from modern biotechnology, particularly in the context of labelling, is a matter currently the subject of debate within the Commission.

## IV. WHO Pharmaceutical Inspection Convention

30. The objective of the Pharmaceutical Inspection Convention is to minimise risks to human health posed by pharmaceutical products by ensuring that pharmaceutical products are manufactured in accordance with appropriate standards. To achieve this objective the Convention requires members to exchange information necessary for mutual recognition of inspections relating to pharmaceutical products, to supply to other members at their request certain information about pharmaceutical manufacturing standards and processes and to notify other members of situations where a pharmaceutical product is of "imminent and serious danger to the public".

Current application to LMOs resulting from modern biotechnology

31. The Convention does not refer specifically to LMOs resulting from modern biotechnology. However, it would, in principle, apply to all LMOs resulting from modern biotechnology associated with pharmaceutical products. The Convention defines pharmaceutical products as "any medicine or similar product intended for human use..." and any product used in the manufacture of such a product. The Convention would therefore not apply to medicines for animals. Nor would it have application to any other situations where the production of LMOs resulting from modern biotechnology had implications for the conservation and sustainable use of biological diversity.

Relevant obligations

32. The requirements of this Convention on states producing LMOs resulting from modern biotechnology for pharmaceutical purposes are very limited. It does not seek to govern either the intended or the unintended transboundary movement of pharmaceutical products. Nor does it require states to guarantee the quality and safety of products produced within their territory or to notify importing countries of risks (other than where there is a danger to public health). It merely provides importing countries with the right to obtain certain information about the way in which pharmaceutical products are manufactured and about manufacturing standards. It does not impose requirements on the release or handling of pharmaceutical LMOs resulting from modern biotechnology in the countries in which they are produced and there are no general obligations on manufacturing states to refrain from activities likely to cause damage outside the limits of territorial jurisdiction.

33. Although there is no explicit requirement for manufacturing states to carry out any risk assessment in relation to the production of LMOs resulting from modern biotechnology, it is probably implicit in the nature of the obligations imposed on "competent authorities" of member states that they are required to make some assessment of the standards and safety of the manufacturing processes (but not necessarily of the products themselves).

Possible Implications for the Biosafety Protocol Negotiations

34. The scope of this Convention does not appear to be relevant to the impact of LMOs resulting from modern biotechnology on the conservation and sustainable use of biological diversity, unless human health were regarded as being encompassed by that term. It may

nevertheless warrant consideration as a possible model for mutual inspection and recognition procedures that might form part of a biosafety protocol.

35. Consideration could be given to the extent to which, if at all, this Convention requires member states or their authorities to assess the risk associated with products and the extent to which it enables other members to obtain meaningful information about such assessments.

36. In the practical application of this agreement have parties sought information about pharmaceutical LMOs resulting from modern biotechnology and the processes used to produce them?

37. Do the mechanisms of this Convention provide access to information sufficient for members to undertake their own risk assessment and management of the produced LMOs resulting from modern biotechnology?

## V. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

38. The SPS Agreement was concluded as part of the package of Agreements establishing the World Trade Organisation. The SPS Agreement defines the basic rights and obligations of member countries with respect to taking 'sanitary and phytosanitary measures' to protect human, animal or plant life or health.

Current application to LMOs resulting from modern biotechnology

39. The measures covered by the Agreement do not specifically refer to LMOs resulting from modern biotechnology but would apply to any LMOs resulting from modern biotechnology that could be regarded, on the basis of scientific evidence, as a threat to human, animal or plant life or health.

Relevant obligations

40. The primary focus of the SPS Agreement is on the conditions under which sanitary and phytosanitary measures can be imposed by importing states. Such measures must be based on 'scientific principles' and 'not maintained without sufficient scientific evidence' (except where adopted provisionally on the basis of available information while seeking to obtain additional information for 'a more objective assessment' to review the measure 'within a reasonable period of time'). The term "sanitary and phytosanitary measure" is defined very broadly to include measures applied to protect animal, plant life or health within the territory of the member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; from risks arising from additives, contaminants toxins, or disease-causing organisms in food, beverages and foodstuffs; from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or to prevent or limit other damage within the territory of the member from the entry, establishment or spread of pests. These definitions are contained in Annex A to the Agreement where it is noted that for the purposes of these definitions "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticides and veterinary drug resides and extraneous matter.

41. Members must base their 'sanitary and phytosanitary measures on international standards, guidelines or recommendations, where they exist', but may impose a 'higher level' than these in some cases. Members must also accept measures imposed by other members as

equivalent - even if different from their own - provided the other member demonstrates that its measures provides an 'appropriate level of sanitary or phytosanitary protection'.

42. Members must ensure their measures are based on an assessment of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations (i.e. the Office International des Epizooties (OIE) for animals and the International Plant Protection Convention (IPPC) for plants). In assessing risks, 'members shall take into account available scientific evidence; prevalence of specific diseases or pests, existence of pest - or disease free areas; relevant ecological and environmental conditions; and quarantine or other treatment'.

43. Members may take into consideration 'relevant economic factors: the potential damage in terms of lost production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing member; and the relative cost-effectiveness of alternative approaches to limiting risks'. Members must ensure that measures are 'not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility'. To achieve transparency, members must notify changes in their sanitary or phytosanitary measures which may affect transfer of goods across national boundaries and provide copies on request to other members.

Possible Implications for the Biosafety Protocol Negotiations

44. The SPS Agreement is aimed at establishing the conditions for using sanitary and phytosanitary measures to protect human, animal or plant life or health from risks posed by the transfer of goods across national boundaries. Accordingly, it appears that the SPS Agreement addresses transfers of LMOs resulting from modern biotechnology but does not cover unintended movements of LMOs resulting from modern biotechnology. There are no obligations imposed on exporting states to refrain from activities likely to cause damage outside the limits of territorial jurisdiction or to make any assessment of the risk posed by material produced within its borders. The Agreement does not seek to regulate the handling or use of goods in the state in which they are produced.

45. It follows that it does not impose any requirement resembling advance informed agreement (AIA) for transfer of goods or for provision or exchange of information about risks associated with products. However, the agreement does not exclude the possibility of importing states adopting SPS measures which require exporting states to provide specified information as a condition of import of LMOs resulting from modern biotechnology that would enable them to make informed decisions about risks of importation. In addition, under the SPS Agreement, permission to import could legitimately be denied if insufficient information about the product was provided by the exporter.

46. The SPS Agreement provides that SPS measures which conform to international standards, guidelines or recommendations are deemed to be necessary to protect human animal or plant life or health and are presumed to be consistent with the relevant provisions of that Agreement and of GATT 1994. Those international standards, guidelines and recommendations are defined to include those produced by the Codex Alimentarius Commission, the Office International des Epizootics and the Secretariat of the International Plant Protection Convention, each of which are discussed above. Consideration could be given to how this relationship could be extended to cover the issues under negotiation in the biosafety protocol context, particularly in recalling that the terms of reference for the

Open-ended Ad Hoc Working Group provide that the biosafety protocol should not "override" existing agreements.

**Other Agreements of limited membership**

45. In addition to the conventions outlined above, which have a broad (but not universal) membership, there are a plethora of environmental protection agreements with limited membership (including regional and bilateral instruments) which may be relevant to the international management of LMOs resulting from modern biotechnology. Many agreements aimed at the preservation or conservation of particular habitats, geographic locations, ecosystems and species of plant, animal and marine life impose general obligations which could apply to LMOs resulting from modern biotechnology that could have an impact on the conservation and sustainable use of biological diversity. For example, the Ramsar Convention on Wetlands of International Importance (1971) imposes general obligations on parties to preserve wetlands and waterfowl, which would presumably cover the situation of a particular release of an LMO resulting from modern biotechnology in a listed wetland which caused a change to the ecological character of that wetland. Many other examples could be provided.

46. This raises the question of how far one needs to go in assessing the operation of "other agreements" in analysing existing instruments "of relevance to the impact of LMOs resulting from modern biotechnology on the conservation and sustainable use of biological diversity". Do we need to examine all agreements that are relevant to the impact of LMOs resulting from modern biotechnology ? If not, where should the line be drawn? It also leads to the important legal question of how a biosafety protocol would or could relate to other agreements addressing the same subject matter.

**Legal Relationship between successive treaties dealing with the same subject matter.**

47. One difficulty with negotiating a protocol dealing with the impact of LMOs resulting from modern biotechnology on the conservation and sustainable use of biological diversity is determining how it should relate to existing agreements which deal, or may deal, directly or indirectly, with LMOs resulting from modern biotechnology. There is clearly scope for provisions of various agreements to conflict. In addition, successive agreements could impose obligations which, whilst not inconsistent, apply to a particular subject in a different way. For example, a biosafety protocol could include a general obligation to notify the secretariat and other parties of the outbreak of a pest or disease resulting from the use of LMOs resulting from modern biotechnology that adversely affect the conservation and sustainable use of biological diversity. Notification provisions are also contained in both the IPPC and OIE agreements.

48. The terms of reference for the Open-ended Ad Hoc Working Group provide that the Protocol will not override or duplicate any other legal instrument (COP-2 decision II/5, paragraph 5(b)). However, if the Protocol were drafted in such a way that it did not expressly supplant or override the notification requirements of the other agreements, there could be an administratively inconvenient duplication of notification requirements. That is, if the new protocol cannot override existing agreements, it may have to duplicate them, at least to some extent. The difficulties become more pronounced in situations where the membership of the various agreements is not uniform.

49. Careful consideration will therefore need to be given to the way in which a new protocol would relate to existing agreements (and to future agreements). If the biosafety

protocol is not to override existing agreements, the ways in which it, or parts of it, could relate to other agreements include, but are not limited to, the following:

- It could seek only to fill "gaps" left by existing instruments by giving precedence to existing instruments, either generally or by referring to specific instruments;

- It could provide that the obligations imposed are additional to those of other agreements; or

- It could adopt or incorporate by reference parts of existing agreements.

50. Clearly, before making judgments about the relationship between the existing international agreements and any new protocol, a clear picture of the scope of the coverage of existing instruments is a vital first step.

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# CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Second Meeting
Montreal, Canada
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**BELARUS**

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# Comments of the Republic of Belarus on the future Protocol on Biosafety

The Republic of Belarus has examined the proposals on the possible contents of the future Protocol on Biosafety and consider possible to note the following:

1. In most cases items of the future protocol are presented only in particular but in all the proposals, in the majority of cases they do not contradict each other. In some cases they determine similar definitions ( for example "Transport and packaging requirements for the transfer of LMOs"),the other cases include definitions complemented of one another or terms extended the contents of some broader categories. The last refer to categories connected with the procedure of Advanced Informed Agreement (AIA). For that reason the Republic of Belarus has the honour to make a proposal the Secretariat to systematize the proposed provisions of the future Protocol giving particular attention to that having intrinsic difference. That provides the grounds for using the Proceedings of the UNEP meetings in Madrid, 1995 and Aarhus, Denmark, 1996.

2. The Republic of Belarus consider important to present it's standpoint on the following item of the future Protocol lacking clarity: necessity for precise identification of organisms to be covered by the Protocol.

For the time being it is being used a wide range of terms and definitions that mostly can not be recognized as easily understandable because they need special explanations. Let us examine the definition "Living modified organisms resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity - LMOs. Article 19(3), Convention on Biological Diversity). Some used terms need additional explanations. Thus, the definition "modified" must be interpreted as "genetically modified organisms resulting from modern biotechnology without applying traditional techniques of breeding: distant and intraspecific hybridization, experimental polyploidy and mutagenesis. The definition "modern biotechnology" means "genetic engineery" etc.

The definition "genetically modified organisms-GMOs) (Report of UNEP Expert Panel IV) has the similar imperfection and might be misunderstood without an additional explanation specifying what sort of genetic modification takes place in each particular case. Furthermore, it should be stressed the fact that all that organisms are not the result of traditional methods of breeding.

The definition "organisms with novel traits" used in the UNEP "International Guidelines for Safety in Biotechnology" seems to be the most imperfect. Is it possible, for example, to give an adequate answer to the question if virus resistancy can be considered a novel trait ? It is known that this trait can be transferred to an organism by virtue of traditional technique or methods of genetic engineery.

The term "biosafety" itself is the result of creation of novel types of organisms do not occur naturally but originated from well studied organisms (i.e. organisms modified using recombinant DNA techniques). In scientific literature they are known as "transgenetic organisms". A wider definition "Genetically engineered organisms-GEOs) appeared not long after. It means that organisms are produced through using different techniques of directed modification of genetic structure and/or genetic activity of some particular genes - genetic engineery. It is genetic engineery that provides new possibilities to produce novel gene combinations do not occur naturally. Creation of such organisms evokes public

anxiety caused by probable unknown consequences that might adversely affect the environment and human health.

We do believe the definition "Genetically engineered organisms-GEOs" should comprise with organisms to be covered by the future Protocol on Biosafety. This definition completely corresponds to the full scope of the above organisms and does not require any additional elucidations (e.g. it is a self-explanatory definition).

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**BOLIVIA**

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# CRITERIOS DE BOLIVIA SOBRE EL CONTENIDO DEL PROTOCOLO DE BIOSEGURIDAD

## Aspectos socioeconómicos

Este tema debe ser incluido en el contenido del protocolo porque el mismo debe evaluar todas las consecuencias, amenazas al medio ambiente, la salud humana, y así como las repercusiones socioeconómicas derivadas de la liberación de organismos vivos modificados genéticamente en el medio ambiente.

Por otra parte, la utilización sostenible de la diversidad biológica, particularmente en el caso de plantas y animales domésticos, depende de las condiciones socioeconómicas de las personas que las han desarrollado y conservado a través de generaciones, de ahí que la introducción de tecnologías de ingeniería genética y organismos vivos modificados genéticamente en los países con rica diversidad genética y biológica no solo puede provocar el menoscabo de las mismas, sino que también puede traer amenazas a la situación económica de dichas personas, lo que provocaría también la discontinuidad de los sistemas agrícolas y la consiguiente erosión genética, entre otra consecuencias.

En lo referente a los mecanismos de evaluación de riesgos y de evaluación de impacto ambiental, los mismos deben también tener un componente que se encargue de los aspectos socioeconómicos.

## Responsabilidad e indeminización

El Protocolo debería imponer responsabilidades por cualquier daño o pérdida en la diversidad biológica, la salud humana y el medio ambiente producto de la liberación de organismos genéticamente modificados, estableciendo para ello mecanismos que permitan probar los daños y pérdidas causadas por parte del país o institución que libera el organismo genéticamente modificado. De ahí que la responsabilidad primaria por cualquier consecuencia con relación a un organismo vivo genéticamente modificado debe ser del que libera el OGM.

## Creación de capacidad

Dado que la mayoría de los países se encuentran en un proceso de desarrollo de la capacidad nacional para la gestión de la seguridad en la biotecnología y en muchos casos están iniciando dicho proceso, es importante que en el Protocolo se tome en cuenta este aspecto donde se exhorte a los países y organismos internacionales con experiencia en el tema a brindar apoyo y cooperación con miras al desarrollo y fortalecimiento de este aspecto, lo que permitiría una adecuada evaluación y gestión de los riesgos.

## Intercambio de información.

Si bien en el párrafo 4 del artículo 19 de la Convención sobre la Diversidad Biológica se establece que la información acerca de las reglamentaciones relativas al uso y la seguridad requeridas por cada país Parte para la manipulación de OGMs, así como la información disponible sobre los posibles efectos

adversos de los organismos genéticamente modificados debe ser intercambiada; es de suma importancia que el Protocolo establezca la creación de un Sistema mundial de información que permita de forma transparente el intercambio de la misma entre los países que así lo requieran. Articulando para ello toda la información disponible actualmente en los diferentes países, organismos (OECD, UNIDO, UNEP, BAC, BINAS, entre otros ) así como en las diferentes instituciones científicas y empresas o transnacionales que trabajan con organismos genéticamente modificados.

**Sensibilización del público**

La inclusión de este tema en el protocolo es de gran importancia, debido a que la educación al público es un factor importante para la prevención de los riesgos que podrían provenir de la liberación y uso de organismos genéticamente modificados, así como para evitar problemas de malos entendidos entre la sociedad civil por falta de información y educación adecuadas.

Por otro lado, el Protocolo debe garantizar la participación del público poniendo a disposición del mismo los resultados de los ensayos o las supervisiones realizadas como parte del proceso de aprobación por parte de las autoridades. El público debe ser informado con anterioridad sobre cualquier intento de liberación de organismos genéticamente modificados, incluyendo el lugar y la extensión de dicha liberación.

El Protocolo también debe establecer que el público deberá contar con las más amplias posibilidades de exponer sus opiniones sobre la información proporcionada antes de que se apruebe la utilización o liberación del organismo genéticamente modificado.

**Mecanismo de Arbitraje o supervisión internacional**

Para impedir obstáculos a las reglamentaciones de control de las exportaciones con respecto a la transferencia de organismos genéticamente modificados, sería necesario establecer un órgano de supervisión internacional para mantener la transparencia, este órgano debería llevar el registro de todas las transferencias de OGMs, que fuera abierto al público.

Para la delimitación de responsabilidades sobre las consecuencias derivadas de la liberación de OGM's de las cuales se quiera eludir responsabilidad por parte del país exportador, sería también necesario establecer un mecanismo de arbitraje internacional, del cual podría estar a cargo el PNUMA u otra organización internacional que la Convención determine.

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**CANADA**

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# PRELIMINARY CANADIAN SUGGESTIONS ON THE CONTENTS OF A BIOSAFETY PROTOCOL

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POSSIBLE CONTENTS OF THE PROTOCOL ON BIOSAFETY (FROM ANNEX TO UNEP/CBD/BSWG/1/4) FOR COMMENT AS PER SECTION 108 OF SAME)

1. Canada provides the following preliminary input, in response to the invitation for governments to submit their views on two lists of items; those included in all proposals and those in some proposals. Canada feels that the scope of the protocol and Advance Informed Agreement (AIA) are two important elements that must be addressed early in the process. Therefore, the main body of our comments focuses on these areas. Other items can be addressed later once the scope and intent of the protocol, including AIA, are clarified, as well as the need for articles and associated terms.

## A. ITEMS INCLUDED IN ALL PROPOSALS

### *Title*

2. Canada suggests that the title could be "International Protocol for the Safe Transfer, Handling and Use of Living Modified Organisms".

### *Preamble*

3. This section of the protocol should be addressed at a later stage.

4. Canada suggests that the protocol may benefit from a ***Principles*** section. One possible inclusion would be reference to the precautionary principle as defined in the Convention.

### *Use of terms/Definitions*

5. Canada supports a strong scientific basis for the Biosafety Protocol and one based on the principles of the Convention on Biological Diversity. We feel that it is not possible to define many of the terms and elements until the scope of the protocol, context and need of a term are determined. Canada does, however, note that a definition of LMO, and the scope of LMOs to be dealt with under Advance Informed Agreement (AIA) should be

*Institutional framework for the functioning of the protocol*

18. This section depends on the scope and substance of the protocol as developed.

*Settlement of disputes*

19. Canada is of the view that provisions to settle disputes among Parties with respect to the interpretation and application of the protocol could be included and consistent with the provisions of the Convention on Biological Diversity. Canada will provide its detailed comments on the dispute settlement text once the substantive provisions of the protocol take shape.

## B. ITEMS INCLUDED IN SOME BUT NOT ALL PROPOSALS

*Scope of the Protocol*

20. Canada suggests that this should be determined later.

*Criteria to determine the use of AIA and/or notification procedures*

21. Details should be developed at a later stage.

*Capacity building*

22. Canada proposes that capacity building should be mentioned in the preamble to the protocol and should be included in the protocol. This element should refer to capacity building for purposes of enabling risk assessment.

*Public awareness*

23. Canada supports further discussion and definition on public awareness as part of the protocol.

*Clearing house*

24. This term needs to be defined after the sort of information that would be considered, resources and processing of information are known. Items could include: how or whether to track decisions to approve, conditionally approve or prohibit transboundary movements of LMOs and sharing of information on risks.

*Liability/Liability and compensation and Consultations on liability*

25. Canada believes that at this juncture the protocol should not have an article on liability and compensation, but will consider proposals from other delegations.

*Monitoring and compliance*

26. Canada is of the view that monitoring and compliance should be kept in mind throughout the negotiations, as this will affect the clarity of the obligations, the role of institutions under the protocol and the procedures that may be established. It is important to design the protocol in a manner that will best yield compliance with it. Canada also envisages the inclusion of an article on compliance.

*Socio-economic considerations*

27.Canada has to date not supported the inclusion of such considerations in the Protocol. However, Canada reserves further comment on this issue until the meaning and significance of these considerations to other delegations are understood.

28. Canada will **not provide comment** on the following headings at this time. Reasons for no comment include: articles usually included in a protocol can be tailored later for the Biosafety Protocol or a better understanding of the scope or other details is needed before text can be crafted. These headings are: ***Amendment, Final clauses, Jurisdictional scope, General obligations, Objectives, Consideration for risk assessment and risk management, Notification procedure, Minimum national standards on biosafety, Mechanisms for risk assessment, Transport and packaging requirements for the transfer of LMOs, Handling, transport and transit requirements for LMOs, Transboundary movement between parties, Mechanisms for risk management, Emergency procedures, Determination of competent authority and national focal point, Illegal traffic, Duty to reimport, Technical information network, Financial issues, Review and adaptation, Signature, Accession, Right to vote, Mechanisms for bilateral agreements, Entry into force, Reservations and declarations, Withdrawal, Depository, Authentic texts, Transboundary movement from a party through States which are not parties.***

**TERMS PROPOSED FOR DEFINITION**

29. Canada will provide and discuss definitions once their need is determined.

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**CENTRAL AFRICAN REPUBLIC**

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MINISTERE DE L'ENVIRONNEMENT DES EAUX
FORETS CHASSES ET PECHES

C A B I N E T

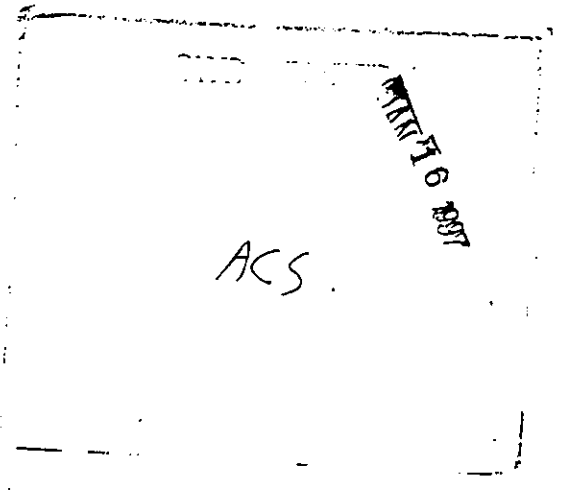
SECRETARIAT GENERAL

DIRECTION GENERALE
DE L'ENVIRONNEMENT

REPUBLIQUE CENTRAFRICAINE
Unité - Dignité - Travail

BANGUI, le 16 JAN 1997

N° 040 /MEEFC/CAB/SG/DGE.-

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BUREAU 300 MONTREAL, QUEBEC
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OBJET : **Accusé de réception**

REF : **V.L datée du 19 Décembre 1996**

Monsieur le Secrétaire Exécutif

J'ai l'honneur d'accuser réception de votre lettre ci-dessus référencée dans laquelle vous priez le Gouvernement Centrafricain de soumettre ses vues sur le projet de protocole sur la biosécurité.

En effet, le Gouvernement a hautement apprécié la qualité de travail fourni par les experts chargés d'élaborer ce projet de protocole. Il a constaté que celui-ci prend en compte les grandes préoccupations actuelles qui sont les siennes, du moins sur le plan national suite à l'évaluation interne qu'il a eu à mener au regard des accords signés ou ratifiés par lui.

Par ailleurs, me référant à ma correspondance datée de Juin 1996 désignant le point focal national en matière de biosécurité, c'est bien ce dernier qui était proposé par mon pays pour faire partie du groupe d'experts sur la biodiversité marine et costale.

Aussi je profite de l'occasion qui m'est offerte pour présenter à toute votre famille, vous même ainsi que tout le personnel du Secrétariat exécutif mes meilleurs voeux de bonheur, santé, succès et longévité pour l'année 1997.

Ministère de l'Environnement des Eaux Forêts Chasses et Pêches
LE MINISTRE
B.P. 6

- Pierre LAKOUETENE -

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**CHILE**

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SERVICIO AGRICOLA Y GANADERO
DEPARTAMENTO PROTECCION AGRICOLA
SUB-DEPTO. DEFENSA AGRICOLA

# SUGERENCIAS AL ANEXO POSIBLE CONTENIDO DEL PROTOCOLO SOBRE SEGURIDAD DE LA BIOTECNOLOGIA

1.- De acuerdo en incluir los temas propuestos en la letra A.

2.- **De los temas incluidos en la letra B, se opina que:**

- **Objetivos:** éstos ya han sido definidos en el CDB por lo que debieran de producirse de allí.
- **Alcance:** éstos ya han sido definidos en al CDB por lo que debieran producirse allí,debiendo especificarse a que OVM se aplica (a todos o sólo a los genes que involucran riesgo)
- **Ambito jurisdiccional:** se entiende que el protocolo debe aplicarse preferentemente al movimiento transfronterizo de OVM.
- **Obligaciones generales:** deben incluirse
- **Criterios:** sí
- **Procedimientos:** sí
- **Consideraciones para la evaluación:** Sí y pueden tomarse de las guías preexistentes (UNEP- IICA) como base.
- **Mecanismos para la evaluación:** Sí.
- **Mecanismos para la gestión:** No, cada país debe hacerlo independientemente.
- **Procedimiento de emergencia:** No, en atención que resultan difíciles de establecer y cada país debe hacerlo.
- **Normas nacionales:** No.
- **Designación de autoridades competentes- Punto focal:** Sí.
- **Creación de capacidad:** Sí, con énfasis en los temas de riesgo, sino que además en la creación de capacidades para hacer biotecnología en los países en desarrollo.
- **Requisitos de transporte:** Sí, en base a legislaciones existentes.
- **Requisitos de manipulación:** Sí, en base a legislaciones existentes.

- **Tráfico ilícito:** No (Lo que no se hace en base al protocolo es ilícito).
- **Obligación de reexportar:** No, ya está sujeto a la legislación de cada país.
- **Red de información técnica:** No.
- **Sensibilidad del público:** No.
- **Mecanismo de facilitación:** No está claro el concepto.
- **Mecanismo de acuerdo bilateral:** Sí.
- **Responsabilidad/responsabilidad e indemnización:** Sí (será un tema muy discutido).
- **Consultas sobre responsabilidad:** Nó está claro el concepto.
- **Vigilancia y cumplimiento.** Sí.
- **Cuestiones financieras:** Sí.
- **Aspectos socio-económicos:** No, considerarlo a posteriori.
- **Revisión y actualización:** Sí (donde se puedan a posteriori incluir otros temas pendientes)
- **Firma:** ?
- **Adhesión:** ?
- **Derecho a voto:** ?
- **Entrada en vigor:** Sí.
- **Reserva y declaraciones:** ?
- **Retirada:** ?
- **Depositarlo:** ?
- **Textos auténticos:** ?
- **Anexos:** Sí.

En relación al APENDICE I.
Conceptos que se proponen para su definición.
Se indican con los necesarios. Todo lo que dice relación a riesgo puede ser definido en el sólo concepto Riesgo.
CCV/lco
20/01/97.

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# CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Second Meeting
Montreal, Canada
12 to 16 May 1997

**CHINA**

/...

## RE : Glossary of Terms Relevant to A Biosafety Protocol

**Adverse effects**

" Adverse effects " means any direct pr omdorect,immediate or delayed adverse consequences caused by LMOs accident on, inter alia, human health, biodiversity.

**Focal Point**

A focal point designated by the Parties responsible for receiving and submitting information of accidents occurring due to transboundary movements of " waste " and other information to the Conference of Parties.(**Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal)**

It should be changed " waste " into " LMOs "

**Advanced Informed Agreement**

Advanced informed agreement refers to the principle that international exchange of transgenic plants and microorganisms that could adversely affect plants should not proceed without the informed agreement o, or contrary to the decision of, the competent authority in the recipient country.(**FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

It should be added animals after plants.

**Accident ( Accidental )**

Any incident involving a significant and unintended release of " **genetically modified micro-organisms** " in the course of their contained use which could present an immediate or delayed hazard to human health and the environment.(**Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms)**

" **genetically modified micro-organisms** " should be changed into " **genetically modified organisms** "

**Biosafty**

Safety aspects related to the application of biotechnologies and to the release into the environment of transgenic plants and " **other**

**organisms** " particularly microorganisms that could negatively affect plant genetic resources, plant, animal or human health , or the environment.(**FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

" **other organisms** " should be indicated the strict range.

**Competent Authority**

A government agency or agencies responsible for regulating biotechnology, biosafety, intellectual property rights and other relevant aspects.(**FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

This definition should be adopted.

**Contained Use**

Any operation involving organisms which are controlled by physical barriers or a combination of physical and /or biological barriers which limit their contact with, or their impacts on, the potentially receiving environment, which includes humans.(**UNEP International Technical Guidelines for Safety in Biotechnology)**

This definition should be adopted.

**Deliberate release**

Introduction into the environment for scientific or commercial purposes of transgenic plants and microorganisms.(**FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

It should be added animals after plants.

**Familiarity**

Knowledge and experience with an organism, the intended application and the potential receiving environment.(**UNEP International Technical Guidelines for Safety in Biotechnology**)

This definition should be adopted.

**Living Modified Organisms(LMOs)**

All organisms produced through the use of recombinant DNA techology, with a wider range of modifying technologies relevant when considering living modified prokaryotes and yeast.(**Report of the Panel of Experts on Biosafty ,Cairo 1995**)
This definition should be adopted.

**Risk Assessment**
The use of scientific data to identify and characterize the nature and magnitude of hazards, if any, and the likelihood of hazards being realized.(**Report of Panel of Experts on Biosafety**)
This definition should be adopted.

**Risk Management**
The implementation of the most appropriate measures to minimize the identified risks and mitigate their effects while achieving the anticipated results.(**Report of Panel of Experts on Biosafety**)
This definition should be adopted.

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**CUBA**

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# PROPUESTA CUBANA SOBRE EL POSIBLE CONTENIDO DEL PROTOCOLO.

**A. Items coincidentes con todas las propuestas.**

Título, Preámbulo, Definiciones, Información y Consentimiento Previo, Intercambio de información, relación con otros Instrumentos Internacionales (en particular Convenio de Diversidad Biológica), Solución de Controversias, Enmiendas y Organización Internacional para el funcionamiento del Protocolo (Secretaría).

**B. Items incluidos pero no en todas las propuestas.**

Alcance, Consideraciones para la evaluación y gestión del riesgo, Procedimientos de emergencia, Designación de la Autoridad nacional, Creación de Capacidad, Movimiento transfonterizo entre las Partes, Redes técnicas de información, Información al público, Responsabilidad e indemnización, Disposiciones financieras, Firma, Adhesión, Derecho de voto, Entrada en vigor, Reservas, Depositario, Textos auténticos y Anexos.

**C. Items no incluidos en A y B.**

Registro Internacional de OGM, Obligaciones de los investigadores o autores de la propuesta de liberación, uso confinado de microorganismos genéticamente modificados, cooperación científico-técnica, Reuniones de las Partes, Informes, Incumplimientos, Ratificación, Aceptación o Aprobación.

**II. Definiciones en la propuesta cubana.**

**a) Coincidentes con el apéndice 1 circulado.**

**Moderna Biotecnología:** Toda aplicación tecnológica que utilice sistemas biológicos y organismos vivos o sus derivados para la creación o modificación de productos o procesos para usos específicos mediante técnicas que impliquen recombinación del ADN.

**Movimiento Transfronterizo:** Todo movimiento de organismos genéticamente modificados procedente de una zona sometida a la jurisdicción nacional de un Estado y destinado a una zona sometida a la jurisdicción de otro Estado, o a través de esta zona, o a una zona no sometida a la jurisdicción nacional de ningún Estado, a través de esta zona, siempre que el movimiento afecte a dos Estados por lo menos.

**Autoridad Nacional:** Es la autoridad gubernamental designada por un Estado Parte para proponer al gobierno de su país, la política nacional en materia de seguridad en Biotecnología, para dirigir, controlar e inspeccionar la actividad, para dictar las disposiciones, establecer las medidas y hacer las recomendaciones necesarias.

**Manipulación:** Toda actividad de investigación y desarrollo que se realiza con los organismos vivos a fin de lograr una modificación genética.

**Consentimiento fundamentado previo:** El principio de que el envío internacional de un OGM, que pueda tener efectos adversos al medio ambiente y la salud humana, no debe realizarse sin el acuerdo, cuando corresponda, o contra las decisión de la autoridad nacional designada del país importador.

**Evaluación de riesgo:** Procedimiento de análisis para determinar los posibles daños, su probabilidad de ocurrencia, y la posible magnitud.

**Gestión del riesgo:** Conjunto de medidas encaminadas a lograr que la manipulación, uso y liberación sean seguras.

**b) No existentes en el apéndice.**

**Organismos Genéticamente Modificados:** Aquellos organismos en que el material genético ha sido modificado, mediante la moderna Biotecnología, en una dirección que no ocurre por apareamiento o recombinación natural.

**Creación de capacidad:** El fortalecimiento y el desarrollo de los recursos humanos y de las capacidades institucionales. Entraña la transferencia de conocimientos prácticos, la creación de instalaciones adecuadas, la formación de ciencias relacionadas con la seguridad de la Biotecnología y la utilización de técnicas de evaluación y gestión de los riesgos.

**III. Otras definiciones contenidas en documentos nacionales y están en el apéndice 1.**

**Seguridad biológica:** Conjunto de medidas científico-organizativas y técnico-ingenieras destinadas a proteger al trabajador de la instalación, la comunidad y el medio ambiente de los riesgos que entraña el trabajo con agentes biológicos o la liberación de organismos al medio ambiente, y en caso de contaminación, efectos adversos, escapes o pérdidas disminuir al máximo los efectos que se puedan presentar y liquidar rápidamente sus posibles consecuencias.

**Liberación:** Introducción en el medio ambiente de un organismo o combinación de estos.

**Area de Liberación:** Zona definida en el medio ambiente donde se produce la liberación de un organismo o combinación de estos.

**Emergencia Biológica:** Situación provocada por la ocurrencia de sucesos que pueden derivar en un daño con repercusión adversa inmediata o retardada en el medio ambiente en general, la población y los trabajadores en particular, debido al escape o la liberación de organismos.

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**EUROPEAN UNION**

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ANNEX

I. COMMENTS ON "A" ITEMS AND PROPOSED ELEMENTS FOR THE PROTOCOL

0. PREAMBLE[1]

The Parties to the Protocol,

RECALLING Article 19, paragraph 3, of the Convention on Biological Diversity;

RECOGNIZING the link between paragraphs 3 and 4 of Article 19;

RECOGNIZING ALSO the link between Articles 8(g) and 19, paragraph 3;

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

RECOGNIZING that in order to allow the community at large to benefit maximally from the potential of biotechnology to contribute to sustainable development, biotechnology must be developed and applied within a sound international framework for safety;

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

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

---

(1) The title could be drafted when all the elements of the Protocol are in place.

NOTING the UN Recommendations on Transport of Dangerous Goods;

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

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

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

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

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

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

RECOGNIZING also that the Protocol should not duplicate other comparable existing legal instruments;

HAVE agreed as follows:

# 1. OBJECTIVES, SCOPE AND DEFINITIONS

## 1.1. OBJECTIVE[1]

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

## 1.2. SCOPE[2]

1.2.1 In order to fulfil its objective [3] the Protocol applies to all LMOs resulting from modern biotechnology except those LMOs and activities which are not likely to have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and which are specified in the protocol or in an annex.

The Protocol should only cover issues which are related to risks to the environment, taking also into account risks to human health, in the context of transboundary movement of LMOs resulting from modern biotechnology which may have an adverse effect on the conservation and sustainable use of biological diversity.

Following decision II/5, the scope of the Protocol is determined by, inter alia:

- the definition of "transboundary movement" and the definition of "LMOs resulting from modern biotechnology";
- the meaning of the term "that may have adverse effects on the conservation and sustainable use of biological diversity".

---

(1) B item.
(2) B item.
(3) see section 1.1.

1.2.2. Adverse effect

comments:

In determining which LMOs resulting from modern biotechnology may or may not have adverse effects, the following elements should be taken into consideration:

- the characteristics of the organisms involved;
- the characteristics of the environment;
- the intended use.

In further exploring how to identify relevant categories of LMOs resulting from modern biotechnology, the following should be taken into consideration:

- in assessing which LMOs may have adverse effects, account should be taken of the fact that organisms may behave differently in different environments and that an organism which is safe in one environment may have adverse effects in another.
- for certain LMOs resulting from modern biotechnology, risk assessment has shown that it is unlikely that they will have adverse effects in a specific environment.
- categories which are unlikely to have an adverse effect may be identified on the basis of the properties of the organisms and/or the intended use.

It should be taken into account that in relation to transboundary movement, the possibility of having adverse effects on the environment using LMOs in containment is unlikely, provided containment measures are satisfactory.

## 1.3. DEFINITIONS

### 1.3.1. LMOs

Living organism: any biological entity capable of replication or of transferring genetic material. This definition covers plants, animals, fungi, micro-organisms, viruses and viroids, including cell and tissue cultures, germinal cells, seeds, pollen and spores.

living modified organism resulting from modern biotechnology: an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

comment:

LMOs resulting from applying certain techniques of alteration of genetic material would be covered by the protocol, while organisms resulting from certain other techniques should not *per se* be considered to be LMOs.

### 1.3.2. TRANSBOUNDARY MOVEMENTS

#### 1.3.2.1. Intended

Intended transboundary movement: the deliberate transfer of LMOs across national borders.

#### 1.3.2.2. Unintended

Unintended transboundary movement: natural or accidental movement of LMOs across national borders. (1)

### 1.3.3. CONTAINED USE

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

### 1.3.4. DELIBERATE RELEASE

deliberate release: any intentional introduction into the environment of a LMO or a combination of LMOs without specific containment measures to limit their contact with the environment.

---

(1) It will be mentioned under the relevant section(s) of part 2 that only those unintended transboundary movements which are likely to have significant environmental effects have to be covered.

## 2. OPERATIONAL PROVISIONS

### 2.1. DESIGNATION OF FOCAL POINTS AND COMPETENT AUTHORITIES[1]

comments:

Focal points/competent authority (authorities) shall be established by all Parties in order to carry out tasks in relation to AIA, notification and exchange of information [in the meaning of section 2.3 below].

Where appropriate, the possibility of establishing regional arrangements for that purpose should be explored.

### 2.2. CONSIDERATIONS FOR RISK ASSESSMENT AND RISK MANAGEMENT[2]

comments:

The key to safety is the prior assessment and consequent management of risk. Therefore the Protocol should reflect general principles for risk assessment and risk management. Risk assessment and risk management should be based on up-to-date scientific data and experience and should take account of:

- the characteristics of the organisms involved, and their potential to have adverse effects on the potential receiving environment, and on conservation and sustainable use of biological diversity;
- the characteristics of the intended application;
- the potential receiving environment.

The UNEP International Technical Guidelines for Safety in Biotechnology provide valuable guidance and information for risk assessment and risk management.

---

(1) B item.
(2) B item.

## 2.3. AIA, NOTIFICATION[1] AND EXCHANGE OF INFORMATION

comments:

### 2.3.1 Exchange of information

An important objective of the Protocol is to ensure that the competent authorities and focal points in receiving countries are given and/or have access to information relevant to proper risk assessment and risk management.

Alongside the procedures referred to under 2.3.2, the development and/or maintenance of international information exchange systems relating to transboundary movement is necessary for the proper functioning of the Protocol. In the case of transboundary movement of LMOs covered by the Protocol, the Protocol should ensure that, where appropriate, Parties receive, or have access to, information relevant to proper risk assessment and risk management.

The Protocol should contain adequate provisions to ensure confidentiality of commercial data in all exchanges of information under the Protocol.

### 2.3.2 Transfer (intended)

A procedure for advance informed agreement (explicit or implicit), alongside a notification procedure, is an important part of the Protocol. These procedures should be differentiated and proportionate to the risks involved and allow for rapid adaptation to scientific and technological progress. The content of notification should consist of data relevant to safety.

---

(1) B item.

For the elaboration of such procedures, the provisions of the UNEP International Technical Guidelines for Safety in Biotechnology as regards "Mechanisms at international level using information supply and exchange" and the experience obtained from the internationally agreed procedures applicable in the fields of chemicals, pesticides and waste could provide useful guidance on developing the details for the different procedures.

The extent of the information contained in a notification or an AIA will depend on the characteristics of the particular LMO, the intended use, and the circumstances of the transboundary movement.

The provisions of such procedures could be differentiated according to the kind of use and transfer.

2.3.3 Movement (unintended)

Other important issues that could be considered under this section are "provision for information exchange" as well as "appropriate measures" in response to an unintended transboundary movement of LMOs.

2.4. MONITORING OF AND COMPLIANCE WITH PROTOCOL OBLIGATIONS[1]

comments:

In relation to monitoring and compliance, the process should be simple, co-operative and transparent and should be guided by the need for all Parties to co-operate in good faith and participate fully.

(1) B item.

2.5. DISPUTE SETTLEMENT PROCEDURES

comments:

Provisions for dispute settlements are already provided for in the Convention itself and according to Art. 27(5) may apply directly to the Protocol. There is therefore no need for specific provisions under the Protocol.

2.6. SIMPLIFIED PROCEDURES

To take into account different technical capacities and while respecting the objective of the Protocol, the Protocol should provide for simplified procedures for movements of LMOs.

For example, the protocol could provide possibilities for mutual acceptability/recognition of data and authorisation procedures.

3. **OTHER ITEMS**

3.1. CAPACITY-BUILDING[1]

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

2. Implementation of the measures referred to in para. 1 is properly addressed in the general framework of the Convention and through programmes and activities under international organizations such as UNEP and UNIDO.

(1) B item.

3.2. INSTITUTIONAL FRAMEWORK FOR THE FUNCTIONING OF THE PROTOCOL

comments:

It is desirable to draw on existing structures where possible for reasons of economy, compatibility and organizational efficiency. The administration of the Protocol and its financial implications should be handled within the existing institutions of the Convention i.e. the permanent secretariat and the financial mechanism.

3.3. REVIEW, AMENDMENTS AND ADAPTATION(1)

comments:

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.

3.4. RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

comments:

The general Article on this matter shall reflect that the substantive provisions of the Protocol take into account the existence of other international agreements. Furthermore, it should be noted that measures taken by Parties to the Protocol are likely to have an impact inter alia on international trade and might thus be covered by WTO Agreements and underline the importance of consistency between the Protocol and the Agreements under the WTO. More generally, the provisions of the Protocol shall be consistent with the relevant international obligations of the Parties.

---

(1) "review" and "adaptation" are B items.

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.

Within regional economic integration organisations, principles of an internal market and regional legislation on biotechnology can provide a sufficient framework for the aspects of the internal movement of LMOs and such a framework can therefore fulfil the objectives of the Protocol.

3.5. FINAL CLAUSES

comments:

Provisions for final clauses should be as far as practicable as in the Convention.

The need for bilateral agreements should be considered.

3.6. JURISDICTIONAL SCOPE[1]

While noting that Article 4 of the Convention addresses this issue, the need for provisions on the jurisdictional scope may have to be considered further.

II. COMMENTS ON B ITEMS

FINANCIAL IMPLICATIONS FOR PARTIES AT THE NATIONAL LEVEL

It is clear that the correct implementation of Article 8(g) related to the control of the risks associated with the use and release of LMOs on a national level will contribute to establishing the necessary capacities for the effective functioning of the Protocol.

(1) B item.

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**CONVENTION ON BIOLOGICAL DIVERSITY**

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**JAPAN**

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# Views of the Japanese Government on the contents of a Biosafety Protocol

*December 27, 1996*

## I . General Views

1. As is stated in Paragraphs 8 and 9 of the Annex to Decision II /5, the process of developing a protocol on biosafety (hereinafter referred to as "Protocol") under the Convention on Biological Diversity (hereinafter referred to as "Convention") shall be guided by the need for all Parties to cooperate in good faith and to participate fully, with a view to the largest possible number of Parties to the Convention concluding the Protocol, and will be carried out on the basis of the best available scientific knowledge and experience, as well as other relevant information.

2. As is stated in Paragraph 6 of the Annex to Decision II /5, the provisions of the Convention will apply to the Protocol.

## II . Views on the Items Included in all Proposals

### 1. Advance informed agreement (AIA)

(1) The AIA procedure should stipulate that a person intending to transfer beyond the national boundary living modified organisms (LMOs) falling into the scope of the Protocol should provide the competent authorities of the recipient State with information on the transboundary transfer of the LMOs in question and receive agreement in advance.

(2) The AIA procedure should include the following provisions:

(a) A standard processing period required for each AIA procedure should be clearly specified in the Protocol, and, if a Contracting Party to the Protocol adopts at the national level a different processing period from the standard one, that national processing period should be notified to the Secretariat of the Protocol.

(b) Items to be included in the information to be provided to the competent authorities of the recipient State should be specified in the Protocol. Such items should be limited to what is indispensable for the appropriate operation of the AIA procedure.

(c) A Contracting Party to the Protocol may decide to exempt, either by means of bilateral, multilateral or regional arrangements or by declaration, certain LMOs from the application of its AIA procedure within the State, if it has been established that there does not exist any risk associated with the use and release of such LMOs. The Secretariat should, on the basis of

(c) The Secretariat should publish periodically a list of LMOs so excluded from the scope of the Protocol.

3. Notification procedure

(1) If it is established that there does not exist any risk associated with the use and release of certain LMOs on the basis of the best available scientific knowledge and experience, as well as relevant information, a Contracting Party to the Protocol may replace the AIA procedure regarding such LMOs with an advance notification procedure in which case no advance agreement of the recipient State is required.

(2) Rules and regulations of the advance notification procedure should be specified.

4. Considerations for risk assessment and risk management

(1) Standardized criteria and procedures for risk assessment should be considered.

(2) Procedures for risk assessment for imported LMOs in a Contracting Party to the Protocol should not be different from those for domestic LMOs. Moreover, imported LMOs should not be treated in a disadvantageous way compared to homologous domestic LMOs.

(3) Pursuant to Articles 8 (g) of the Convention, each Contracting Party to the Protocol should establish or maintain 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 the human health.

5. Emergency procedure

In the Protocol Paragraph 1(d) and 1(e) of Article 14 of the Convention should be applied to Emergency procedure with respect to the implementation of the Protocol.

6. Designation of competent authority and national focal point

The Contracting Parties to the Protocol should designate or establish one or more competent authorities and/or national focal points to facilitate the implementation of the Protocol.

7. Mechanisms for bilateral agreements

(1) Any Contracting Party to the Protocol may enter into bilateral, multilateral, or regional agreements concerning transboundary transfer of LMOs falling into the scope of the Protocol with other Contracting or Non-contracting Parties to the Protocol, provided that such agreements do not derogate from necessary risk management of LMOs as required by Article 8 (g) of the Convention.

(2) The contents of the agreements mentioned above should be notified to the Secretariat of the Protocol.

8. Liability and compensation

Liability and compensation with respect to the implementation of the Protocol should be dealt with in Article 14 Paragraph 2 of the Convention, but not in the provisions of the Protocol.

9. Financial issues

In the Protocol the financial mechanism established by Article 21 Paragraph 1 of the Convention should be applied; accordingly, no new financial mechanism is necessary for implementation of the Protocol.

10. Socio-economic considerations

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. Review and adaptation

In order to integrate timely the best available scientific knowledge and experience, as well as other relevant information into the Protocol, and following Paragraph 5(c) of the Annex to Decision II /5, the Protocol should provide for a review mechanism.

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**MOROCCO**

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ROYAUME DU MAROC

MINISTERE DES AFFAIRES ETRANGERES
ET DE LA COOPERATION

24 JAN. 1997

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FAX

URGENT

1) Il est indispensable que ce Protocole souligne la nécessité de renforcer les capacités des pays en développement en matière de transfert, manipulation et utilisation des Organismes Vivants Modifiés (OVM), ainsi qu'en matière de gestion des risques liés à ces activités. En effet, sans ce renforcement des capacités, ces pays ne peuvent ni appliquer ledit Protocole, ni gérer les risques éventuels.

2) Le Protocole doit souligner clairement la responsabilité des pays à l'origine des dommages causés par les OVM, ainsi que l'indemnisation de ces dommages par ces pays. Sans le principe de dommage/indemnisation, ce Protocole serait sans aucun effet, et les pays signataires, notamment ceux du Nord, n'auraient pris aucun engagement réel. L'Article 14/2 de la Convention sur la Diversité Biologique serait la seule référence dans ce sens.

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3) Les références à la Convention de Bâle et à sa procédure PIC, ne sont pas applicables sur ce Protocole, car les OVM ne peuvent être considérés comme des déchets toxiques ou dangereux (ils sont absents des Annexes I et II de la Convention de Bâle), mais des organismes vivants, et seul le Protocole élaboré dans le cadre de la Convention sur la Diversité Biologique doit les réglementer.

4) Il faudrait instituer, au terme de ce Protocole, un mécanisme financier, composante spéciale du FEM, qui servirait à financer d'une part, les activités de renforcement des capacités des pays en développement, et d'autre part, assister financièrement ces pays, en cas de catastrophes biologiques liées aux OVM.

Une partie de ce mécanisme pourrait être allouée à la recherche biologique ou médicale, ayant pour objectif de diminuer ou supprimer les impacts négatifs des catastrophes biologiques (exemple : la mouche ovine en Libye a été éliminée grâce aux résultats obtenus par les chercheurs mexicains).

5) Enfin, le Secrétariat doit aider financièrement les pays en développement pour qu'ils puissent participer activement aux réunions préparatoires du Protocole.

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**NEW ZEALAND**

/...

**BIODIVERSITY CONVENTION: OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY: DEFINITIONS: NEW ZEALAND'S SUGGESTIONS**

Where we have suggested modifications of definitions used in other international agreements the amended text is underlined.

**Adverse Effects**

Potential or probable Changes in the physical environment or biota, including changes in climate, which have significant deleterious effects on human health or on the composition, resilience and productivity of natural and managed ecosystems, or in materials useful to humans.
(Modified from the 1985 Vienna Convention on the Protection of the Ozone Layer).

"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 the factors in (i) and (ii); (iv) material assets and cultural heritage, including historical monuments.
(Modified from 1992 Convention on the Transboundary Effects of Industrial Accidents)

**Accident (Accidental)**

Any incident involving a significant and unintended release of a living modified organism in the course of its contained use which could adversely affect the conservation and sustainable use of biological diversity (Modified from Council Directive 9O/219/EEC on the Contained use of Genetically Modified Microorganisms).

**Advanced informed agreement (see Prior Informed Consent)**

Advanced informed agreement refers to the principle that international exchange of transgenic organisms that could affect other biota should not proceed without the informed agreement of, or contrary to the decision of, the competent authority in the recipient country.
(Modified from FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilisation of Plant Genetic Resources).

(Modified from Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal etc.)

**BIOSAFETY**

UNEP

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# CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Second Meeting
Montreal, Canada
12 to 16 May 1997

**NORWAY**

/...

# SUBMISSION BY NORWAY TO THE SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY ON ELEMENTS TO BE INCLUDED IN A PROTOCOL FOR THE SAFE TRANSFER, HANDLING AND USE OF LIVING MODIFIED ORGANISMS

## Title (A)

Protocol for the safe transfer, handling and use of living modified organisms

## 1 Preamble (A)

Recalling Article 19, para 3 of the Convention on Biological Diversity;

Recognizing the link between paragraphs 3 and 4 of Article 19;

Recognizing also the link between Articles 8(g) and 19, paragraph 3;

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

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

Noting also the advantages which lies in the potential of modern biotechnology to contribute to sustainable development;

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

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

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

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

Have agreed as follows:

## 2 Objectives, scope and definitions

### 2.1. Objectives (B)

"The objective of the Protocol is to ensure safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity taking into account the risks to human health."

"The objective is also to ensure that these activities take place in accordance with the principle of sustainable development and in a socio-economically justifiable way."

### 2.2. Scope (B)

"This protocol applies to all LMOs resulting from modern biotechnology that may have adverse effects on human health and the conservation and sustainable use of biological diversity."

Comment: The scope of the protocol will naturally de decided on the basis of definitions to be developed.

### 2.3. Definitions (A)

"Living modified organism resulting from modern biotechnology, means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Contained use means any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a closed system in which physical barriers are emplyed, either alone or together with chemical and/or biological barriers, to limit contact between the organism on the one hand and humans and the environment on the other.

Deliberate release means any production and use of living modified organisms that is not considered to be contained use."

Comment: This list of definitions is not exhaustive and we recognize that we need to define also other terms used in the protocol such as intended and unintended transboundary movements etc.

## 3 Operational provisions

### 3.1. General obligations (B)

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

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

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

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

### 3.2. Designation of a national focal point/competent authority (B)

"A national focal point/competent authority shall be designated for the purposes of the protocol. This authority shall be responsible for procedures related to Advance Informed Agreement (AIA), notification and exchange of information."

### 3.3. Risk asssessment (B)

"States shall establish, designate or strengthen national and/or regional authorities to implement adequate risk assessments.

A complete risk assessment shall be carried out prior to the transfer of an LMO for the first time into a new country.

The State of Export and the State of Import shall ensure that risk assessments in accordance with the provisions of this protocol are carried out prior to the transfer, handling and use of living modified organisms with regard to the risks or possible adverse impacts on human health and/or the environment in their respective territories.

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

The assessment of the risks to human health and the environment associated with a transfer, handling and use of LMOs shall be based on the following elements:

a) The characteristics of the LMO, taking into account:

- the recipient/parental or host organism;
- the relevant information on the donor organism and the vector used;
- the genetic modification, including the inserts and the encoded trait;
- the centre of origin, when known.

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 and any management procedures and waste treatment.

c) Description of the potential receiving environment, with an assessment that includes possible short term and long term adverse effects on human health and the conservation and sustainable use of the biological diversity in the receiving environment."

(Examples of more detailed elements to consider in a risk assessment are given in Annex xx.)

### 3.4. Risk management (B)

"The Parties shall take appropriate risk management decisions based on the risk assessment.

If the risk assessment shows that the level of risk of the transboundary movement and the intended use is not acceptable, risk-management measures are to be taken and implemented until the risks have been minimized to an acceptable level. It is up to the State of Import to decide what is to be considered as "acceptable level of risk". The Parties can in the case of deliberate releases issue specific conditions, such as monitoring and restrictions in application, in the permission issued by the authorities. If the risk cannot be minimized in this way, it may be decided not to allow the transfer."

### 3.5. Advance informed agreement (A)

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

The State of Export shall supply or shall require the exporter to supply through the channel of the competent authority of the State of Export the following

information to the competent authority of the State of Import, prior to the first intended transfer of LMOs:

- 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 results of a risk assessment carried out by the exporting country including a summary of risks to human health and the environment, including the environment of the State of Import
- 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
- methods for safe disposal and suitable procedures in case of accidents
- intended use of the organism
- information on relevant previous releases
- any differences in the environment of the exporting country and the environment into which the organism is intended to be released.

The competent authority in the State of Import shall be obliged to respond to the State of Export within 90 days. A response may consist of either:
1) explicit consent to import;
2) not consent to (or prohibit) import; or
3) consent to import only under specified conditions
or
4) 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.

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 adverse effects of an LMO, the burden of proof lies with the State of Export.

If at any time before, during or after the transboundary transfer, the State of Export/Import becomes 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 shall be informed within 30 days and the terms of the Advance Informed Agreement may be changed accordingly."

Comment: Procedures for transit countries should also be considered in the protocol.

### 3.6. Notification procedures (B)

"Notification of exports of LMOs shall be conducted in all cases not covered by the procedure for Advance Informed Agreement e.g for other than initial exports of a specific LMO to a certain country. The notification shall be sent to the state of import prior to the intended transfer. Such notification may or may not require a positive response from the competent authority in the State of Import. If the State of Import has not reacted within 90 days, the export can proceed ("tacit consent")."

### 3.7. Information and consultation in case of accidental or unintended movements

"The Parties shall:
(a) whenever it comes to their knowledge, ensure that, in the case of an accident occurring during the transboundary movement of an LMO, or, in the case of an accident/unintended movement within their territories which may have transboundary effects, which are likely to present risks to human health and/or the environment in other states, these states are immediately informed;
(b) introduce appropriate procedures for environmental impact assessments of planned activities within their territories that are likely to have significant adverse effects on human health and/or the environment within their own territories or such transboundary effects on other states.

The information supplied shall include the identity, the relevant characteristics and numbers/volumes of the LMOs involved and any available information regarding the handling of the organisms and information related to risk assessment and risk management.

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

### 3. 8. Minimum national regulations for biosafety (B)

"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 at the national level two years after the date of ratification or accession of this Protocol. Such regulations shall contain adequate measures for both contained use and deliberate release.

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."

### 3.9. Monitoring requirements (B)

"The Parties shall establish monitoring programmes of the use of LMOs in order to inter alia monitor that LMOs released do not spread across national borders, and in order to monitor the long-term effects of the use of LMOs."

Comments: Two types of monitoring can be appropriate in connection with transboundary movement, handling and use of LMOs;

Monitoring during the research period, which can contribute significantly to gaining knowledge and experience with the LMO. Monitoring is often used to verify the assumptions made in a risk assessment and should be used to evaluate whether the risk-management measures used are appropriate and effective.

Monitoring can be used after an LMO has been put on the market, to verify whether conditions given in a permission for the intended use is appropriate and effective, or to evaluate if any possible long term effects on biodiversity may arise.

### 3.10. Capacity-building (B)

"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
- the development of national legislation related to biosafety
- 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."

### 3.11. Transmission of information (B)

"The Parties shall inform each other, through the Secretariat of inter alia:
-designations of focal points/competent authorities and changes in such designations
- information about national legislation in this area
- decisions made not to consent to the import of LMOs
- any other relevant information

The Parties shall transmit, through the Secretariat to the Conference of the Parties, before the end of each calendar year, a report containing the following information:
- information regarding transboundary movements of LMOs covered by this Protocol, including:
- the amount of LMOs exported, category, characteristics, states of import etc.
- information on the measures adopted by them in implementation of this Convention

- information on available statistics on the effects on human health and the environment
- information on accidental/unintended movements
- other relevant information

### 3.12 Financial implications for the implementation of the Protocol

Comment: An effective implementation of art. 8g of the Convention (risks associated with the use and release of LMOs) and the protocol will require financial resources. Since the protocol must be considered as an instrument for the implementation of the Convention, the financial provisions of the Convention should also apply to the Protocol.

"Financial resources shall be applied in accordance with Article 20 of the Convention, through national resources, bilateral, regional or multilateral channels and through the financial mechanism referred to in Article 21 of the Convention."

### 3.13. Institutional framework for the functioning of the protocol (A)

Comment: One should as far as possible draw upon existing institutions. The administration of the Protocol and its financial implications should be handled within the existing institutions of the Convention i.e. the permanent secretariat and the financial mechanism.

"An international database shall be established for the purposes of the protocol."

The clearing-house meachanism established under the Convention could serve this function.

### 3.14. Packaging and labelling (B)

In order to maintain safety levels during transport and transit, LMOs should be packed and labelled adequately. In order to maintain safety during transport, existing international UN recommendations and agreements on transport should be applied. This needs to be reflected in the protocol.

"Parties shall require labelling of living modified organisms intended for food purposes. Other living modified organisms shall be labelled if necessary with regard to environmental, health or ethical concerns".

### 3.15. Liability and compensation (B)

According to art. 14(2) of the Convention, the Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation for damage to biological

diversity. In order to finalize the protocol negotiations in 1998, this matter may be addressed after the priority matters included in Decision II/5 have been dealt with. The protocol should recognize the importance of this matter and initiate further work to be carried out in this area.

### 3.16. Monitoring compliance with the protocol (B)

"Any Party which has reason to believe that another Party is acting or has acted in breach of its obligations under this Protocol shall inform the Secretariat thereof, and in such an event, shall also inform directly or through the Secretariat, the Party against whom allegations are made. All relevant information shall be submitted by the Secretariat to the Parties."

Compliance procedures might be developed in addition to the settlement of disputes procedures.

### 3.17. Public awareness and participation (B)

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

In cases where Advance Informed Agreement is required under the present protocol, the competent authority may decide that a public hearing is to be carried out. The decision to carry out a public hearing shall be publicly announced."

## 4 Other provisions

### 4.1. Review, amendment and adaptation (B)

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.

### 4.2. Relationship with other international agreeements (A)

The Convention regulates the relationship with other international agreements, in that the provisions of the Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

### 4.3. Settlement of disputes (A)

The dispute settlement procedure in the Convention shall apply with respect to any Protocol except as otherwise provided in the protocol concerned. This

procedure could thus be strengthened in the protocol by providing for an opting out clause insted of the existing opting in clause with regard to accepting arbitration or the International Court of Justice as compulsory dispute settlement procedures. This means that Parties upon ratification or accession may declare in writing that it does not accept compulsory settlement of disputes (arbitration or International Court of Justice) e.g. the starting point is that Parties accept compulsory dispute settlement.

This procedure can also be strengthened by requiring Parties to use Arbitration in accordance with Annex II of the Convention if they have not accepted compulsory dispute settlement.

### 4.4. Final clauses (A)

Provisions for final clauses should as far as practicable be similar to those in the Convention.

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Additional comment: It should be considered whether the protocol could cover phase-out of certain traits used in an LMO, for example antibiotic resistance marker genes which have no necessary functions in commercial products.

## 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 can 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 can 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 compered to similar not modified organisms;

## 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 can 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.

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# CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Second Meeting
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**PANAMA**

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República de Panamá
Instituto Nacional de Recursos Naturales Renovables

Despacho del Director
Tels.: 232-6643 Fax: (507) 232-6612

Panamá, R. de P.
Apartado 2016 - Panamá - Panamá

Panamá, 26 de diciembre 1996
DIRG. 1712



Señor
CALESTOUS JUMA
Secretario Ejecutivo

Estimado señor Juma:

Hemos revisado los términos propuestos que se utilizarán en el Protocolo de Bioseguridad los cuales estamos de acuerdo, al igual que con el glosario de la terminología más relevante, presentado en el anexo CDB del 26 de septiembre de 1996.

Sin embargo, nos parece oportuno que se incluyan, las definiciones sobre:

1- Criterios para definir el riesgo.

2- Criterios para establecer los estándares mínimos sobre la Bioseguridad.

Esperando que nuestra sugerencia sea de mucha utilidad, nos despedimos, no sin antes reiterar nuestro sincero apoyo.

Atentamente,

Instituto Nacional de Recursos Naturales Renovables
DIRECCION GENERAL
INRENARE
PANAMA

LCDA. MIREI ENDARA
Directora General

UNEP

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**CONVENTION ON BIOLOGICAL DIVERSITY**

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**PERU**

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**MUY URGENTE** (2)

**REPUBLICA DEL PERU**

**SECRETARIA EJECUTIVA DEL CONVENIO SOBRE LA DIVERSIDAD BIOLOGICA**

**EVALUACION SOBRE BIOSEGURIDAD**

El Perú a través de la Comisión Nacional de Diversidad Biológica y su grupo de trabajo sobre Recursos Genéticos y Bioseguridad, se encuentra aún en proceso de evaluación y análisis de los acuerdos y documentos internacionales, cuyo contenido se relaciona con las directrices del futuro Protocolo sobre el manejo seguro de la Biotecnología; considerando prioritaria la aprobación del Protocolo de Bioseguridad, apoya la declaración emitida por el Grulac en la última reunión de Aarhus, Dinamarca. Considera que las medidas de bioseguridad deben circunscribirse exclusivamente a los organismos transgénicos y no a aquellos mejorados genéticamente aprovechando la variabilidad que en forma natural se da dentro de cada especie y para la cual existen acuerdos internacionales.

Los vacíos importantes en todos los instrumentos internacionales se concentran en:

- La efectividad de los sistemas de alerta sobre los acuerdos de investigación y liberación de Gmo's, los cuales son poco efectivos, permaneciendo en muchos casos esta acción;
- Un sistema de información, diferente de internet, para aquellos países que no han incorporado aún en sus niveles de decisión este instrumento;
- El programa de monitoreo en algunos instrumentos es solamente visual y no considera las condiciones heterogéneas de los hábitats y ecosistemas en países como el Perú;
- La evaluación del riesgo se enfoca mas sobre las características fenotípicas del organismo antes que en las técnicas moleculares empleadas o en la alteración de la secuencia genética;
- Cada instrumento internacional es especifico y no consideran elementos clave como: definición y amplitud de los GMO's, principio de precaución, entre los principales;
- En muchos casos, enfocan de manera tangencial el tema de capacitación en recursos humanos e infraestructura para investigar, prevenir y tomar acciones sobre bioseguridad, aspecto fundamental para mejorar la capacidad de respuesta de un país ante la liberación accidental o provocada; cabe anotar que el Registro Internacional de Químicos potencialmente tóxicos si posee un programa intensivo de entrenamiento.
- En estos instrumentos se observa que no se toma en cuenta las diferentes capacidades de los países para manipular información sobre riesgos ambientales.
- Muchos de estos instrumentos utilizan el Consentimiento Fundamentado Previo (PIC) de manera correcta para sus objetivos y que, en casos como el procedimiento aplicable a los desechos y productos químicos no sería aplicable.

Finalmente, consideramos que se debe mantener la definición de organismos vivos modificados por la biotecnología contenida en el Convenio sobre la Diversidad Biológica

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REPUBLICA DEL PERU

SECRETARIA EJECUTIVA DEL CONVENIO SOBRE LA DIVERSIDAD BIOLOGICA

## EVALUACION SOBRE BIOSEGURIDAD

El Perú a través de la Comisión Nacional de Diversidad Biológica y su grupo de trabajo sobre Recursos Genéticos, se encuentra aún en proceso de evaluación y análisis del futuro Protocolo sobre el manejo seguro de la Biotecnología. En ese marco, ha elaborado la propuesta contenida en este documento, y por la premura del tiempo la definición dada no se considera como definitiva

## 1. GLOSARIO DE TERMINOS RELEVANTES

- **EFECTOS ADVERSOS**: No necesariamente debe restringirse exclusivamente a accidente industrial, deben incluirse otras causas. Consecuencias sobre el ambiente físico, incluyendo la composición, resiliencia, y productividad de ecosistemas naturales o manejados, la biota y la salud humana causadas por la experimentación en el medio natural, la liberación o movimientos transfronterizos de organismos vivos modificados por la biotecnología

- **AUTORIDAD COMPETENTE**: Entidad u organismo público estatal designado por cada país miembro, autorizado para administrar el protocolo de bioseguridad, notificar y proporcionar información ....
  No incluir el manejo de residuos tóxicos, solo el manejo de la bioseguridad o productos biotecnológicos.

- **PUNTO FOCAL:** Un punto focal designado por los países responsable de recibir y remitir información acerca de .... Que puede o no estar comprendida dentro de la Autoridad Nacional competente.

- **MOVIMIENTO TRANSFRONTERIZO:** Significa cualquier movimiento de organismos y sustancias o productos obtenidos por medios de biotecnología, fuera de la jurisdicción nacional de un Estado o a través de un área dentro de la jurisdicción nacional de otro Estado o bien a través de un área que no está bajo la jurisdicción natural de un Estado (tierra, espacio aéreo y marino dentro del cual el estado ejerce autoridad y responsabilidad administrativa y regulatoria. Se estima que al menos dos Estados están involucrados en el movimiento.

- **UTILIZACION CONFINADA:** De acuerdo con la denominación de las guías técnicas del PNUMA

- **LIBERACION DELIBERADA:** Es más acorde con el sentido del protocolo, la definición de Borrador del Código de Conducta Internacional de la FAO sobre biotecnología vegetal.

- **ACCIDENTAL:** La definición de accidental no se circunscribe solamente a la liberación accidental al medio desde un medio confinado, ocurrirá también en el medio natural.
  El Perú considera que es necesario implementar los mecanismos (antidotos) para corregir la liberación al medio natural.

- **FAMILIARIDAD:** De acuerdo con la definición de las guías técnicas del PNUMA

- **ORGANISMOS VIVOS MODIFICADOS**: Organismos genéticamente modificados, de acuerdo a la propuesta del panel IV de Expertos.

- **EVALUACION DE RIESGO:** De acuerdo con la definición de las guías técnicas del PNUMA

- **GESTION DEL RIESGO:** De acuerdo con la definición de las guías técnicas del PNUMA. Consideramos necesario incluir dentro de la definición un sistema de alerta y prevención sobre la liberación al medio.

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## 2. CONTENIDO DEL PROTOCOLO

- El alcance jurisdiccional es un elemento importante para darle fuerza legal al protocolo y permita a los países cumplirlo.
- Obligaciones generales
- Inclusión obligatoria de una AIA. y procedimientos de notificación.
- Consideraciones para la evaluación y manejo de riesgo, los mecanismos deben ser manejados caso por caso.
- Procedimientos de emergencia
- Autoridad Nacional Competente y Punto Focal Nacional
- Fortalecimiento de la Capacidad.
- Requerimientos para manejo, transporte y tránsito de LMOs
- Movimiento transfronterizo entre Partes.
- Red de información técnica
- Temas financieros
- Consideraciones socioeconómicas.
- Conciencia pública.
- Responsabilidad y compensación
- Monitoreo y cumplimiento
- Los elementos siguientes de la lista son inherentes al manejo de un protocolo y estamos de acuerdo con su inclusión.

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# CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Second Meeting
Montreal, Canada
12 to 16 May 1997

**SOUTH AFRICA**

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# PROPOSED CONTENTS OF PROTOCOL ON BIOSAFETY

Title
Preamble
Glossary of terms/Definition of terms
Objectives
Scope
General obligations
Institutional framework
Competent authorities
Minimum national standards
Transboundary transfer - between parties
- between a party and non-parties
Packaging and labelling
Illegal traffic
Advance informed agreement
Notification procedure
Clearing house
Information exchange
Risk assessment
Risk management
Emergency procedures
Socio-economic issues
Liability
Compensation
Relationship with other international agreements
Settlement of disputes
Financial issues
Right to vote
Review and amendment
Signature
Entry into force
Ratification, Acceptance, Approval and Accession
Reservations
Withdrawal
Depository
Authentic text
Annexes

# PROPOSED GLOSSARY/DEFINITION OF TERMS IN PROTOCOL ON BIOSAFETY

Acceptable risk level
Advance informed agreement
Adverse effects
Centres of origin
Compensation
Competent authority
Contained use
Disposal
Handling of LMO's
Liability
Field trial - limited
- open
Living Modified Organisms (LMO's)
Minimum national standards
Modern biotechnology
Products of LMO's
Release - intended
- unintended/accidental
- trial
Risk assessment
Risk management
Transboundary movement
Transfer
Use of LMO's

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போக்குவரத்து, சுற்றாடல், மகளிர் விவகார அமைச்சு
MINISTRY OF TRANSPORT, ENVIRONMENT & WOMEN'S AFFAIRS

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## FAX MESSAGE

TO - Mr. Calestous Juma
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Biodiversity Secretary
Fax No. - (1-514) 288.65.88

From - Chandra Amerasekara
Additional Secretary
For Secretary - Ministry of Transport, Environment and Women's Affairs

JAN 6 1997

My Ref.- TEWA/E/27/3/33/1
Date - 31/12/96

CJ/CB

Subject - **Possible Content of the Protocol on Biosafety**

Reference to your letter dated 26/09/96 regarding the above mentioned subject.

Our comments on the passible content of the protocol on biosafety and terms proposed for the definitions are mentioned below.

1 The list B -"Items included in some but not all proposals" contains a more comprehensive list of items which are important to us. In our view, this list should be included in its entirety in the protocol.

2. Terms proposed for definition are adequate. One extra definition to be included is "illegal traffic".

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**SWITZERLAND**

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# Eléments pour l'élaboration du protocole sur la prévention des risques biologiques - Contribution de la Suisse

### Considérations générales

Le protocole sur la prévention des risques biologiques se concentrera principalement sur les aspects liés aux mouvements transfrontaliers d'organismes vivants modifiés résultant de la biotechnologie moderne susceptibles d'avoir des effets défavorables sur la conservation et l'utilisation durable de la diversité biologique (organismes vivants modifiés dans le texte). Le contrôle devra se baser sur la mise en place d'une procédure d'accord préalable donné en connaissance de cause.

Le protocole devra s'occuper uniquement des questions de sécurité. Les implications socio-économiques liées au développement des biotechnologies devront être traitées dans un autre cadre. Celui-ci devra être défini par la Conférence des Parties à la Convention sur la diversité biologique.

La compatibilité et si nécessaire la complémentarité du protocole avec les autres instruments internationaux existants, en particulier les accords de l'OMC, devra être assurée. De plus, la procédure d'amendement du protocole devra être aussi rapide et efficace que possible pour permettre une adaptation adéquate des dispostions du protocole à l'évolution des connaissances scientifiques et techniques.

## 1. Objectifs

Les objectifs de protection du protocole devront être définis en priorité. S'agit-il uniquement de la protection de la diversité biologique au sens ou l'entend la Convention sur la diversité biologique ou désire-t-on de manière plus large couvrir l'environnement dans son ensemble ainsi que la santé humaine.

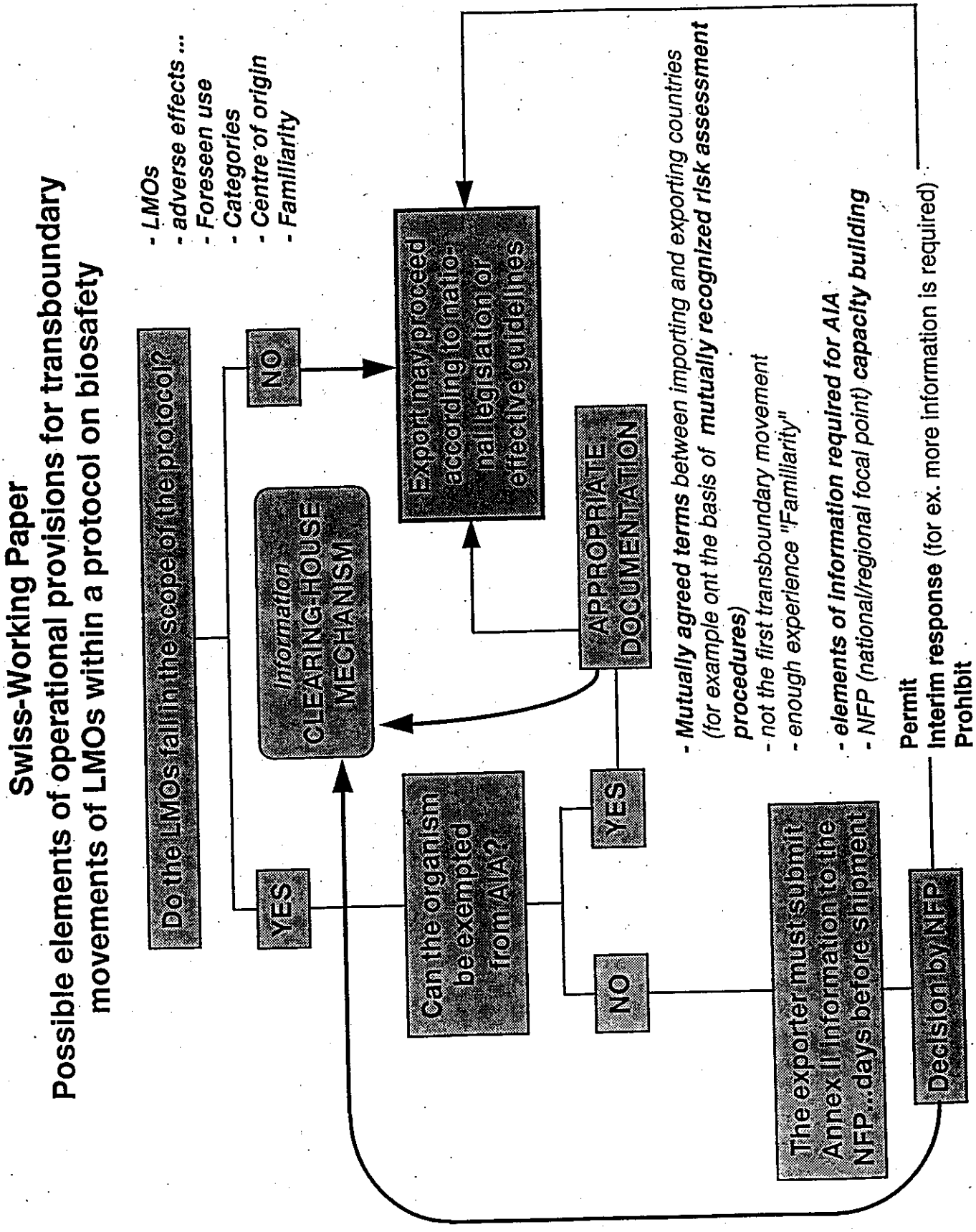
## 2. Champ d'application

### 21 Type d'organismes

Les concepts suivants critiques pour la détermination du champ d'application du protocole devront être définis en priorité:

- *Organismes vivants modifiés résultant de la biotechnologie* Selon notre interprétation, ce concept correspond aux organismes génétiquement modifiés définis dans notre législation comme: "organismes dont le matériel génétique a été modifié d'une manière qui ne se produit pas naturellement, soit par croisement ou par recombinaison naturelle". Sous cette définition on entend les organismes obtenus à l'aide des techniques de modification génétique interspécifique (transformation à l'aide de systèmes vectoriels, injection, bioballistique) ou par fusion interspécifique de protoplastes et/ou de cellules.
- *Effets défavorables sur la conservation et l'utilisation durable de la diversité biologique.* La précision de ce concept sera un des éléments clés pour la détermination du champ d'application du protocole.(voir point 1 Objectifs). Traditionnellement, d'autres impacts potentiels sur l'environnement et la santé sont pris en compte dans la procédure d'évaluation du risque. Veux-t-on se concentrer sur la diversité biologique ou au contraire adopter une approche plutôt orienté sur le risque global. Dans le premier cas il semble alors peu logique de se limiter aux seuls organismes transgéniques puisque d'autres catégories d'organismes, comme par exemple les exotiques, sont également susceptibles d'avoir des effets négatifs sur la diversité biologique. Une analyse comparative des instruments internationaux en vigueur pour le contrôle du mouvement transfrontalier des organismes exotiques permettrait d'identifier les lacunes existantes et de définir de manière pertinente le champ d'application.

ANNEXE


Swiss-Working Paper
Possible elements of operational provisions for transboundary movements of LMOs within a protocol on biosafety
- LMOs
- adverse effects ...
- Foreseen use
- Categories
- Centre of origin
- Familiarity
Do the LMOs fall in the scope of the protocol?
NO
YES
Information CLEARING-HOUSE MECHANISM
Export may proceed according to national legislation or effective guidelines
APPROPRIATE DOCUMENTATION
- Mutually agreed terms between importing and exporting countries (for example ont the basis of mutually recognized risk assessment procedures)
- not the first transboundary movement
- enough experience "Familiarity"
- elements of information required for AIA
- NFP (national/regional focal point) capacity building
Can the organism be exempted from AIA?
YES
NO
The exporter must submit Annex II information to the NFP ... days before shipment
Decision by NFP
Permit
Interim response (for ex. more information is required)
Prohibit

# Définition des termes - Contribution de la Suisse

Les définitions ci-dessous sont tirées des dispostions de notre législation fédérale, essentiellement de la loi fédérale sur la protection de l'environnement.

*Organismes*:

Par organismes, on entend les entités biologiques et cellulaires ou non cellulaires capables de se reproduire ou de transférer du matériel génétique. Le mélanges ou objets contenant de telles entités leur sont assimilés.

*Organismes génétiquement modifiés:*

Par organismes génétiquement modifiés, on entend les organismes dont le matériel génétique a été modifié d'une manière qui ne se produit pas naturellement, soit par croisement, soit par recombinaison naturelle.

*Utilisation en milieu confiné:*

Des organismes sont dits utilisés en milieu confiné lorsque leur contact avec la population ou l'environnement est limité ou empêché par des barrières physiques ou par des barrières physiques combinées à des barrières chimiques ou biologiques

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**THAILAND**

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## Views from the Royal Thai Government (RTG)

( with reference to the Report of the first meeting of the Working Group (UNEP/CBD/BSWG/1/4) for the future work of the Working Group )

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### I. Possible Content of the Protocol on Biosafety :

The RTG would like the Working Group to consider the content of the future protocol with reference to Annex A. and B. with the following views ;

1. The items to be included in all proposals under Annex A. should remain as is and should further serve as the main items in the development of the protocol.

2. The items included in some but not all proposals under Annex B. should be sorted out on the basis of relevance to the national requirements and existing related national regulations. For Thailand, these items may include ;

   - Scope
   - Mechanisms for risk assessment and risk management
   - Capacity building
   - Handling, transport and transit of GMOs
   - Monitoring and compliance

   The Working Group could help formulate and develop the related text and leave the final inclusion to the jurisdiction of the party or government concerned.

   The items deemed important and relevant to a country/ countries may not be so in another country/ countries. Thus, to formulate and develop the texts of respective items, the country/ countries proposing items should be assigned to formulate and develop the text for the items they proposed. The Secretariat records could reveal the country/ countries making such proposal.

### II. Definition in the Protocol :

Referring to Appendix I : Terms proposed for definition, the views of the RTG are that most of the terms proposed and as defined in the draft copy by CBD Secretariat date 26 September 1996 are acceptable except the terms " Living Modified Organisms (LMOs)" whose definition is certainly acceptable but the term itself is not. The term "Genetically Modified Organisms (GMOs)" is preferable from the view point of the RTG. Its the RTG understanding that the protocol is intended to consider only the organisms developed through genetic engineering process ( transfer of novel gene (s) into organisms). The resulting organisms are called "transgenic organisms". Modified organisms developed by other biotechnology such as the molecular markers aided selection are not GMOs or transgenic organisms and they are the same those developed by conventional breeding. the RTG thus requests the Working Group to reconsider this terminology during the course of its future work. It is also suggested

the semantics be kept at the minimal in the development of the definitions of these terms.

**III. Background documents to be compiled on existing international agreements**

In addition to existing international agreements, some of which are already stated and many of which could have been compiled by the Secretariat, the RTG would like to add to the list additional Regional regulation closely related to biosafety issue in the ASEAN region, namely, the ASEAN Ministerial Understanding on Plant Quarantine Ring, 1982 and the ASEAN Guidelines for the Introduction of Biological Control Agents, 1985. The texts of these agreements are appeared herewith (Appendices I and II ).

The RTG would also like to bring to your attentions, if this has yet to be compiled, the FAO International Code of Conduct on the Introduction of Biological Control Agents, whose text could probably be available with FAO Office in Rome. Another international "agreement" is the Guidelines for biological Control Projects in the Pacific developed by the South Pacific Commission in 1991. A copy is appended as Appendix III.

In close relation and association with existing international agreement, the RTG would like to propose that any national and/or regional agreements of related nature should also be compiled. the Secretariat could bring this proposal up to the Working group to solicit any available biosafety guidelines in member countries as an additional effort to help support relevant protocol. In Thailand, the National Biosafety Committee has developed BIOSAFETY Guideline in Genetic Engineering and Biotechnology (I) For Laboratory Work and (ii) For Field Work and Planned Release. The essence of which is similar to the UNEP International Technical Guidelines for Safety in Biotechnology, no date, 1996 ?. A set of the said guidelines has been earlier dispatched to the CBD Secretariat in Montreal and another set is appended herewith ( Appendices IVa and Ivb)

**IV. Other matters :**

The RTG would like to bring it to your attention that although the country has not ratified the CBD yet, the concern authority is attempting at its utmost ability to expedite the ratification through the cabinet. In the meantime, the country has developed to a very large extent certain mechanism to enable the country to accommodate the CBD effectively.

The RTG would also like to extend our appreciation to the Secretariat for all the supports rendered to the RTG in the implementation of the Convention. THANK YOU.

Appendix I

# ASEAN MINISTERIAL UNDERSTANDING ON PLANT QUARANTINE RING

We, the undersigned, attending the Fourth Meeting of the ASEAN Ministers on Agriculture and Forestry in Kuala Lumpur, Malaysia, on 8–9 October, 1982, upon the invitation of his Excellency, Datuk Abdul Manan bin Othman, Minister of Agriculture, Malaysia;

Recalling the Declaration of ASEAN Concord signed in Bali, Indonesia on 24th February 1976, which provides that ASEAN member countries shall take cooperative action in their national and regional development programmes;

Realizing that plant pests do not recognize national boundaries and therefore more effective cooperation is necessary among member countries in controlling plant pests;

Reaffirming the principles guiding ASEAN cooperation in the field of food and agriculture to promote a strong, peaceful and resilient ASEAN community;

Noting the Manila Consensus arising from the First Meeting of ASEAN Agriculture Ministers in Manila in August 1979;

Recognizing the ever-increasing threat of having exotic plant pests and diseases introduced into the countries of the ASEAN due to:

a) increased movement of people and commodities in international trade;

b) expending agricultural programmes; and

c) the urgent need to introduce new or improved plant varieties.

Recalling that many of the world's most destructive plant pests and diseases still are not known to occur within the ASEAN Region;

Noting further that the ASEAN Regional Plant Quarantine Centre and Training Institute (PLANTI) has carried out a pest risk analysis of plant pests;

Fully aware of the adverse economic consequences that could result from the introduction and establishment of some of the most injurious exotic plant pests and pathogens into any ASEAN country;

We, Representing Member Countries in the ASEAN, do hereby agree that:

(i) All member countries shall follow the ASEAN pest risk analysis for excluding dangerous and exotic pests from entry into the ASEAN Plant Quarantine Ring;

(ii) All member countries shall practise inter and intrastate quarantine;

(iii) In the event of the report of the presence of a dangerous pest, immediate action should be taken to eradicate the pest from within the ASEAN Quarantine Ring;

(iv) Member countries which intend to introduce beneficial insect and biological control agents not present in the ASEAN Region should inform other member countries.

Done at Kuala Lumpur on the Ninth Day of October, One Thousand Nine Hundred and Eighty-Two. □

Appendix II

# ASEAN Guidelines for the Introduction of Biological Control Agents

The ASEAN PLANTI meeting on Weeds of Plant Quarantine Importance, held in Tagaytay City, the Philippines from 19-21 July 1985 formulated and agreed on the guidelines for the introduction of any biological control agent. These guideline are as follows:

- Importation of biological control agents should be prohibited without authorisation from the importing country's Department of Agriculture.
- The Plant Quarantine Section of the Department of Agriculture on behalf of the agency concerned should issue permits for such imports.
- A Working Group on Biological Control of Weed (WGBCW) should be established in each ASEAN country. This group should comprise research scientists from government and private agencies, plant quarantine/plant protection officers of the country, officers from PLANTI, researchers from the universities and any other competent researcher. The objective of WGBCW should be to review proposals for the introduction of organisms. The WGBCW should also provide recommendations to the Plant Quarantine/Protection Service of the Department of Agriculture and to the importer on the testing and release of biological control agents. The importer may request that the WGBCW review proposals before initiating foreign surveys on a target weed and to be advised on potential conflicts of interest. The WGBCW may suggest a list of hosts to be screened in specificity testing.
- Whenever practical, a potential biological control agent should be screened and evaluated in its native habitat before importation. This can be done by maintaining overseas biological control laboratories or alternatively, by collaboration with overseas scientists.
- Exotic biological control agents may be imported into an approved quarantine laboratory for evaluation of host range safety and efficacy. The construction and operation of the facilities and the technical competence of investigators should be well established and it should be the responsibility of the Plant Quarantine/Plant Protection Services of the Department of Agriculture.
- Before introducing exotic biological control agents into quarantine facilities, it is desirable to first identify the species of the organisms and to obtain information on the preliminary host range.
- Any shipment of biological control agents must be in containers meeting plant quarantine safety standards and shipped to approved quarantine facilities under the appropriate plant quarantine permits.

Pathogens especially fungi, need not be single-spored strains. A mixture of strain is preferred, not only for increasing the prospect of long term control of the weed (through effectiveness against several forms of the weed and by recombination of the virulent strains), but also for indicating the potential for the pathogen's variability.

For the shipment of insects, the survival capabilities of the organisms have to be considered. It is important to select a developmental stage of the insect that is capable of surviving for the projected duration of the trip, plus a few days in case of delay, and upon arrival will be healthy enough for the required study or culturing. If conditions do not permit a choice of developmental stages of the insect, speed and cool temperatures during transit become even more important.

- The biological control agent should not be distributed to other researchers or laboratories without approval from the Plant Quarantine/Plant Protection Services. If a biological control agent is found to be a potential pest of valued plants, the organism should be destroyed immediately.
- Once an exotic organism has been found to be a desirable biological control agent, a proposal should be made by the importer to the agency concerned for review and recommendation for its release from quarantine. In reviewing the proposal, the WGBCW should be concerned primarily with the safety of the proposed introduction. The host range data provided by the importer should form much of the basis for approval or disapproval of the organism. Efficacy of the organism and the economic need for biological control should be secondary, although they are also important considerations. The WGBCW should concur with all the regulatory agencies of the ASEAN countries before recommending release of the exotic organism. On the recommendation of the WGBCW, plant quarantine may authorise such release for field use or testing. An exotic organism may not be initially cleared for mass release but might be approved for limited field tests. Further release will often depend on the success of these initial tests.

It was agreed that all ASEAN countries which intend to introduce beneficial insects and biological control agents not present in the ASEAN Region, should inform other member countries of their action.

- A culture or specimen of the biological control agent must be deposited at a recognised institute or centre (eg. PLANTI).
- Pesticides capable of controlling the biological control agent, be it insect, pathogen or nematode, must be known before any introduction.

These safety guidelines are necessary since there is continued interest among agencies to introduce biological control agent into the ASEAN. Literature available from the ASEAN indicates that there have only been a few example of successful introductions of biological control agents for suppressing weeds.

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*Condensed from an article on the same subject published in the PLANTI News. Vol. 4, No. 2*

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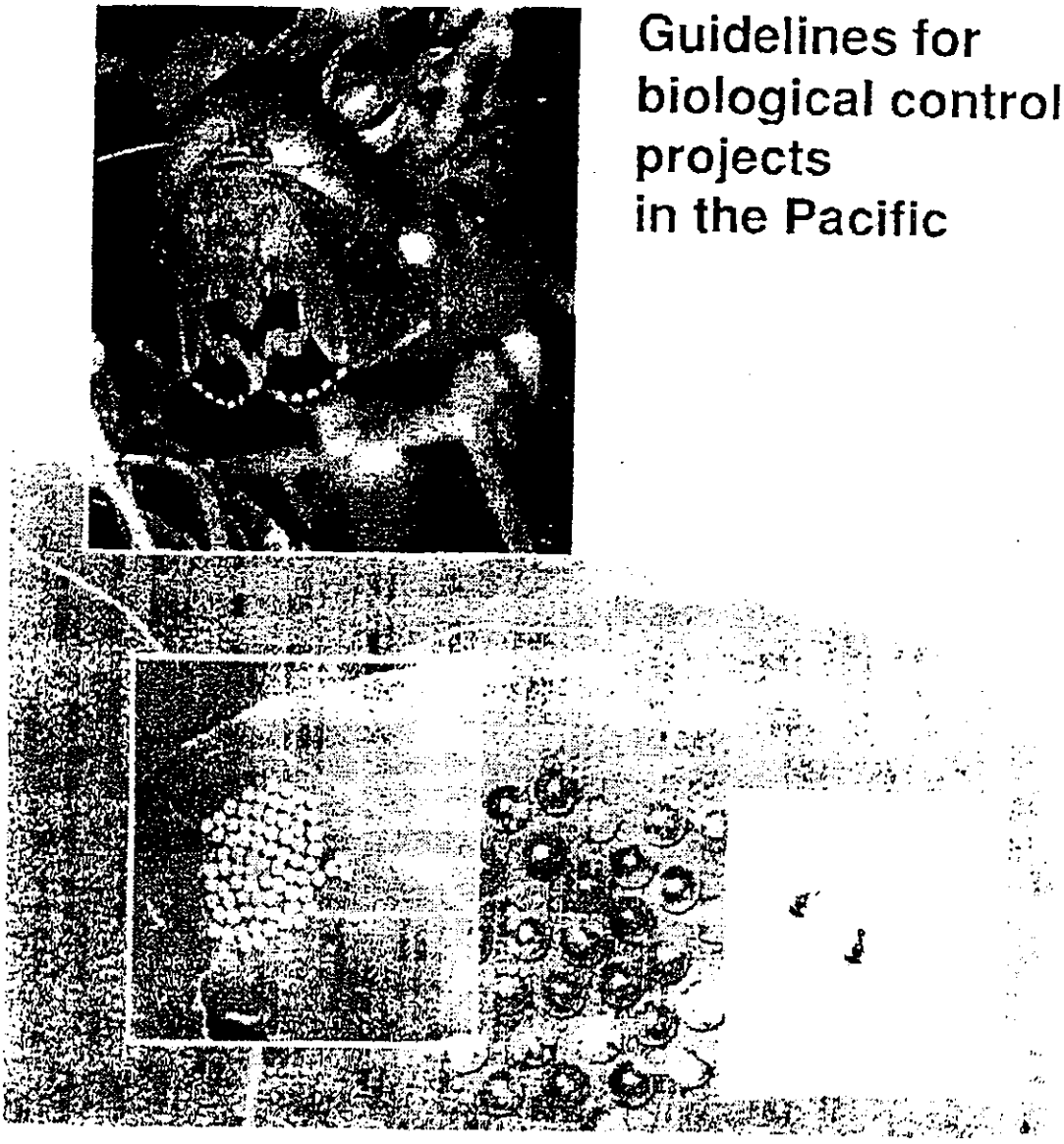
Information Document No. 57

Appendix III

South Pacific Commission

ACIAR
AUSTRALIAN CENTRE FOR INTERNATIONAL AGRICULTURAL RESEARCH



# Guidelines for biological control projects in the Pacific

South Pacific Commission
Noumea, New Caledonia

UNEP

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**UNITED STATES OF AMERICA**

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Submission by the United States of America to the Secretariat of the Convention on Biological Diversity for the Elaboration of a Protocol on Biosafety

I. Introduction.

1. At the first meeting of the Open-ended Ad Hoc Working Group of Experts on Biosafety, held in Aarhus, Denmark, from 22 to 26 July 1996, it was agreed that the basic document for consideration at the Ad Hoc Working Group's May 1997 meeting should be a compilation of the submitted views of governments on the contents of the future protocol on biosafety.

2. This submission by the United States is in accordance with the terms of this discussion and is transmitted in response to the Secretariat's 26 September, 1996, invitation to governments to submit their views.

3. Two sets of possible protocol items emerged in Aarhus; a set of "Items included in all proposals" and a set of "Items included in some but not all proposals." The United States believes that the development of an effective protocol will be facilitated if, before moving into consideration of other items, the May meeting of the Ad Hoc Working Group considers the views of governments on two of the "Items included in all proposals," advance informed agreement and information sharing, and any institutional structures required to implement them. For this reason, although the attached U.S. submission addresses briefly all of the "Items included in all proposals," it focuses on the two central items identified above.

II. Views on "Items Included in All Proposals" for Consideration as Contents of the Protocol.

Preamble.

4. The negotiation of this element should be secondary to the negotiation of the substantive provisions of the protocol and should be addressed at a later stage in the negotiation process.

Use of Terms/Definitions.

5. We believe the components of this element also should be undertaken later in the negotiation when the Ad Hoc Working Group has had a greater chance to work through the conceptual bases of the key components of the protocol.

Information Sharing.

6. In determining the appropriate scope of protocol provisions on information sharing and how the information-sharing mechanism would work, we believe it will be important to consider the purpose of such provisions as well as the operating mechanism required to implement it. (In our view, determining which processes, activities, and/or organisms particular protocol provisions should cover is the most constructive way to address the "scope issue." At this stage, we are not convinced of the need for the protocol to contain a more general article on scope. The Convention on Biological Diversity (CBD) contains no such provision, and the legal relationship between it and other provisions in the protocol whose coverage is described in different terms might be unclear. However, we do believe that a "Jurisdictional Scope" provision, could, like article 4 of the CBD, clarify those processes and activities in respect of which the obligations of parties to implement the protocol will apply, and should be considered by the Ad Hoc Working Group at a later date.)

7. Purpose. We believe that making general information available on a broad class of living modified organisms (LMOs) could serve to address issues of concern that competent authorities and interested others may have about biotechnology, LMOs and LMO-based products. Thus, the protocol's information-sharing requirements could extend even to those LMOs that are not likely to have adverse effect on the conservation and sustainable use of biological diversity.

8. A provision on information sharing:

--could seek to facilitate the exchange of information on and experience with LMOs to enable parties to make informed decisions related to biosafety;

--should take into account the existing obligations of the Convention, Articles 17(1), 17(2), and 19(4); and

--could cover a broad class of LMOs the production and/or use of which has been or is regulated by the party to the protocol.

9. Operating Mechanism. Information sharing could be facilitated through a centralized clearinghouse or database, coordinated by an existing organization. Parties to the protocol could make available to the clearinghouse mechanism publicly available information:

--on domestic laws/regulations applicable to the production and/or use of LMOs; and

--on risk assessments or environmental reviews generated by the regulatory process.

Advance Informed Agreement.

10. As for the information-sharing provisions, the Ad Hoc Working Group will need to consider the purpose, scope, and procedures necessary for implementation of the protocol's advance informed agreement (AIA) mechanism.

11. Purpose and Scope. An AIA mechanism ensures that an importing country has had an opportunity for informed decision making prior to importation. In our view, such a safeguard would be appropriate when: the LMO fits into a category of LMOs whose importation and intended use raise reasonable concerns regarding conservation and sustainable use of biodiversity; the strain or variety of LMO covered by the AIA provisions has not been imported into the intended country of import since the entry into force of the protocol; and the intended country of import is not itself producing the strain or variety of LMO covered by the AIA provisions. The Ad Hoc Working Group will need to identify such categories of LMOs, e.g., by focusing on specific product sectors.

12. It is important for the protocol to be able to take into account up-to-date scientific knowledge; thus, mechanisms under the AIA provisions must be both commensurate with identified risks and adaptable.

13. Operating Mechanism. As noted above, the AIA provisions should set out appropriate procedures for advance notification of an exporter's intent to ship an LMO that falls into one of the categories set forth in the AIA provisions and has neither been imported into the intended country of import since the entry into force of the protocol nor is being produced by it. The provisions should also describe possible responses by the importing country. In order to ensure effective operation of the AIA regime, this notice and response process should not be overly bureaucratic . Therefore, the AIA provisions should operate primarily bilaterally with an important, though limited, role for a central clearinghouse. (We do envision copies of all relevant AIA activities being sent to the central clearinghouse for the information of other parties and to ensure transparency under the AIA regime.)

14. With respect to the infrastructure through which the AIA would function, we envision the steps outlined in paragraphs 15-19.

15. An exporter under the jurisdiction of a party to the protocol and arranging for the export of a shipment containing an LMO would first contact the national focal point in the exporting country to ascertain whether the strain or variety of LMO falls under one of the categories set forth in the AIA provisions. (Designation of the national focal point(s) in both exporting and importing countries would be a requirement of the protocol.) The exporter would also need to find out whether the strain or variety of LMO had been imported into the intended country of import since the entry into force of the protocol or was being produced by the intended country of import. We anticipate that this

information would come from the central clearinghouse, either directly or through the exporting country's national focal point. (The clearinghouse would thus need to be a repository for both importation and production information and would likely need to use a standard classification scheme to ensure effective verification of the status of importation and domestic production of LMOs falling into the specified categories.) If the exporter was informed that the strain or variety of LMO did not fall under a category set forth in the AIA provisions or that the LMO did fall into a specified category but had been imported into the intended country of import since the protocol's entry into force or was being produced by the intended country of import, the exporter could ship to that country without notifying the importing country's national focal point. If, however, the exporter was informed that the strain or variety of LMO did fall under a category set forth in the AIA provisions and had not been imported into the intended country of import since the protocol's entry into force and was not being produced by the intended country of import, the exporter would be required to notify the importing country's national focal point of the intended shipment. (An information copy of this notification would also go to the central clearinghouse and to the national focal point in the exporting country.)

16. Following any advance notification, the importing country's national focal point would have a specified period of time to respond, after which consent would be deemed to have been given. The importing country's national focal point would also have a specified period of time to provide an information copy of its response to the exporting country's national focal point and to the central clearinghouse.

17. Noting paragraphs 20 and 22 of this submission, we envision the protocol specifying that the importing country could take the following actions in response to notification: express consent to import ; be silent, which would be deemed consent to import after the specified period of time had elapsed; request further information; consent to import with stated conditions of acceptance (e.g., procedural requirements such as acceptance subject to risk assessment); consent to import but with defined restrictions; or communicate a decision not to allow import.

18. The importing country's national focal point would notify the clearinghouse of importation of a strain or variety of LMO for which advance notification has been given. The importing country's national focal point would also be responsible for notifying the clearinghouse of changes in its policies regarding the importation of particular strains or varieties of LMO that fit into the categories set forth in the AIA provisions.

19. The Ad Hoc Working Group should also consider the type of information that should be provided by the exporter in any advance notification. This consideration could be based on relevant provisions of the UNEP International Technical Guidelines on Safety in Biotechnology which apply to first time shipment.

20. The protocol, including the AIA mechanism, should be implemented in a manner that is fully consistent with the provisions of the WTO. Specific provisions should be

incorporated into the protocol which require that decisions by countries to restrict or prohibit import of LMOs must apply uniformly to all sources of import as well as to domestic production for domestic sale or use.

Institutional framework for the Functioning of the Protocol/Amendment/Final Clauses.

21. Issues such as protocol structure, amendment procedures, and other issues arising in relation to the protocol's final clauses should be based on full knowledge of provisions of the protocol and should therefore be addressed at a later stage in the negotiation process. (It should be noted, however, that, in addressing these issues, the protocol should provide for evolving scientific and technological expertise to be taken into account. In addition, consideration should be given to the use of the existing CBD infrastructure.)

Relationship with Other Agreements.

22. The protocol should specify that nothing in it shall affect the rights and obligations of countries under agreements that have entered into force prior to the adoption of the protocol.

Dispute Settlement.

23. Consistent with Convention article 27.5 and with Decision II/5 of the Conference of Parties, which specified that the provisions of the Convention would apply to the protocol, the protocol should make clear that the dispute settlement mechanism set out in article 27 of the CBD would apply to any disputes regarding the interpretation or application of the protocol.

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# CONVENTION ON BIOLOGICAL DIVERSITY

OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY
Second Meeting
Montreal, Canada
12 to 16 May 1997

**ZAMBIA**

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REPUBLIC OF ZAMBIA

# MINISTRY OF ENVIRONMENT AND NATURAL RESOURCES

P.O. BOX 34011
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December 23, 1996

Mr Calestous Juma
The Executive Secretary
Convention on Biological Diversity
World Trade Centre
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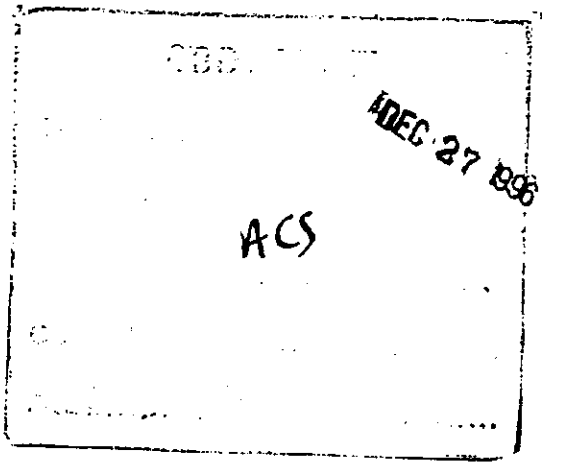


Dear Mr Juma,

**DRAFT BIOSAFETY PROTOCOL**

As you may be aware the African Group held a Consultative Meeting on Biosafety Protocol in Addis Ababa, Ethiopia from 23-25 October, 1996 during which the experts drew up a Draft Biosafety Protocol.

Considering the importance of this subject, Zambia would like to study this Draft Biosafety Protocol in more detail to ensure that our interests and concerns are adequately covered, and that the Protocol is in harmony with our existing legislation.

Therefore, in the meantime, we are only able to indicate to you the elements (contents) that Zambia would like the Biosafety Protocol to cover as reflected on the attached two pages.

Yours sincerely,

S. C. Zimba
Acting Head, Planning and Information Department
/ PERMANENT SECRETARY
MINISTRY OF ENVIRONMENT AND NATURAL RESOURCES

ELEMENTS OF THE DRAFT BIOSAFETY PROTOCOL

1. PREAMBLE;
2. ARTICLE 1: DEFINITIONS;
3. ARTICLE 2: OBJECTIVE;
4. ARTICLE 3: SCOPE;
5. ARTICLE 4: GENERAL OBLIGATIONS;
6. ARTICLE 5: DESIGNATION OF A COMPETENT AUTHORITY;
7. ARTICLE 6: ADVANCED INFORMED AGREEMENT;
8. ARTICLE 7: TRANSBOUNDARY TRANSFER AND NOTIFICATION PROCEDURES;
9. ARTICLE 8: ILLEGAL TRAFFIC AND RIGHT TO DESTROY;
10. ARTICLE 9: LABELLING, PACKAGING AND TRANSPORTATION;
11. ARTICLE 10: RISK ASSESSMENT AND MANAGEMENT;
12. ARTICLE 11: EMERGENCY MEASURES;
13. ARTICLE 12: SOCIO-ECONOMIC IMPACTS
14. ARTICLE 13: CAPACITY BUILDING;
15. ARTICLE 14: INTERNATIONAL COOPERATION;
16. ARTICLE 15: BIOSAFETY CLEARING HOUSE;
17. ARTICLE 16: NATIONAL ARRANGEMENTS TO IMPLEMENT THE PROTOCOL;
18. ARTICLE 17: LIABILITY AND COMPENSATION;
19. ARTICLE 18: MONITORING
20. ARTICLE 19: PUBLIC AWARENESS AND PARTICIPATION;
21. ARTICLE 20: EXCHANGE OF INFORMATION;
22. ARTICLE 21: MEETINGS OF THE PARTIES
23. ARTICLE 22: SECRETARIAT;
24. ARTICLE 23: FINANCIAL MATTERS;
25. ARTICLE 24: AMENDMENTS TO THE PROTOCOL OR ANNEXES;

26. ARTICLE 25: SETTLEMENTS OF DISPUTES;

27. ARTICLE 26: RIGHT TO VOTE;

28. ARTICLE 27: RELATIONSHIP OF THIS PROTOCOL TO THE CONVENTION;

29: ARTICLE 28: SIGNATURE;

30. ARTICLE 29: RATIFICATION, ACCEPTANCE, APPROVAL AND ACCESSION;

31. ARTICLE 30: ENTRY INTO FORCE;

32. ARTICLE 31: RESERVATIONS;

33. ARTICLE 32: WITHDRAWALS;

34. ARTICLE 33: DEPOSITORY;

35. ARTICLE 34: AUTHENTIC TEXTS

~~The Draft Biosafety Protocol has the following annexes~~:

Annex 1: Information required in order to obtain advance informed agreement;

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

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

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**SUBMISSIONS RECEIVED PAST DUE DATE**

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**INDIA**

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India's views on the elements/contents of the Protocol on Biosafety.

1. Objectives and scope

The objective of this Protocol should be as per the decision II/5 of the second Conference of the Parties to the Convention on Biological Diversity held in Jakarta in November, 1995.

The scope of this Protocol should include all aspects of research and development, handling, use, transfer (intended or unintended) and disposal after use, whether under contained conditions, during field trials or release into the environment.

2. Advanced Informed Agreement (AIA)

There should be no transfer of LMO or its product without the prior consent of the importing country. To facilitate an informed decision by the importing country, the exporting country or the actual exporter, must furnish complete information to the importing country based on which an **Advanced Informed Agreement (AIA)** between the importing country and the exporting country/exporter may be reached. **AIA** should interalia include:

- full description of the characteristics of the LMO including prescribed and desired ecological and other parameters.
- regulations concerning safe transfer, handling and use of the LMO in the exporting country
- risk assessment
- conditions of real containment in the case of contained use, such as closed laboratories, inactivation of waste water, sludge, used air etc.
- testing under real conditions, with growing plants and living soil organisms, in different soil types and under different water conditions, prior to the release of the LMO.
- comparison of actual impact during testing phase with the prior risk assessment.
- full risk management procedures adopted
- reception and response by the people and stake holders in biodiversity conservation in the country of origin
- reception and response by the people and stake holders in biodiversity conservation in the country where field test

conducted

- full information on prior releases of the LMO including ecological conditions and socio-economic impacts.
- reception and response in the country where released
- institutional requirements

3. Risk Assessment

Risk assessment interalia should be based on the characteristics of the organism, the introduced trait, intended use, the receiving environment, knowledge about ecological interactions, possible socio-economic impacts, and the interaction among these. Special consideration should be applied to risk assessment in centres of origin and genetic diversity.

The parameters for risk assessment should interalia include:

- Nature and toxicity of transgene
- Interactions between LMO and the environment
- Downstream effects of transgene in food chain/chemical process chain
- Analysis of the survival rate of LMOs, their competitiveness with indigenous organisms, their reproduction rates and their dispersal abilities by both passive and vector mediated movement.
- A full assessment of ecological consequences of the release of LMO in terms of productivity, nutrient uptake, competitiveness and allelopathic potential, to be carried out on a case-by-case basis, and separately for different situations, locations and countries.
- Monitoring procedures of the effects for adequate length of time.
- Risks to health and environment
- Socio-economic impacts

4. Risk Management

Measures ensuring safe handling, transfer and use of LMOs constitute risk management. Risk management should include contingent management plans in case of accidents. In addition, provisions of compensation and liability should also be included.

5. Liability and Compensation

The protocol should have provision for liability and compensation.

6. Definition of some important terms

(i) Living modified organisms (LMOs)

LMOs are organisms or components thereof having reproductive capability, produced by genetic modification and where the resultant genetic make up is unlikely to occur in nature.

(ii) Transboundary movement

Transboundary movement should imply movement across boundaries of countries, and should include intended as well as unintended movement.

7. Other important issues

Other important contents of the protocol should include interalia:

- Public participation
- Information to transit countries
- Export of banned products
- Emergency plans
- Capacity building
- Financial mechanism
- Settlement of disputes

The above-mentioned issues require considerable attention and should be deliberated upon extensively by the open-ended Ad-hoc Working Group on Biosafety.

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**INDONESIA**

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# Indonesia's View on the Possible Content of the Protocol on Biosafety

## Possible Content of the Protocol on Biosafety

Title
Preamble
*Objectives*
*Scope*
Use of Terms / Definition
Biosafety Principles
- Protection Against the Unknown
- Protection to Human Health and Safety
- Protection to the Environment and Biodiversity

Biosafety Arrangement and Regulation
- Categorization of GMO's
- Social and Culture Consideration
- Economic Consideration
- Approval of the Contained Use
- Consent for the Development of GMO's
- Consent for the Release of GMO's
- *Mechanisms of Risk Assessment*
- *Mechanisms of Risk Management*
- *Emergency Procedure*
- *Transport of Packaging Requirements for the Transfer of LMO's*
- *Handling, Transport and Transit Requirements for LMO's*

*Transboundary Movement Between Parties*
*Transboundary Movement from a Party through States which are not Parties*
Advanced Informed Agreement
*Capacity Building*
Information Sharing
Relationship with Other International Agreements
Traditional Farmers and Practice Consideration
Institutional Framework for the Functioning of the Protocol
*Liability/Liability and Compensation*
*Designation of Competent Authority and National Focal Point*
*Notification Procedure*
*Clearing House*
Settlement of Disputes
Amendment
Final Clauses
*Annexes*

## Terms proposed for definition:

Living Modified Organisms (LMO's)
Transboundary Movement of LMO's

Transboundary Movement of LMO's
Transboundary Consequences due to LMO's without Physical Transboundary Transfer
Packaging of LMO's
Transfer of LMO's
*Competent Authority*

**Adverse Effect**
**Contained Use**
**Intended / Deliberate Release**
**Unintended Release**
**Accidental Release**
**Focal Points**
**Risk Assessment**
**Risk Management**
**Modern Biotechnology**
**Modern Biotechnology Products**
**Advance Informed Agreement / *Prior Informed Consent***
**Biosafety**
**Field Trial**
**Limited Field Trial**
**Open Field Trial**
**Open Environment**
**Handling of LMO's**
**Use of LMO's**
**Use of LMO Products**
**Centres of Origin**
**Centres of Diversity**
**Centres of Genetic Diversity**
**Liability**
**Compensation**
**Socio-cultural Considerations**
**Economic Considerations**

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Note: bold = items included in all proposals (report of the Aarhus Meeting, July 22-24, 1996)
bold with underline = new proposal by the Government
Italics = items included in some but not all proposals (report of the Aarhus Meeting, July 22-24, 1996)

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**RUSSIAN FEDERATION**

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PRELIMINARY

# Proposals of the Russian Federation to the structure of Biosafety Protocol within Convention on Biological Diversity (CBD)

1.It seems natural and obvious that the Parties to the CBD will ever have their national and regional peculiarities in building and managing regulatory and informational systems. Therefore, the main aim of the Protocol is to become an instrument enabling "equal rights dialogue" in transfer of "living modified organisms" (LMO) as well as LMO based products and technologies.

2.Thus, of "Items included in all proposals" two are of basic significance: "Information sharing" (IS) and "Advance informed agreement" (AIA). It seems reasonable that all other items should be discussed by the Ad Hoc Group after IS and AIA are finalised.

3.Information Sharing (IS):

the structure of this element includes "Jurisdictional scope" (on the level provided by Art. 4, CBD), aims and operation mechanism.

Aims: IS should in compliance with the Convention give provisions for free submission and distribution of information which the Parties have on LMOs and LMO base products and technologies, basically biosafety related necessary for the mechanisms of risk assessment/management. The Information should be provided on any LMO not only on those which are now known to have a potential adverse effect on conservation and sustainable use of biodiversity.

Operational mechanism: should be based as a network of national focal points with the central node (hub) being a kind of a Clearinghouse which is operated by an existing international organisation (the example is BIOTRACK-OECD and BIOBIN-OECD/UNIDO). The main task of the hub is gathering and validation/verification of information on existing legislative and regulatory acts and systems, introduction of LMOs and LMO based products and technologies, provision of assistance in performing risk assessment/management procedures.

4.Advance Informed Agreement (AIA):

AIA mechanism should ensures submission, to the possible extent, complete required information on LMOs and LMO based products and technologies using genetically engineered material which are to be imported into a country (a Party) prior to the importation in the case the imported material (technology) has not been produced/used or imported into the recipient country since the entry into force of the Protocol. In the first turn AIA should be applied to those LMOs (products/technologies) that might have an adverse effect on conservation and sustainable use of biodiversity. It seems reasonable that the Ad Hoc Group take an effort to draw a regularly updated list of such LMOs on a basis of sectoral approach.

Operational mechanism: similarly to paragraph 3 should base on direct interaction between exporter and the national focal point of importing Party which estimates necessary volume and level of submitted information. The focal point should also accomplish all necessary formalities with national competent authorities in order to issue a permit to import of to

forbid it. It is obvious that there should be a direct connection between IS and AIA mechanism to provide adequate estimate of risk/benefit by importing Party and to be able to keep in line with up-to-date scientific knowledge and also to enable, when possible, notification instead of application procedure.

5.It is obvious that the Protocol should be able to use up-to-date knowledge, therefore, it seems useful to add a new element to its structure "Generic/Basic guidelines" which similarly to UNEP Guidelines (UNEP International Technical Guidelines for Safety in Biotechnology) could give generic principles of risk assessment/management procedures, choice and operational principles of national focal points, projection of direct bilateral information exchange on multilateral. It could also contain a thesaurus of terms and definitions which could be regularly updated.

6.Relations with other international agreements: it is obvious that agreements which were signed and came into force before the entry into force of the Protocol should not be affected by the latter. Implementation of the protocol should be completely consistent with the provisions of WTO (TRIPPS is extremely important).

7.Thus, the basic structure of the Protocol includes "Items included in all proposals" with the addition of two elements "Generic/Basic guidelines" and "Jurisdictional scope". However, finalisation of the structure and of the implementation mechanism of the Protocol is possible after the detailed elaboration of IS AIA and "Generic/Basic guidelines".

Предварительные

## Предложения Российской стороны по структуре Протокола по биобезопасности в рамках Конвенции о биологическом разнообразии

1. Представляется естественным и очевидным, что Стороны всегда будут иметь свои национальные и региональные особенности регуляторных и информационных систем, равно как и различный уровень развития и заинтересованности в продвижении биотехнологий, поэтому основная задача Протокола состоит в том, чтобы стать инструментом, обеспечивающим возможность равноправного диалога при передачи "живых измененных продуктов" (ЖИО) равно как продуктов на их основе и технологий. Это, в свою очередь, диктует целесообразность реализации Протокола на основе системы двухсторонних связей с вычленением области схождений в разнообразии прямых двухсторонних соглашений.

2. Таким образом, из элементов структуры Протокола "Items included in all proposals" основное значение приобретают два: "Совместное пользование информацией" (Information sharing) и "Предварительно обоснованное согласие" (Advance Informed Agreement). Остальные пункты должны, по всей видимости, обсуждаться после "кристаллизации" вышеупомянутых двух.

3. Совместное пользование информацией (СПИ):

структура элемента состоит из сферы юрисдикции (достаточно, по-видимому, на уровне ст.4 КБР), задач и механизма реализации (operating mechanism).

Задачи: представляется, что задачами являются наиболее свободное предоставление и распределение информации, имеющейся в наличии у Сторон о ЖИО, продуктах на их основе, технологиях, главным образом, необходимой для механизмов оценки и управления рисками. Информацию следует предоставлять о всех ЖИО, а не только о тех, о которых в настоящее время известно достоверно, чти они могу нанести ущерб сохранению и устойчивому использованию биологического разнообразия. в соответствии с положениями Конвенции

Механизм реализации: очевидно должен быть построен на базе сети национальных контактных узлов (focal points) с централизованным узлом, играющим роль "Clearing House", управляющимся уще существующей структурой. Примером может являться BIOTRACK (OECD) и BIOBIN (OECD/UNIDO) Главная роль центрального узла - сбор, подтверждение и предоставление информации о существующих законах и регуляторных системах, использовании ЖИО и продуктах на их основе, материалы по оценке и управлению рисками.

4. Предварительно обоснованное согласие (ПОС):

механизм ПОС должен обеспечить по возможности наиболее полной информации о ЖИО, продуктах на их основе, технологиях, использующих генетически измененный материал, импортируемых в страну заблаговременно (до поставки) в том случае, когда импортируемый материал (технология) не импортировался, не

производился/использовался в стране импортере с момента вступления Протокола в силу. В первую очередь использование механизма ПОС касается ЖИО (и технологий), о которых в настоящее время известно, чти они могу нанести ущерб сохранению и устойчивому использованию биологического разнообразия. По-видимому, целесообразно, чтобы специальная группа в рамках РГЭБ составила на основе сектор-специфичного подхода списки таких ЖИО, которые могли бы периодически (по мере накопления знаний, обновляться).

Механизм реализации: так же как и в п.3, заключается в прямом взаимодействии экспортера с национальным контактным узлом, который определяет необходимый объем и уровень предоставления информации, согласует решение о разрешении или запрете на импорт. Очевидно, что должна быть прямая связь между механизмами ПОС и СПИ для соответствия принимаего решения современному уровню развития знаний и адекватной оценки соотношения "риск/выгода", а также для перехода, по возможности от разрешительного механизма к уведомительному.

5. Очевидно, что Протокол, включая механизмы ПОС и СПИ, должен соответствовать современному уровню развития знаний, поэтому представляется целесообразным дополнить его структуру таким элементом как "Правила/руководство общего характера" (Generic guidelines), которые, аналогично Руководству ЮНЕП (UNEP International Technical Guidelines for Safety in Biotechnology), могли бы содержать общие принципы механизмов оценки и управления рисками, принципы выбора и функционирования национальных контактных узлов, принципы распространения прямого двухстороннего обмена информацией на многосторонний равно как и содержать обновляемый, по мере накопления знаний, список используемых в Протоколе список терминов и определений.

6. Отношения с другими международными соглашениями: для нас очевидно, что соглашения, заключенные и вступившие в силу до принятия Протокола не должны быть ущелены последним. Принципиально важным является полное соответстве механизма реализации Протокола, включая ПОС и СПИ положениям ВТО и ТРИПС (WTO, TRIPPS).

7. Таким образом, представляется, что принципиальными элементами структуры Протокола являются упомянутые в списке "Items included in all proposals" с добавлением таких элементов как "Правила/руководство общего характера" (Generic guidelines) и сфера юрисдикции (Jurisdictional scope). Окончательное формиулирование структуры и механизма реализации элементов Протокола возможно только после детальной проработки трех принципиальных элементов: СПИ, ПОС и "Правила/руководство общего характера".