UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/BSWG/2/2
18 March 1997

ORIGINAL: ENGLISH

OPEN-ENDED AD HOC WORKING
GROUP ON BIOSAFET
Second meeting
Montreal, 12-16 May 1997

COMPILATION OF THE VIEWS OF GOVERNMENTS ON THE CONTENTS OF THE FUTURE PROTOCOL*

I. ITEMS INCLUDED IN ALL PROPOSALS

A. Title

AUSTRALIA

Australia suggests that the title of the protocol can 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 th negotiations.

---

* Submissions from other Governments in their original form will be available as information documents.

Na. 97-1189

CANADA

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

EUROPEAN UNION

The title could be drafted when all the elements of the protocol are in place.

NORW

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

B. Preamble

AFRICA

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 th assessment and management of the potential risks arising from the development, use, release and transfer of living modified organisms and products thereof,

Mindful of the obligation imposed by Article 19, paragraph 4, of the Convention on Biological Diversity on any Contracting Party, directly or by requiring any natural or legal person

under its jurisdiction, to provide any available information about the use, the potential advers 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 th 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, releas 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,

Recalli 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 Articl 19, paragraph 3, of the Convention on Biological Diversity in setting out appropriate procedures, in particular advance informed agreement, in the field of the safe transfer, handling and use of living modified organisms resulting from biotechnology,

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

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

Have agreed on the following:

AUSTRALIA

Australia agrees on the need for a preamble. It should contain introductory languag 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 th head agreement. It could set out general guiding principles relevant to the protocol. These could be drawn largely from the language of decision II/5 adopted by the Conference of the Parties to th Convention on Biological Diversity at its second meeting. The preamble should not attempt to address issues more appropriately covered in the provisions of the protocol.

Australia considers negotiation of the preambular text would be best considered at a later stage of the negotiations. The Ad Hoc Working Group should concentrate first on elaborating th 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.

Have agreed as follows:

CANADA

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

Canada suggests that the Protocol may benefit from a "Principles" section. One possibl inclusion ould be reference to the precautionary principle as defined in the Convention.

EUROPEAN UNION

The Parties to the Protocol,

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

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

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

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

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

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

Noting the United Nations Recommendations on Transport of Dangerous Goods,

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

Recognizing that the interaction between living modified organisms (LMOs) resulting fro 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 th 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 th 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:

NORW

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

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

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

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

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

Noting also the advantages that lie in the potential of modern biotechnology to contribut 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 cas -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 sustainabl development and without adverse effects on human health and the environment,

SWITZERLAND

The protocol on biosafety will focus mainly on the aspects related to transboundary movements of living modified organisms resulting from modern biotechnology that may hav adverse effects on the conservation and sustainable use of biological diversity. The control will have to be based on the establishment of an advanced informed agreement procedure.

The protocol should deal solely with safety issues. The socio-economic implications of th development of biotechnologies will have to be addressed in another framework. That framework should be defined by the Conference of the Parties to the Convention on Biological Diversity.

The compatibility and, if necessary, the complementarity of the protocol with existing international instruments, particularly the World Trade Organization Agreements, will have to b ensured. In addition, the procedure for amending the protocol will have to be as fast and effectiv as possible so that the protocol can be suitably adapted to developments in scientific and technical knowledge.

UNITED STATES

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

C. Use of terms/Definitions

AFRICA

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 th State of import to the transfer of any living modified organisms or products thereof based on th information supplied by the State of export with the understanding that the information is accurat and complete;

"Affected Party" means any Party or Parties affected or likely to be affected by th 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 b 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 cas 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 th 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□une 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 us r 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 hich 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 plac 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, th 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 on Biological Diversity;

"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 th 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"

AUSTRALIA

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 th protocol arising from a lack of clear agreement over the meaning of these terms. The importanc 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 thos listed in the appendix to the report of the first meeting of the Ad Hoc Working Group, which th 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.

Issues needing to be considered include which of the terms in the appendix should b 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 fin -tuning and endorsement, to avoid the possibility of the Ad Hoc Working Group 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.

CANADA

Canada supports a strong scientific basis for the biosafety protocol and one based on th principles of the Convention on Biological Diversity. Canada feels that it is not possible to defin many of the terms and elements until the scope of the protocol, context and need of a term ar determined. Canada does, howev r, note that a definition of LMO, and the scope of LMOs to b dealt with under Advance Informed Agreement (AIA) should be agreed early in the process. Canada would like early determination of whether LMOs subject to AIA are a subset of LMOs under the Protocol in general or are one and the same.

Canada proposes a definition of LMO (not including humans in this context) as follows: "living organisms that have been deliberately modified to exhibit one or more traits, that do not exist in/are novel to the species in the receiving country, not excluding when the LMO is a modified form of an organism that is a new species (exotic) to the receiving country.

Novel traits are defined as: "Characteristics in an organism that have been created or introduced through a specific genetic change and that make the organism different from th unmodified organism. Deliberately modified means: altered by any means". It may be noted that Canada also includes non-modified exotic species in its domestic safety assessment schemes.

Further, the definition of LMOs could be further qualified by a list of exclusions, but not of inclusions. Further discussion will be needed regarding the means or need for exclusions.

Canada bases its domestic decisions on a general definition of biotechnology: "Th application of science and engineering in the direct or indirect use of living organisms or parts of

living organisms in their natural or modified forms." Canada views biotechnology as a developmental tool and that the traits and characteristics of individual organisms (or their "newness") are more important to safety assessments than how they were incorporated.

CUBA

Modern biotechnology. Any technological application that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for specific use using recombinant DNA techniques.

Transboundary movement. Any movement of genetically modified organisms from an area under the national jurisdiction of one State to or through an areaunder the national jurisdiction of another State or to or through an area not under the national jurisdiction of any State, provided that at least two States are involved in the movement.

National authority. Is the government authority designated by a State party to propose to its Government national policy on safety in biotechnology, to manage, control and inspect th activity, and to establish procedures, draw up measures and make the necessary recommendations.

Handli . Any research and development activity carried out with living organisms with a view to achieving a genetic modification.

Advance informed agreement. The principle that international shipment of a GMO that could have adverse effects on the environment and human health should not proceed without th agreement, where such agreement exists, or contrary to the decision of the designated national authority in the importing country.

Risk assessment. Analytical procedure to determine possible harm, the likelihood of its occurrence, and its possible scale.

Risk management. The measures to ensure that handling, use and release are safe.

Biosafety. The scientific-organizational and technical-engineering measures to protect th worker in the establishment, community and the environment from the risks involved in working with biological agents and the release of organisms into the environment and, in the event of contamination, adverse effects, leakages or losses, to minimize any possible effects and rapidly eliminate the consequences.

Release. Introduction into the environment of an organism or combination of organisms.

Area of release. Defined area in the environment where the release of an organism or combination of organisms occurs.

Biological emergency. Situation caused by events that may result in harm with advers impacts, either immediate or delayed, on the environment in general, and the public and workers in particular, due to the escape or release of organisms.

EUROPEAN UNION

Living modified organisms

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 th 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.

Intended

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

Unintended

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

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

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.

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 th environment.

NORW

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 us 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 employed, 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 releas 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 Norway recognizes the need to define also other terms used in the protocol such as intended and unintended transboundary movements, etc.

SWITZERLAND

The following definitions are taken from Swiss legislation, basically the Swiss Law on Environmental Protection.

Organisms:

Organisms means the biological and cellular and non-cellular entities that are capable of reproducing themselves or of transferring genetic material. Mixtures or objects containing such entities are assimilated to them.

Genetically modified organisms:

Genetically modified organisms means organisms whose genetic material has been modified in a way that does not occur naturally, either by mating or by natural recombination.

Contained use:

A use of organisms is said to be contained when their contact with the population or th environment is restricted or prevented by physical barriers or by a combination of physical and chemical or biological barriers.

UNITED STATES

The United States believes that 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.

D. Advance informed agreement

AFRICA

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 th 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:

(i) Its taxonomy, ecology and reproductive behaviour;

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

(iii) 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:

(i) information on methods of using it, whether it is a novel chemical, or on 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.

AUSTRALIA

Australia considers the Ad Hoc Working Group should be guided by the following general principles in considering an AIA procedure for the protocol. Any AIA procedure should:

(a) Be designed to allow fully informed decisions by the importing country regarding the intended import of LMOs;

(b) 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;

(c) Operate effectively and efficiently, in order to minimize costs and timing delays;

(d) Be consistent with the provisions of the World Trade Organization Agreements;

(e) Be implemented through existing institutional mechanisms where practical and appropriate.

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

(a) All or only some LMOs that are to be covered by the protocol should be covered under AIA;

(b) A positive or negative list approach should be adopted in determining coverage of LMOs under AIA;

(c) The appropriate trigger mechanisms for determining whether an LMO would come under AIA should be specified.

Coverage

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 b 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 th likelihood that some LMOs will be regarded as posing no significant risk for biodiversity. In th 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 pos different types and degrees of risk to biodiversity. For example, as UNEP International Technical Guidelines for Safety in Biotechnology state, "it is generally anticipated that, in most cases, ther 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".

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 th first meeting of the Ad Hoc Working Group 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. a positiv -list approach), or whether they should identify LMOs which are deemed not to, or unlikely to, have an adverse effect on biodiversity (i.e. a negative-list approach).

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 the first meeting of the Ad Hoc Working Group that there are advantages and disadvantages to the various approaches. Further consideration of the various options is required before definitive views can b reached.

The Working Group 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.

AIA trigger mechanis

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 th 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 procedur (i.e. how a notice of intent and consent to import scheme would operate).

Criteria

There are a number of factors whose suitability as criteria for the AIA trigger mechanis should be considered. Thes are: the intended use of the LMO in the receiving country; the natur 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 geneti cally modified plants. For other categories of LMOs (such as micro-organisms or animals) different trigger factors may be appropriate.

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.

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 comprehensiv level of assessment.

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 th application of the protocol to those parties.

Risk assessment

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 for 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 th receiving environment, they should not form part of an international legally binding instrument.

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

(a) Risk assessment should be applied within a well-defined technical/scientific methodology for safety in biotechnology including a step-wise and cas -by-case basis;

(b) Assessment should be made of the possible adverse effects from LMOs on th conservation and sustainable use of biological diversity;

(c) Risk assessment should be based on the characteristics of the organism, th genetic modification and the receiving environment;

(d) Special considerations should apply to risk assessment in centres of origin and areas with high genetic diversity.

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

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 b mandatory.

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.

AIA operating mechanis

It has been suggested that existing PIC procedures may provide a model for an AI operating procedure for biosafety. It would be useful to examine the operation of thes mechanisms to assess whether there are aspects which may be suitable for application to AIA. However, as the Secretariat's background paper to the first meeting of the Working Group 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 appropriat because receiving environments vary between countries.

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

(a) Should the trigger be limited to the exporting country notifying the importing country of relevant details concerning the LMO it intends to export;

(b) 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;

(c) Should details of the proposed export and the response of the importing country b forwarded to a clearing-house type of agency for the information of other Parties;

(d) 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;

(e) 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;

(f) 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.

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 th 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 th 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 cooperat in the provision of this information, either directly or through the exporter as appropriate. Th 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.

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 th 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 quarantin arrangements regarding plants, animals and their products, there would appear to be a strong cas 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 b specified in the protocol.

The Working Group could also consider the desirability of depositing relevant information in publicly accessible databases, to enable other parties and interested bodies to be informed of proposed transfers of LMO. Account should be taken of the potential of existing databases to fulfil this function. The potential for "clearing-house" type mechanisms, including th Convention's clearing-house mechanism, could also be considered.

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, paragraph 1 of the Convention, which hav the effect of excluding confidential information held by a Contracting Party's public or privat 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 b appropriate to provide for the purpose of risk assessment.

CANADA

Canada believes that AIA is an important component of the Protocol. The scope of LMOs subject to advance informed agreement remains to be defined and should be determined early in the process.

Canada understands that AIA will include:

(a) Notification to an importing Party competent authority prior to importation of an LMO subject to AIA;

(b) Provision of information on the LMOs with or following notification;

(c) Assessment by the competent authority of information supplied; and

(d) Decision by the competent authority or whether to approve importation with or without conditions or without conditions or prohibit importation.

Those responsible and their roles (if any) for providing information and making decisions (e.g., importing entity, exporting entity, competent authority or importing and exporting Parties) need to be defined. Canada recognizes that considerable discussion will be needed regarding th administration and implementation of this provision.

Canada recognizes that many countries have a regulatory framework in place for notification of intent to import LMOs and suggests that this protocol will complement already existing frameworks. Canada, therefore, proposes that the protocol could provide for:

(a) Guidance and technical support for AIA for countries to develop and implement a regulatory framework along with mechanisms for information exchange;

(b) Universally agreed principles for all parties for a harmonized approach to AI within the protocol; and

(c) A core set of information requirements that may be requested by the importing country competent authority to conduct risk assessments for biosafety.

Canada proposes that AIA be required for the first intended transboundary movement (importation) to the importing party of a subject LMO.

Subsequent AIA action on a particular LMO would depend on national requirements and on the results of the assessment by the national authority in the importing Party. National authorities may wish to establish subcategories of LMOs after assessment, such as no further AI action required for each importation of the LMO. Examples of LMOs that may fall into th category requiring AIA at each importation could include: those that could have adverse effects on a species in its centre of origin or diversity; pathogenic, infective, or invasive organisms; and ones with insufficient information to determine if they can be freely released.

Further, Canada sees the need to discuss possible general provisions such as renotification (regardless of previous decisions) for imports on the basis of changes in use, containment and conditions of release; and reassessment of LMOs on the basis of new information to competent authorities regarding risk. Canada proposes that consideration of a requirement to provide new information to competent authorities regarding risk. Canada proposes that consideration of a requirement to provide new information regarding risk be considered as a general provision.

JAPAN

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 provid the competent authorities of the recipient State with information on the transboundary transfer of the LMOs in question and receive agreement in advance.

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 b 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 th 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 notification by that contracting party, publish information on the arrangements or the declaration, including the kind of the LMOs so exempted and the areas where such exemption is applied.

The Protocol should provide for a mechanism facilitating repeated transboundary transfer of LMOs, including replacement of the AIA procedure with an advance notification procedure. If it has been 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 may replace, either by means of bilateral, multilateral or regional arrangements or by declaration, its AIA procedure with an advance notification procedur for such LMOs in which case no advance agreement of the recipient State is required. Th Secretariat should, on the basis of notification by the contracting party, publish information on th arrangements or the declaration, including the kind of LMOs for which the AIA procedure has been replaced by the advance notification procedure.

Moreover, the protocol should provide for a mechanism to further exempt LMOs from th application of the AIA procedure, taking into account the purpose and conditions of their use as well as their users. Due attention should be paid so that the exchange of LMOs for research purposes should not be unnecessarily restricted if such LMOs are developed and used with adequate safety measures for the environment and human health.

NORW

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:

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

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

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

(d) Description of all traits introduced or modified and characteristics of th organism;

(e) Purpose of the genetic modification;

(f) 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;

(g) Intended dates of transfer;

(h) Number of organisms to be transferred or volume or culture and physical state;

(i) Any relevant requirements to ensure safe handling, storage, subsequent transport and use;

(j) Methods for safe disposal and suitable procedures in case of accidents;

(k) Intended use of the organism;

(l) Information on relevant previous releases;

(m) 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:

(a) Explicit consent to import;

(b) Not consent to (or prohibit) import; or

(c) Consent to import only under specified conditions;

or

(d) 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 Stat 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 b informed within 30 days and the terms of the Advance Informed Agreement may be changed accordingly.

UNITED STATES

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.

Purpose and scop . An AIA mechanism ensures that an importing country has had an opportunity for informed decision making prior to importation. In the view of the United States, such a safeguard would be appropriate when: the LMO fits into a category of LMOs whos importation and intended use raise reasonable concerns regarding conservation and sustainable us 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 AI provisions. The Ad oc Working Group will need to identify such categories of LMOs, e.g., by focusing on specific product sectors.

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.

Operating mechanis . As noted above, the AIA provisions should set out appropriat procedures for advance notification of an xporter's intent to ship an LMO that falls into one of th 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 effectiv 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 clearing-house. (The United States does envision copies of all relevant AIA activities being sent to the central clearing-house for the information of other parties and to ensure transparency under the AIA regime.)

With respect to the infrastructure through which the AIA would function, the United States envisions the steps outlined in paragraphs 15-19?

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 th 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 sinc the entry into force of the protocol or was being produced by the intended country of import. W anticipate that this information would come from the central clearing-house, either directly or through the exporting country's national focal point. (The clearing-house 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 cat gories.) If the exporter was informed that th strain or variety of LMO did not fall under a category set forth in the AIA provisions or that th 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, th 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 sinc the protocol's entry into force and was not being produced by the intended country of import, th 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 clearing-house and to the national focal point in the exporting country.)

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 clearing-house.

The United States envisions the protocol specifying that the importing country could tak 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.

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

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

The protocol, including the AIA mechanism, should be implemented in a manner that is fully consistent with the provisions of the World Trade Organization. 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

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

E. Information-sharing

AFRICA

The Parties shall facilitate and encourage the collection and exchange of scientific, technical, environmental, socio-economic, commercial and legal information relevant to th implementation of this protocol. Such information shall be transmitted to the Secretariat, th biosafety clearing-house and other relevant bodies and parties as the case may be.

AUSTRALIA

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, parties will benefit from having broader access to information about LMOs, such as th development of new LMOs, details of any releases of LMOs in other countries, and risk-assessment and risk-management procedures in other countri s. 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.

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 databases. The Convention's clearing-house mechanism and other clearing-house type arrangements could also play a useful rol in this regard.

Australia considers the provision and exchange of such information should be based on th existing obligations of the Convention. Article 17 provides for the general facilitation of exchang of information, including biotechnology, subject to certain qualifications. Under Article 17, paragraph 1, the facilitation of information exchange is limited to information relevant to th conservation and sustainable use of biological diversity, and to information from publicly availabl sources. Article 17, paragraph 2, refers to an exchange of indigenous and traditional knowledg and technology (i.e. technology being transferred pursuant to Article 16, paragraph 1, which would include biotechnology). Article 19, paragraph 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 decision II/5 of the Conference of the Parties to the Convention, and could b 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.

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. Consideration will need to b 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.

The protocol should provide for parties to make available, through a centralized international database, the following types of information, where known, in the case of domestic releases of LMOs:

(a) Organization proposing the release (including details of contact person);

(b) 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);

(c) The genetic modification and its effect (donor organism, genes inserted, phenotypic effect of the genetic modification);

(d) 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);

(e) 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;

(f) 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;

(g) Transport (procedures to be used for transport of the LMO to and from the release site);

BOLIVIA

While article 19, paragraph 4, of the Convention on Biological Diversity provides for th exchange of information about the use and safety regulations required by each Party in handling living modified organisms, as well as any available information on the possible adverse impact of such organisms, it is extremely important that the Protocol should establish a Global Information System to allow for transparent information sharing among the countries that need it. The System should bring together all the information currently available in the different countries, organizations (OECD, UNIDO, UNEP, BAC, BINAS, etc.), as well as in the various scientific institutions and companies or transnationals working with genetically modified organisms.

CANADA

Canada agrees that there should be a section on information-sharing in the protocol. It is Canada view that this element refers to the sharing of information for the purposes of enabling risk assessment. Procedures for protection of confidential data and proprietary information relativ to information-sharing will need to be addressed.

JAPAN

This item should include the following provisions:

(a) Information to be submitted to the Secretariat of the Protocol. The contracting parties should provide periodically the secretariat of the protocol information on the transboundary transfer of LMOs falling into the scope of the protocol, including reports on the implementation of the AIA and advance notification procedures and bilateral, multilateral and regional arrangements.

(b) Information to be submitted to recipient States. In the protocol, the provisions of Article 19, paragraph 4, of the Convention should be applied.

UNITED STATES

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

Purpose. The United States beli ves 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 thos LMOs that are not likely to have adverse effect on the conservation and sustainable use of biological diversity.

A provision on information-sharing:

(a) Could seek to facilitate the exchange of information on and experience with LMOs to enable parties to make informed decisions related to biosafety;

(b) Should take into account the existing obligations of the Convention, Article 17, paragraphs 1 and 2, and Article 19 paragraph 4; and

(c) 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.

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

(a) On domestic laws/regulations applicable to the production and/or use of LMOs; and

(b) On risk assessments or environmental reviews generated by the regulatory process.

F. Relationship with other international agreements

AUSTRALIA

The relationship between the protocol and other existing international agreements will b 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 th Working Group 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 Working Group, in consultation with relevant organizations, could usefully identify the potential for thes agreements to meet the objectives of the protocol, including the feasibility of modifying thes agreements as appropriate to address the effects on biodiversity of LMOs.

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 the second meeting of the Conference of the Parties to th Convention on Biological Diversity (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 b noted. For example, the outcome of negotiations on the protocol would need to ensure that th instrument does not derogate from the provisions of the Agreement Establishing the World Trad Organization (WTO) or affect the rights and obligations of members of WTO.

One difficulty with negotiating a protocol dealing with the impact of LMOs on th 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. Successiv 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 th 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 th International Plant Protection Convention and Office International des Epizooties agreements contain requirements to notify their respective international authority on any new pest outbreak.

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, th following:

(a) It could seek only to fill "gaps" left by existing instruments by giving precedenc to existing instruments, either generally or by referring to specific instruments;

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

(c) It could adopt or incorporate by reference parts of existing agreements.

Australia has undertaken a preliminary analysis of the capacity of a range of thes agreements to meet the objectives of the biosafety protocol. This 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 Protocol on Biosafety (UNEP/CBD/COP/3/27).

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 th Application of Sanitary and Phytosanitary Measures (SPS).

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 mor detailed analysis is required.

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 to 5 □ay 1995 (see annex II to annex I of document UNEP/CBD/COP/2/7).

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 marin 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 Especially as Waterfowl Habitat (1971) imposes general obligations on parties to preserve wetlands and waterfowl, which would presumably cover th situation of a particular release of an LMO in a listed wetland which caused a change to th ecological character of that wetland.

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 fro 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 lin be drawn?

CANADA

Canada supports the inclusion of this element and expects that the Protocol will b consistent with Canada□ obligations under other international agreements. For example, given in part the aims of the Convention on Biological Diversity under which the Protocol is proposed, that imported and domestic LMOs be treated similarly.

EUROPEAN UNION

The general article on this matter shall reflect that the substantive provisions of th 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 importanc of consistency between the protocol and the Agreements under the WTO. More generally, th provisions of the protocol shall be consistent with the relevant international obligations of th Parties.

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

NORW

The Convention regulates th relationship with other international agreements, in that th 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.

UNITED STATES

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.

G. Institutional framework for the functioning of the Protocol

AFRICA

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 otherwis 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 on 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 th 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.

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 kno -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 th 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) Cooperate 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 b determined by the meeting of the Parties.

AUSTRALIA

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

Secretariat

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 th 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 contribut to the cost of secretariat services for the protocol.

Conference of the Parties

The protocol would be required to hav a decision-making/governing body (a meeting of the parties). Australia considers the Convention's Conference of the Parties could serv concurrently as the meeting of the parties to the protocol. The differential voting procedur specified in Article 32, paragraph 2, of the Convention limiting voting on decisions under any protocol to parties to the protocol would apply in this case.

Alternatively, the protocol could have its own meetings of a decision- making/governing body. In this case, the instru ent would need to make provision for the creation of a separat meeting of parties to the Convention's Conference of the Parties. For reasons of administrativ convenience and expense, consideration could be given to scheduling its sessions immediately before or after those of the Convention. To minimize 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

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 (SBSTTA) provide this function in a manner broadly similar to the provision of services to the Conference of the Parties to the Convention. Th 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, paragraph 2, of th Convention.

BOLIVIA

To avoid obstruction of the export control regulations for the transfer of genetically modified organisms, an international oversight body would have to be established to maintain transparency. This body would keep a register of GMO transfers, which would be open to the public.

CANADA

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

EUROPEAN UNION

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.

JAPAN

Pursuant to the provisions of Article 24, paragraph 1 (b), of the Convention, th Secretariat of the Convention should perform as the secretariat of the protocol the functions assigned by the protocol.

NORW

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

An international database should be established for the purposes of the protocol. Th clearing-house mechanism established under the Convention could serve this function.

UNITED STATES

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 th protocol and should therefore be addressed at a later stage in the negotiation process. (It should b 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 infrastructure of the Convention on Biological Diversity.)

H. Settlement of disputes

AFRICA

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 th 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 th Convention;

(b) Submissi n 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 th 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.

AUSTRALIA

At some stage, the Working Group 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."

BOLIVIA

In order to assign responsibilities for the consequences resulting from the release of GMOs and for which the exporting country does not assume responsibility, an international arbitration mechanism should be established, which could be placed in the charge of UNEP or another international organization decided upon by the Convention.

CANADA

Canada is of the view that provisions to settle disputes among Parties with respect to th 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 th dispute-settlement text once the substantive provisions of the Protocol take shape.

EUROPEAN UNION

Provisions for dispute settlement are already provided for in the Convention itself and according to Article 27, paragraph 5, may apply directly to the Protocol. There is therefore no need for specific provisions under the Protocol.

Simplified procedures

To take into account different technical capacities and while respecting the object of th 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 authorization procedures.

JAPAN

Pursuant to Article 27, paragraph 5, of the Convention, the provisions of Article 27 should be applied to settlement of disputes bet een contracting parties to the protocol concerning th interpretation of application of the protocol.

NORW

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 b strengthened in the protocol by providing for an opting out clause instead of the existing opting in clause with regard to accepting arbitration or the International Court of Justice as compulsory dispute-settlement proc dures. This means that Parties upon ratification or accession may declar in writing that it does not accept compulsory settlement of disputes (arbitration or International Court of Justice), i.e. 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 disput settlement.

UNITED STATES

Consistent with Article 27, paragraph 5 of the Convention and decision I/5 of the Conference of Parties, which specified that the provisions of the Convention would apply to th protocol, the protocol should make clear that the disput -settlement mechanism set out in Articl 27 of the Convention would apply to any disputes regarding the interpretation or application of th protocol.

I. Amendment

AFRICA

The procedures set out in Article 29 of the Convention regarding amendments to th 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.

AUSTRALIA

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

EUROPEAN UNION

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.

NORW

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

J. Final clauses

AUSTRALIA

Provisional application. 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 befor joining the protocol because of domestic processes.

EUROPEAN UNION

Provisions for final clauses should be as far as practicable as in the Convention. The need for bilateral agreements should be considered.

NORW

Provisions for final clauses should as far as practicable be similar to those in th Convention. It should be considered whether the protocol could cover phas -out of certain traits used in an LMO, for example, antibiotic resistance marker genes which have no necessary functions in commercial products.

II. Items included in some but not all proposals

A. Objectives

AFRICA

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.

EUROPEAN UNION

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

JAPAN

The objectives of the protocol should reflect decision II/5 of the Conference of the Parties.

NORW

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 th 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 th principle of sustainable development and in a socio-economically justifiable way.

SWITZERLAND

The objectives of the protocol relating to protection will have to be defined as a matter of priority. Is the purpose only to protect biological diversity in the sense understood by th Convention on Biological Diversity or is there a broader desire to cover the environment as a whole, together with human health.

B. Scop

AFRICA

1. This Protocol applies to living modified organisms and to activities involving thos 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, th 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.

CANADA

Canada suggests that this should be determined later.

EUROPEAN UNION

In order to fulfil its objectiv 2/ the protocol applies to all LMOs resulting from modern biotechnology except those LMOs and activities that are not likely to have an adverse effect on th 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:

(a) The definition of "ransboundary movement" and the definition of "MOs resulting from modern biotechnology";

(b) The meaning of the ter "hat may have adverse effects on the conservation and sustainable use of biological diversity". In determining which LMOs resulting from modern biotechnology may or may not have adverse effects, the following elements should be taken into consideration:

(i) The characteristics of the organisms involved;

(ii) The characteristics of the environment;

(iii) The intended use.

2/ See section 1.1.

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

(a) 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 organis which is safe in one environment may have advers effects in another;

(b) 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;

(c) Categories which are unlikely to have an adverse effect may be identified on th 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.

JAPAN

LMOs falling into the scope of the Protocol

(a) All LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity should be with in the scope of th Protocol;

(b) At the time of this comment, it is the view of the Japanese Government that modern biotechnology, for the purpose of this protocol, should focus on the recombinant DN technique. Due attention should be paid to the fact that among the contracting parties to th Convention most of the existing national rules and regulations with respect to the safety of LMOs are applied mainly to the recombinant DNA technique and products derived therefrom;

(c) Organic materials which are components of LMOs but are not self-reproducible in the environment, such as DNA or RNA segments, plasmids, peptides, fall outside the scope of th protocol.

Exclusion of LMOs from the scope of the Protocol

(a) Those LMOs which are cover d by any other existing international agreement related to transboundary transfer of LMOs should be excluded from the scope of the Protocol;

(b) 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, the Conference of the Parties to the Protocol may decide on th exclusion of such LMOs from the scope of the protocol;

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

NORW

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

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

SWITZERLAND

Types of organisms

The following critical concepts for the determination of the scope of the protocol should b defined as a matter of priority:

- Living modified organisms resulting from biotechnology. According to our interpretation, this concept corresponds to genetically modified organisms defined in our legislation as: "organisms in which the genetic material has been altered in a way that does not occur naturally, either by mating or by natural recombination". This definition includes organisms produced by inter-species genetic modification techniques (transformation using vectoral system, injection, bioballistics) or by cross fusion of protoplasts and/or cells.

- Adverse effects on the conservation and sustainable use of biological diversity. The precis definition of this concept will be one of the key elements in determining the scope of th protocol (see section 1 above, "Objectives"). Traditionally, other potential impacts on th environment and health are taken into account in the risk assessment procedure. The question is whether the focus should be on biological diversity or whether an approach more orient d toward overall risk should be adopted. In the first case, it would then seem rather illogical to deal only with transgenic organisms, since other categories of organisms, for

example exotic species, are equally capable of having adverse effects on biological diversity. A comparative analysis of existing international instruments for the control of transboundary movements of exotic organisms would allow the gaps to be identified and the scope to b pertinently defined.

- Use of other criteria related to the properties of the organism to determine the scop , such as "familiarity", "centres of origin" or even "categorization" of organisms on the basis of th properties of the host organism and the genes introduced.

Type of activities

While recognizing the need to integrate all activities involving living modified organisms within the overall framework of a safety mechanism (for example, the UNEP International Technical Guidelines for Safety in Biotechnology), the protocol itself should be limited to intentional transboundary movements of living modified organisms intended to be used in th environment. The transboundary movement of living modified organisms intended for laboratory or other contained use setting, as well as trade in commodities intended for the food or processing industries, should be excluded from the scope of the protocol.

C. Jurisdictional scop

EUROPEAN UNION

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

D. General obligations

AFRICA

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, th 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 th 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 th Secretariat and the Biosafety Clearing-House of their decision.

5. No Party shall export or import living modified organisms or products thereof to or fro 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 releas 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 th 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 Stat 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 environ entally 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 th 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 th 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 th point of use or release.

9. The Parties agree that failure to provide all the necessary information available about th living modified organisms or products ther of 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 thos 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.

NORW

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.

SWITZERLAND

During the first meeting of the Ad Hoc Group of Experts on Biosafety, Switzerland submitted a preliminary draft of a flo -chart describing the operational elements applicable in th event transboundary movements of living modified organisms, including an advance informed agreement procedure. Switzerland is ready to present it in detail at the next meeting of the Group.

The provisions of the protocol should b flexible enough to allow for the possibility, under conditions to be determined, or exempting from the AIA procedure certain transboundary movements of LMOs that fall within the scope of the protocol. These conditions could b improved knowledge of the safety profile of the organism (greater familiarity), when it is not th first transboundary movement of that organism to the country of destination or where the country of destination does not require AIA on the basis of mutual recognition agreements.

The AIA procedure should be simple and effective and use as far as possible existing structures. The procedure need not necessarily be implemented through State institutions alone.

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

CANADA

Details should be developed at a later stage.

EUROPEAN UNION

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 transfer intended, 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.

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.

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 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.

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.

F. Notification procedur

AFRICA

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 th 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, u se 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 th 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 th notifications under paragraphs 1 and 2 above with the requirements of this Protocol and the Stat 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 b 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 b 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 evaluat their safety in the various anticipated conditions in the State of import.

8. Any transboundary transfer shall b 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 th 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.

JAPAN

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 th recipient State is required.

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

NORW

Notification of exports of LMOs shall be conducted in all cases not covered by th 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").

G. Considerations for risk assessment and risk management

EUROPEAN UNION

The key to safety is the prior assessment and consequent management of risk. Therefor 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:

(a) Sustainable use of biological diversity;

(b) The characteristics of the intended application;

(c) The potential receiving environment.

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

JAPAN

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 no be different from those for domestic LMOs. Moreover, imported LMOs should not b treated in a disadvantageous way compared to homologous domestic LMOs.

3. Pursuant to Article 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.

SWITZERLAND

The control of transboundary movements implies the existence of national structures for risk assessment and management. In order to ensure a minimal degree of harmonization, it may b necessary to include in the protocol the basic principles of risk assessment and management.

H. Mechanisms for risk assessment

AFRICA

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 th risk assessment and on a cas -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 th 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, 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 b before it is put to its intended use. Risk-management schemes shall take due account of th different purposes or uses for which the living modified organisms or the products thereof ar developed or produced.

NORW

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 th 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 th 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 follo ing elements:

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

(i) The recipient/parental or host organism;

(ii) The relevant information on the donor organism and the vector used;

(iii) The genetic modification, including the inserts and the encoded trait;

(iv) The centre of origin, when known;

(b) The intended use, i.e. the specific application of the contained use or deliberat 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.

I. Mechanisms for risk management

NORW

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 th 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.

J. Emergency procedures

AFRICA

1. Parties shall take the necessary measures to ensure that, in the event of an accident, th 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.

JAPAN

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

NORW

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, thes 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 r garding 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.

K. Minimum national standards on biosafety

NORW

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.

L. Designation of competent authority and national focal point

AFRICA

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.

EUROPEAN UNION

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.

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

JAPAN

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

NORW

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

SWITZERLAND

A national focal point should be designated by each country. As far as possible, the focal point should also be involved at the national level in assessment and management procedures for applications of living modified organisms.

M. Capacity-building

AFRICA

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 th concerned Parties. The Secretariat and the Biosafety Clearing-House shall, in particular, assist developing countries in their efforts to identify and plan their capacity-building requirements and secure funds for the implementation of their capacity-building programmes.

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

BOLIVIA

Since most countries are engaged in a process of capacity-building for the manag ment of safety in biotechnology and, in many cases, are initiating such a process, it is important that th protocol takes this aspect into account and urges the countries and international organizations with relevant experience to lend support and cooperation for its development and strengthening to allo proper risk assessment and management.

CANADA

Canada proposes that capacity-building should be mentioned in the preamble to th Protocol and should be included in the Protocol. This element should r fer to capacity-building for purposes of enabling risk assessment.

EUROPEAN UNION

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 th Protocol.

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

NORW

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:

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

(b) The development of national legislation related to biosafety;

(c) 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;

(d) That states are able to achieve safety when certain LMOs are transferred into and/or to be used in their territories.

N. Transport and packaging requirements for the transfer of LMOs

AFRICA

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 hav not been approved for consumption are packaged in such a way as to ensure their complet 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.

NORW

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 United Nations recommendations and agreements on transport should be applied. This needs to b 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.

SWITZERLAND

This sector certainly requires harmonization and coordination at the international level. The protocol should therefore contain a provision that includes the general principles on labelling, packaging and transport. A study should be undertaken to identify the most appropriate way of including the technical details.

O. Illegal traffic

AFRICA

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 advanc 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 releas 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 th 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.

P. Public awareness

AFRICA

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, subregional and regional levels, as appropriate, and in accordance with national laws and regulations, and within their respectiv 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 modifi d 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.

BOLIVIA

It is very important to include public awareness in the protocol, since it is a key factor in preventing risks that can result from the release and use of genetically modified organisms, as well as in avoiding problems of misunderstandings in civil society because of lack of proper information and education.

At the same time, the protocol should guarantee public participation by making publicly available the results of tests or monitoring exercises carried out as part of the approval process by the authorities. The public must be informed in advance of any intended release of genetically modified organisms, including the place and extent of such release.

The protocol should also provide that the public should have the greatest possibl opportunity to express its views on the information provided before the use or relea se of a genetically modified organism is approved.

CANADA

Canada supports further discussion and definition on public awareness as part of th Protocol.

NORW

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, th 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.

Q. Clearing-house

AFRICA

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 advanc informed agreement. The modalities of establishment of the Biosafety Clearing-House shall b 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:

(i) The development, use and transfer of living modifi d organisms and products thereof;

(ii) Methodologies, techniques, experts, equipment, materials, availabl 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:

(i) Preparing or evaluating risk assessment reports or impact statements;

(ii) Developing or evaluating risk management schemes and appropriat monitoring programmes, procedures and standards;

(iii) Preparing emergency plans and other safety measures;

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

(v) 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 th Biosafety Clearing-House.

CANADA

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

SWITZERLAND

A clearing-house for information in the following areas will be an essential tool for th implementation of the protocol:

- National procedures for the regulation, assessment and management of risks;

- Scientific references necessary for risk assessment and management;

- Databank on experiments on living modified organisms and on products on th market;

- Information on transboundary movements and on the results of the AI procedures.

Such a clearing-house can be effective only if the protocol requires the parties to provid all the necessary information. At the formal level, the provisions of article 19, paragraph 4, of th Convention seem to satisfy the information-sharing needs of the protocol. If so, article 19, paragraph 4, of the Convention could be incorporated into the protocol as it stands.

At the operational level, such a clearing-house should be developed on the basis of existing structures. Switzerland would therefore draw attention to the BIOBIN project developed jointly by UNIDO and OECD, which provides this type of information to a number of countries (http://www.oecd.org/binas).

R. Mechanisms for bilateral agreements

JAPAN

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 th Protocol.

S. Liability/Liability and compensation

AFRICA

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 b bound to negotiate with the affected State or States to determine the legal consequences of th 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 welfar of the affected State:

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

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

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

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

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

6. The preceding paragraphs shall not prevent:

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

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

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

BOLIVIA

The protocol should impose liability for any damage or loss to biological diversity, human health and the environment resulting from the release of genetically modified organisms and, to this end, create mechanisms to establish loss or harm caused by a country or institution releasing th organism. Hence, the primary responsibility for any consequence resulting from a genetically modified organism would belong to whoever released it.

CANADA

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

EUROPEAN UNION

Liability and compensation for damage to biological diversity are important matters. To date, the question has not been considered by the Conference of the Parties. In order not to prejudge this discussion, the Protocol should not contain any specific provision on this issue.

JAPAN

Liability and compensation with respect to the implementation of the Protocol should b dealt with in Article 14, paragraph 2, of the Conven tion, but not in the provisions of the Protocol.

T. Consultations on liability

NORW

According to Article 14, paragraph 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. T he Protocol should recognize the importance of this matter and initiat further work to be carried out in this area.

U. Monitoring and complianc

AFRICA

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 th 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.

CANADA

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 th 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.

EUROPEAN UNION

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

NORW

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

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

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

(b) Monitoring can be used after an LMO has b n 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.

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.

V. Financial issues

AFRICA

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 cas of emergency situations to minimize damage fro 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 b established to cover the cost of regional or subregional centres for training and capacity building as specified under Article 13 (3).

EUROPEAN UNION

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 th necessary capacities for the effective functioning of the Protocol.

In this context, the Protocol must be considered as an instrument for the implementation of the Convention. Because of this, the financial provisions of the Convention also apply to th Protocol. This implies that financial resources for the implementation of the Protocol should b provided in accordance with Article 20 of the Convention, namely through national resources, bilateral, regional or multilateral channels and through the financial mechanisms under th Convention.

JAPAN

In the Protocol the financial mechanism established by Articl 21, paragraph 1, of the Convention should be applied. Accordingly, no new financial mechanism is necessary for implementation of the Protocol.

NORW

An effective implementation of Article 8 (g) of the Convention (risks associated with th 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.

W. Socio-economic considerations

AFRICA

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.

BOLIVIA

This subject should be included, since the protocol should assess all the resultant threats to the environment, human health, as well as the socio-economic impacts of the release of living modified organisms into the environment.

At the same time, since the sustainable use of biological diversity, particularly in the cas of domestic plants and animals, depends on the socio-economic conditions of the people who hav developed and conserved them for generations, the introduction of genetic engineering technologies

and genetically modified living organisms into countries with a rich biological and genetic diversity can not only result in the depletion of that diversity but can also threaten the economic situation of those people, which in turn can lead to a discontinuation of the agricultural systems and th resultant genetic erosion, among other things.

The risk and environmental impact assessment mechanisms could also include an element covering socio-economic considerations.

CANADA

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 theses considerations to other delegations are understood.

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 b fore text can be crafted. These headings are: Amendment, Final clauses, Jurisdictional 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 risks management, Emergency procedures, Determination of competent authority and national focal point, illegal traffic, Duty to reimport, T chnical 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.

EUROPEAN UNION

As regards socio-economic considerations, the European Union looks forward to a thorough consideration of the bibliography of the relevant literature regarding both positive and negative potential socio-economic effects of biotechnology to be compiled by the Secretariat. However, the Union does not consider that provisions covering socio-economic impacts should b included in the Protocol.

JAPAN

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.

X. Review and adaptation

JAPAN

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.

NORW

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

Y. Signature

AFRICA

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 _____.

Z. Accessi__

AFRICA

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 th Protocol. In the cas 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 th 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 th Protocol. These organizations shall also inform the Depositary of any relevant modification in th 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.

AA. Right to vot

AFRICA

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

BB. Entry into force

AFRICA

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of th 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 th 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.

AUSTRALIA

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

CC. Reservations and declarations

AFRICA

No reservations may be made to this Protocol.

DD. Withdrawal

AFRICA

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 th 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 th withdrawal.

EE. Depositary

AFRICA

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

FF. Authentic texts

AFRICA

The original of this Protocol of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic shall be deposited with the Secretar y-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 _____.

GG. Annexes

AFRICA

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 organis 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 accordanc
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 th 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 wer 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 th 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 releas 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 th 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 gen (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 th 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 introduc d 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 th 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 f rom 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 th 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 th 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 th environment.

7. Socio-economic considerations:

(a) Anticipated changes in the existing social and economic patterns resulting from th 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 th 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 th 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 accordanc
with Article 10 (4)

The user shall employ the following risk management schemes and procedures from th 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 paragraph 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 paragraph 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 th premises and in the surrounding environment, and (ii) genetic transfer into other micro-organisms and implications thereof on human and animal health and th 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 th laboratory in complete containment;

(b) Trials with experimental animals under strict containment;

(c) Experiments in complete containment to evaluate the extent of transfer of th 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 gen -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 b thoroughly evaluated by the National Biosafety Committee. Particular emphasis shall be given to whether the applicable regulations in the previous release hav been adequate to ensure safety;

(b) If the regulations mentioned in (a) above have not been found adequate, th 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 fro 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 appropriat 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 b 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, th 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 b 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 organis 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 th environment (soil including micro-organisms and terrestrial communities) will b made in enclosed fields but not fully contained. At the end of the experiment, th 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 procedur in paragraph 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 cas 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 complet containment in an experimental environment which simulates the intended area of release in climatic, microbial, animal and plant communities. The observations shall include th 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 th condition of the living modified organism, its micro-organisms focusing on gen transfer, and the ecology of the microbial, plant and animal communities in th 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 Subcommittees 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 th 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 th 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 b in place.

AUSTRALIA

Adoption and amendment of annexes

Article 30 of the Convention sets out procedures for the adoption and amendment of annexes to th 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

Other final provisions would include Signature, Consent to be bound, Withdrawal, Authentic texts, and Depositary.

NORW

Annex XX

Risk assessment: examples of points to consider

INFORMATION RELATING TO THE LMO

Characteristics of the organism from which the LMO is derive

The relevant biological, physiological and genetic and environmental characteristics of th recipient/parental/host organism include, as appropriate:

(a) The name and identity of the organism;

(b) 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);

(c) The natural habitat and the geographic origin of the organism, its distribution and its role in the environment;

(d) Mechanisms by which the organism survives, multiplies and disseminates in th environment;

(e) 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

(a) Identity, origin, natural habitat, and the relevant safety characteristics of the vector;

(b) The frequency at which the vector is mobilized or can transfer itself to other organisms;

(c) 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

(a) Functions coded by the inserted or deleted nucleic acid, including any residual vector;

(b) Information on the expression of the inserted or deleted nucleic acid and th activity of the gene product(s).

Characteristics of the LMO

The LMO should be compared with the organism from which it is derived, examining, wher relevant the following points:

(a) Pathogencity, toxicity and allergenicity to humans and other organisms (In th 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);

(b) Survival, persistence, competitive abilities and dissemination in the environment or other relevant interactions;

(c) Capacity to transfer genetic material and the ways in which this might occur;

(d) Methods for detecting the organism in the environment and for detecting th transfer of the donated nucleic acid;

(e) Functions which might affect its ecological range;

(f) 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 th 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 includ

(a) Number or volume of organisms to be used;

(b) Scale of the operation;

(c) Proposed containment measures, including verification of their functioning;

(d) Training and supervision of personnel carrying out the work;

(e) Plans for waste management;

(f) Plans for safety of the health of personnel;

(g) Plans for handling accidents and unexpected events;

(h) Relevant information fro previous uses.

For deliberate releases, this can includ

(a) Purpose and scale of the release;

(b) Geographical description and location of the release;

(c) Proximity to residences and human activities;

(d) Method and frequency of release;

(e) Training and supervision of personnel carrying out the work;

(f) Likelihood of transboundary movement;

(g) Time and duration of the release;

(h) Expected environmental conditions during the release;

(i) Proposed risk-management measures including verification of their functioning;

(j) Subsequent treatment of the site and plans for waste management;

(k) Plans for handling accidents and unexpected events/disasters;

(l) Relevant information from any previous releases. New or changed use or practic compared 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 b released, its interaction with other organisms and its intended or unintended use. Relevant information can include:

(a) The geographical location of the site, the identity and any special features of th receiving environments that expose them to damage;

(b) The proximity of the site to humans and to significant biota;

(c) Any flora, fauna and ecosystems that could be affected by the release, including keystone, rare endangered or endemic species, potential competitive species and non-target organisms;

(d) the potential of any organism in the potential receiving environment to receiv genes from the released organism.
