

**CONVENTION ON
BIOLOGICAL DIVERSITY**

Distr.
GENERAL

UNEP/CBD/BSWG/6/8
9 December 1998

ORIGINAL: ENGLISH

OPEN-ENDED AD HOC WORKING
GROUP ON BIOSAFETY
Sixth meeting
Cartagena, Colombia, 14-19 February 1999

Note from the Secretariat

Overview and Annotated Draft Negotiating Text of the Protocol on Biosafety.

In accordance with the instructions received at the Meeting of the Extended Bureau of the Working Group on Biosafety, the Secretariat has prepared an overview and an Annotated Draft Negotiating Text of the Protocol on Biosafety,

The Overview gives a synopsis of the Protocol, the Annotated Draft Negotiating Text identifies each bracketed item in the Draft Negotiating text, and are intended to facilitate discussions at the 6th Meeting of the Open Ended Working Group on Biosafety

The footnotes to the Draft Negotiating Text are also included in the Annotated Text, but there are no annotations to these footnotes Since they refer frequently to other Articles or conditions for negotiations.

Annotations are made on the following basis:

- a) To identify consistency in the text.
- b) To identify where a relationship can be established to other Articles.
- c) To identify possible relationships between the text and other relevant instruments.
- d) Where the Secretariat considered that any annotation could be interpreted as judgmental there is no annotation to the bracketed text.

In the annotated text, the entire Draft Negotiating Text is reproduced in bold, and each bracketed item is reproduced below the provision, in bold, and followed by a colon. The annotation follows in normal script.

The annotated text is provided at this time in English only, but will be available prior to the Regional and Interregional Consultations in Cartagena in languages.

Overview Draft Negotiating Text of the Biosafety Protocol

Decision II/ 5 of the Conference of the Parties established the Open Ended ad hoc Working Group on Biosafety to elaborate the modalities and elements of 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 procedures for advanced informed agreement.

The Working Group has met five times and has developed a draft negotiating text which will form the basis for negotiations at the sixth and final meeting of the Working Group in Cartagena Colombia February 14-19 1999.

The Draft protocol can be considered in several segments, that are interrelated, but may be more simply reviewed individually.

Preamble

The Preamble is under negotiation in Contact Group 2, Chaired by Ambassador Ashe (Antigua and Barbuda) and Ms K. Kummer (Switzerland). In earlier meetings of the Working group the Contact Group agreed that negotiations on the Preamble should not be initiated until the draft of the Protocol had reached a higher level of clarity. Negotiations on the Preamble will begin at the Sixth Meeting. In addition to the draft text, the Co-chairs have requested all previous government submissions on the Preamble to be included in the negotiating text. These previous submissions are contained in the document UNEP/CBD/BSWGG6/Inf 2.

General Provisions:

Objectives, Obligations and Terms:

Articles 1,2 and 3.

Articles 1 and 2 lay out the objective of the protocol, i.e. to ensure an adequate level of protection with regard to possible adverse effects on the conservation and sustainable use of biodiversity, taking into account risks to human health. The obligations include the implementation of the protocol and a requirement for advanced informed agreement.

Parties have identified specific terms that need to be defined. The most important term is "LMO" since it establishes in some respects the scope of the protocol. Consultation is still on-going with respect to these definitions.

Scope of the Protocol:

Article 4

Scope concerns to what the protocol will apply. There are four basic issues in the question of scope; a) products thereof, b) commodities c) contained use d) first transboundary movement, and in addition to that e) the issue of human health. The issue of scope relates to most other components of the protocol.

The scope of the protocol is also related to the over all view of the protocol in that the negotiations may determine that not all provisions of the protocol must apply to all LMO's each time. There is a direct interrelation between the scope of the protocol and the application of the AIA procedures.

The current text is not clear as to which provisions would apply to LMO's that are not subject to the AIA procedure, for instance notification or risk assessment.

Application of the AIA procedure:
Article 5

Separating the Scope of the protocol and the application of the AIA provisions, the current text permits that the scope of the protocol could be broader than the range of LMO's, or conditions, to which the Advanced Informed Agreement procedures would apply.

Procedures:

AIA Procedures:

- Article 6: Notification**
- Article 7: Acknowledgement of receipt of the notification**
- Article 8: Decision procedure**
- Article 9: Review of the decision**
- Article 10: Notification of transit (has been recommended for deletion)**
- Article 11: Simplified procedure**
- Article 12: Subsequent imports (has been recommended for deletion)**
- Article 13: Multilateral and Bilateral Agreements/Arrangements**

The AIA procedures are contained in the provisions for notification, acknowledgement of receipt, notification of transit, simplified procedures, subsequent imports, decision and review of the decision. Associated requirements that could apply to transboundary movements covered by the protocol under either AIA or non AIA procedures, include multilateral or bilateral agreements or arrangements, risk assessment and risk management, minimum national standards, unintentional transboundary movement.

In simplified terms the procedures require that a notifier must provide to the competent authority of the receiving Party minimum specified information that would allow a risk assessment to be made. The receiving authority must respond to the notifier in a set time acknowledging receipt of the notification. Within a yet to be determined time the competent authority must respond to the notifier with a decision based on the risk assessment. Negotiations continue on who should initiate the notification and subsequent actions. These are in part connected to discussions on legal responsibility for the accuracy of the information.

There exists opportunities for simplified procedures for notification that could also apply to LMO's under the scope of the Protocol, but not within the scope of the AIA procedures.. Also, there is a provision in the current text allowing for bilateral or multilateral agreements or arrangements outside the application of the protocol.

Risk Assessment and Risk Management:

- Article 14: Risk Assessment**
- Article 15: Risk Management**
- Article 16: Minimum National Standards (has been recommended for deletion)**

The procedures require that a risk assessment be performed for LMO's subject to the protocol. The risk assessment must be based at a minimum on the information identified in Annex II, as supplied in the notification under Article 6. Similarly, in accordance with Article 8(g) of the convention, the protocol

requires that appropriate mechanisms are put in place to regulate and manage the risks identified in the risk assessment.

Article 17: Unintentional transboundary movements and emergencies

Article 18: Handling, transport, packaging (and labelling)

Article 17 outlines requirements to notify and provide information to affected or potentially affected parties of unintentional transboundary movement. Article 18 calls for appropriate measures for handling and transport of LMO's. The need and modalities of labelling is under discussion.

General Provisions required for the operation of the Protocol and AIA:

Article 19: Competent National Authority/National focal Point

Article 20: Information Sharing/Biosafety Clearing House

Article 21: Confidential Information

Article 22: Capacity Building

Article 23: Public Awareness and Participation

Provisions in the protocol require Parties to designate focal points to Liaise with Parties and the CBD Secretariat and to be responsible for administering the protocol (the competent national authority).

Relevant to the objectives of the protocol are provisions regarding illegal traffic, confidential information, non-parties and non-discrimination.

Provisions embedded in the convention, and germane to the protocol include provisions on information sharing, capacity building and public awareness. These provisions and the relevant Articles are interconnected through the requirements within the protocol that Parties send information to the Biosafety Clearing House. The Biosafety Clearing House is the vehicle for achieving objectives of communication, information sharing, public awareness and some aspects of capacity building under the protocol.

Trade Related Issues:

- Article 24: Non Parties**
- Article 25: Non-discrimination**
- Article 26: Legal Traffic**
- Article 34: Relationship with other International Agreements**

These items are commonly contained in instruments for the purposes of clarity in relation to how trade will be dealt with between Parties and non Parties and the relationship between different sources of a traded item, or one subject to the protocol. The relationship with other international agreements is dealt with in Article 34.

- Article 27: Socio-economic considerations**
- Article 28: Liability and Redress**
- Article 36: Compliance**

The text reflects significantly different views on how Parties could address the issues of socio-economics and liability in the protocol. The text does not contain specific procedures for determining compliance nor procedures to deal with non-compliance.

Institutional Arrangements:

- Article 29: Financial Mechanism and Resources**
- Article 30: Conference of the Parties**
- Article 31: Subsidiary Bodies and Mechanisms**
- Article 32: Secretariat**
- Article 33: Relationship with the Convention**
- Article 35: Monitoring and Reporting**
- Article 37: Assessment and Review of this Protocol**
- Article 38: Signature**
- Article 39: Entry into Force**
- Article 40: Reservations**
- Article 41: Withdrawal**
- Article 42: Authentic Text**

The only item under negotiation is Article 40 on reservations to the protocol. There is also ongoing consultation on the relationship between Article 22 on Capacity Building and Article 29 on Financial Mechanism and Resources.

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ANNOTATED DRAFT NEGOTIATING TEXT OF A PROTOCOL ON BIOSAFETY

PREAMBLE

The Preamble has not been the subject of negotiation yet, therefore there is no annotation to this text.

Option 1

The Parties to this Protocol,

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

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

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

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

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

Have agreed as follows:

Option 2

The Parties to this Protocol,

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

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

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

Reaffirming decision III/20 of the Conference of the Parties to the Convention and, in particular its support for a two-track approach through which the promotion of the application of the UNEP International Technical Guidelines for Safety in Biotechnology can contribute to and complement the implementation of this Protocol,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Have agreed as follows:

PREAMBLE

Option 1

The Parties to this Protocol,

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

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

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

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

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

Have agreed as follows:

Option 2

The Parties to this Protocol,

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

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

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

Reaffirming decision III/20 of the Conference of the Parties to the Convention and, in particular its support for a two-track approach through which the promotion of the application of the UNEP International Technical Guidelines for Safety in Biotechnology can contribute to and complement the implementation of this Protocol,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Have agreed as follows:

ARTICLE 1 - OBJECTIVES

The objective of this Protocol is [[, in accordance with the precautionary principle,] to contribute to ensuring an adequate level of protection in the field of] [the safe, transfer, handling and use [in a transboundary context] [specifically focusing on]] [the safe] [transboundary movement] of living modified organisms [and products thereof] resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity [, taking also into account risks to human health [and socio-economic imperatives]].

With the exception of “products thereof, and socio-economic imperatives, all the terms in brackets relate to Decision II/5. Once a decision has been made on the following items:

products thereof
taking also into account human health
socio-economic imperatives

for Articles 1, 2,3,4, 5 and 14 these terms may only need to be repeated in subsequent Articles not relating to the application of the AIA procedure, since they will be implicit in all articles relative to application of AIA.

ARTICLE 2 - GENERAL OBLIGATIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement [and enforce] its obligations under this Protocol.

[and enforce] : Requirement for enforcement at the national level of obligations set out in the provisions of the protocol.

[2. Parties shall co-operate to facilitate the implementation of the provisions of this Protocol, and may involve interested organizations in implementation, as appropriate.]

Specification of a requirement for co-operation in implementation. Optional involvement of other interested organizations. See also Article 22.

[3. Parties shall not allow the export of LMOs [or products thereof] until such time as they have obtained an advance informed agreement in writing from the State of import for the specific import, based on scientific risk assessment procedures.] ^{1/}

General obligation to not allow export of LMOs without AIA from the importing country based on a risk assessment; This provision may be inconsistent with obligations appearing in the current Article 4(2)
Article 5 (2)

^{1/} This paragraph should be referred for consideration under Article 8, paragraph 9.

Article 9 (4)
 Article 11 (1)(a),(b)
 Article 13 (3)

and duplicated in Article 8

[or products thereof]: See Article 4 Scope of Protocol.

[4. Parties shall ensure that the development, handling, transport, use, transfer and release of any LMOs [or products thereof] are undertaken in a manner that prevents or reduces the risks to biological diversity [, taking also into account human health].]

[products thereof]: See Article 4 Scope of protocol

[taking also into account human health]: See Article 1 Objectives.

Part of this provision may be duplicated in the current Article 15.

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

6. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biodiversity than that called for in this Protocol, provided that such action is consistent with the [provisions] [objectives] of this Protocol [and is in accordance with its obligations under international law].

[provisions] [objectives]: Choice of the general (objectives) or the more specific obligations (provisions).

[and is in accordance with its obligations under international law].: Refers to the rights provided for in Article 34.

[ARTICLE 3 - USE OF TERMS

[LMO means any living organism containing a novel combination of genetic material obtained through the use of modern biotechnology.

Living organism means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

Modern biotechnology means the application of in vitro nucleic acid techniques^{2/} [and cell-fusion techniques] that overcome natural physiological reproductive or recombination barriers, other than traditional breeding and selection.]

[and cell-fusion techniques]: To what extent does "modern biotechnology" include "cell-fusion techniques",

Parties have identified specific terms that need to be defined and have reached preliminary agreement on working definitions on the most important terms, such as LMOs, which, in some respect relate to the scope of the protocol. Consultation is still ongoing with respect to the definitions.

(The terms below were **not considered by the Working Group at its fifth meeting**)

Transboundary movement

Transboundary movement [of an LMO^{3/}] means any movement [of an LMO] from [an area under the jurisdiction][the territory] of one Party[/State] to [an area under the jurisdiction][the territory] of another Party[/State].

[of an LMO]:

Party[/State]:

[an area under the jurisdiction]/[the territory]:

Export

[of an LMO]:

[area under the jurisdiction]/[territory:]

Party[/State]:

[does not include transit through a...State]:

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

^{2/} Contact Group 1 agreed that these techniques include recombinant nucleic acid techniques and in vitro direct injection of nucleic acid into cells and organelles.

^{3/} At a later stage, Contact Group 2 will check the consistency of the use of the term "of an LMO" throughout the entire document.

Import

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

[area under the jurisdiction]/[territory]:

Party[/State]:

[does not include transit through a...State]:

Exporter

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

Party[/State]:

[arranges]/[is responsible]:

Importer

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

Party[/State]:

[arranges]/[is responsible]:

Party of export

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

[State]: Would include exports from Non-parties under the protocol.

[transboundary movement] / [export]: May be synonyms, depending on the definition of transboundary.

[of an LMO]: Makes explicit the scope of the term..

[is planned to be initiated or]: relates to the transboundary movement of an LMO.

Party of import

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

[State]: Would include exports from Non-parties under the protocol.

[transboundary movement] /[export]: May be synonyms, depending on the definition of transboundary.

[of an LMO]: Makes explicit the scope of the term..

[is planned to be initiated or]: relates to the transboundary movement of an LMO.

ARTICLE 4 - THE SCOPE OF THE PROTOCOL ^{4/}

[1. This Protocol shall [, without prejudice to paragraph 2 below,] apply to the transboundary movement [, handling and use] of LMOs [or products thereof] [resulting from modern biotechnology] that may have an adverse effect on the conservation and sustainable use of biological diversity [and socio-economic well-being] [,taking also into account risks to human health].]

[without prejudice to paragraph 2 below]: Permits exclusions identified in paragraph 2.

[handling and use]: See Article 1.

[or products thereof]: The term "products thereof" following LMO's extends the protocol beyond "living modified organisms" to include, potentially, non-living materials such as naked DNA, chemicals produced through the use of LMO's e.g. food additives or drugs; materials that are dead e.g. wood Discussion is on-going on this central issue. The term appears in some Articles following the term LMOs, but not in others.

Agreement on the term "products thereof" may affect discussions on the following Articles:

Article 1 Objectives

Article 2 General Obligations

Article 3 Use of Terms,

Article 5 Application of AIA procedures

Article 14 Risk Assessment

Article 15 Risk Management.

Article 17 Unintentional transboundary movements and emergency measures

Article 18 Handling Transport Packaging [and labelling]

Article 20 Information Sharing/Clearing House

Article 28 Liability and Redress

[resulting from modern biotechnology]: Establishes the scope of the Protocol as LMOs resulting from modern biotechnology (See Decision II/5 paragraph 1). Duplicates Article 1.

^{4/} The provisions relating to the scope of the Protocol require further discussion.

[and socio-economic well-being]: See Article 1.

[taking also into account risks to human health]: See Article 1.

[2. This Protocol shall not apply to:

Defines limits to the application of the protocol..

[(a) Transboundary movements of LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, [taking also into account risks to human health,] as specified in Annex X;]^{5/}

[taking also into account risks to human health]: See Article 1.

[(b) Requirements for transport operations;]

[(c) Transit of LMOs and transboundary movements destined for contained use, except as regards Articles 2 (General obligations) and 17 (Unintentional transboundary movements).]]^{6/}

This provision may be inconsistent with current provisions in the following Articles:

Article 5(d) large scale contained use.

Article 6.(1) notification to Party of transit

ARTICLE 5 - THE APPLICATION OF THE AIA PROCEDURE

1. [All] [The first]^{7/} **[intentional] transboundary movements of [an] [all] [a specific] LMO[s] [or products thereof], [as defined in this Protocol] [for a specific use]:**^{8/}

[All]/[first]: [All] may be inconsistent with the concept of subsequent imports as identified in Article 9 (4) and Article 11 (2).

^{5/} A proposal for inclusion in Annex X is "LMOs which are pharmaceuticals for humans".

^{6/} This provision will be reconsidered as a result of the outcome of Articles 5, 18 and others.

^{7/} What constitutes a "first" transboundary movement in relation to the novel status of an LMO in the receiving environment of a Party of import will be considered by Contact Group 2. This also applies to the use of "first" transboundary movement in Article 6, paragraph 1.

^{8/} Parties must be allowed to impose more stringent or comprehensive notification requirements to protect their biodiversity, where these: (a) are based on [sound scientific rationale] [and the precautionary principle]; (b) do not discriminate; and, (c) are communicated to all Parties. (This could be covered in other parts of the Protocol, leading to the later deletion of this footnote.)

[intentional]: The concept of intentional may be implicit as the concept of unintentional transboundary movement appears in Article 17. However, the current definition of transboundary movement does not specify “intentional”.

[an] [all] [a specific]: [A specific] if retained would probably require definition. Use of the term "all" here may be inconsistent with the current Article 4

[or products thereof]: See Article 4

[as defined in this protocol]: Duplicative of Article 2.

[for a specific use]: This makes the protocol a "use specific" instrument. This would probably require definitions of the specific uses.

See also Article 6. For definition of the term [first]

[[a) Intended for field testing in the Party of import;]

[(b) Intended for [first] deliberate [introduction] [release] in[to] the environment] [of the Party of import for growth or propagation];]

[first]: limits the application of this provision to the first introduction/release. See also Article 6.

[introduction][release]: In this context the terms may be synonymous..

in[to]: Editorial

[of the Party of import for growth or propagation]: Identifies specified uses for the LMO to which the provision would apply.

[(c) That has been banned in the Party of export;]

[(d) LMOs [exclusively] destined for [large scale production in] contained [use] [facilities]]]

[exclusively]: Identifies destined use of LMOs.

[large scale production in]: Criteria for the application of the provision further identifies the destined use as being for large scale production.

[use] [facilities]: Frequently used interchangeably, contained use means used under some form of containment, contained facilities generally refers to a facility where the process of containment is identified and meets criteria.

shall be subject to [an] AIA.

[an] AIA.: Editorial

[2. The AIA procedure [shall] [may] not apply to [the transit of LMOs or to] the [intentional] transboundary movement of: ^{9/}, ^{10/}

[shall] [may]; “Shall” results in an obligation., “may” permits options and provides that the AIA procedure need not apply to all cases of transit.

[shall]not apply to [the transit of LMOs or to]: Excludes transit from AIA procedures..

[intentional]: Explicit identification of intentional excludes unintentional transboundary movement. May be redundant if the term “intentional is retained in Article 5(1).

[(a) LMOs exempted under the domestic regulatory framework of the Party of import [or, in the absence of a specific regulatory framework, specified by the Party of import that the transboundary movement can take place at the same time as the movement is notified to the Party of import] ^{11/}; or exempted pursuant to bilateral, multilateral or regional agreements [or arrangements]; where these are: [consistent with the objectives of this Protocol] [and obligations under international law] [and] [do not result in a lower level of protection than that provided for by the Protocol]; and communicated to the Secretariat and to all Parties [via the Biosafety Clearing-House];] ^{12/}

[or, in the absence of a specific regulatory framework, specified by the Party of import that the transboundary movement can take place at the same time as the movement is notified to the Party of

^{9/} Such exemptions must not result in lower levels of protection than would be provided by following the AIA process under the Protocol; be based on [sound scientific rationale] [and the precautionary principle]; not be discriminatory; and be communicated to all Parties. (This could be covered in other parts of the Protocol, leading to the later deletion of this footnote.)

^{10/} The following text: LMOs which are subject to any other international agreement [providing for a safety level with respect to transboundary movement of LMOs, higher than that provided for by this Protocol] will be given to Contact Group 2 for legal advice as to whether this provision is necessary.

^{11/} This provision attempts to reflect a concept present in Article 11.

^{12/} The following text: LMOs requested to be imported by the competent authority of the Party of import for the purpose of carrying out risk assessment as a process of the AIA procedures stipulated in this Protocol has been deleted, pending the outcome of discussions on para. 2(a) covering its content.

import]: Allows for advance consent by Parties of import in the absence of a receiving Party biosafety framework.

[or arrangements]: See Article 13.

[consistent with the objectives of this Protocol]: Requires domestic regulatory framework to be consistent with the objectives of the protocol

[and obligations under international law]:

[and]: Editorial

[do not result in a lower level of protection than that provided for by the Protocol]:

[via the Biosafety Clearing-House]: Communication via the Biosafety Clearing House ensures transparency and communication to all Parties. Terminology used in other Articles and provisions is “ and to the Biosafety Clearing House”

[(b) LMOs [exclusively] destined for [research in] contained [use] [facilities];] ^{13/}

[exclusively]: See Article 5 paragraph 1

[research in]: Explicitly specifies use.

[use]/[facilities]: See Article 5 paragraph 1

[(c) LMOs identified in a decision by the Meeting of the Parties to the Protocol ^{14/} as not likely to have adverse effects on the conservation and sustainable use of biological diversity [taking also into account risks to human health];]

[taking also into account risks to human health]: See Article 1.

[(d) LMOs destined for placing on the market in the Party of import provided that the Party of import has previously granted an AIA for that specific purpose, without prejudice to any decision made by the Party of import under Article 8, para. 3 (a).]

^{13/} A final decision on this provision will depend on the definition of contained use.

^{14/} Contact Group 2 is requested to provide advice as to whether reference to an annex will be necessary.

ARTICLE 6 - NOTIFICATION

1. The Party of [import] [export] [may] [shall] [notify] [or] require the [importer] [or] [the exporter] to notify in writing [the competent national authority of] the Party of import [and the Biosafety Clearing-House] [and, where applicable, [the designated national competent authority of] the Party of transit] prior to the [first] intentional transboundary movement of an LMO that falls under the scope of Article 5. The notification shall contain at a minimum the information specified in Annex I.^{15/}

As currently titled, these provisions are not restricted to AIA notifications.

See relationship with :

Article 2 (a) Current text may require AIA for all LMO transboundary movements,

Article 5 Current text may provide for exemptions

Party of [import]/[export]: Identifies who shall take the action.

[may]/[shall]/[notify]: If coupled with [Party of] this makes governments responsible for the notification. Shall is obligatory, may is conditional and may require the identification of “under what conditions would the provision apply”. See also financial obligation under Article 14 (3).

[importer][or][exporter]: Would make the importer or exporter the notifier.

[the competent national authority]: Identifies the point of notification.

[and the Biosafety Clearing House]: See Article 20(3)(a) where Parties must make information available to the BCH.

[and where applicable[the designated national competent authority][of the party of transit]: See Article 10 , and Article 4(2)(c).

[first]: See Article 5

[2. The Party of [export] [import] shall make its [exporter] [importer] legally responsible for the accuracy of information provided by the [exporter] [importer].]

Party of [export][import]: The government shall ensure legal responsibility of the “exporter” “importer” for the accuracy of the information provided by the “exporter” “importer”.

[exporter][importer]: Identifies who would be legally responsible for the accuracy of the information.

^{15/} The concept contained in the wording "and such other information as the Party of import may require in accordance with its national legislation [consistent with the objectives of the Protocol]" will be considered in the context of Article 2.

[**exporter**]/[**importer**]. Identifies that the provider of information identified in paragraph 1 is the [exporter] [importer] not the Party.

ARTICLE 7 - ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION [FOR AIA]

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

[[ninety]]: Period of time in which to acknowledge receipt of the notification.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, prima facie, contains the information specified in Article 6; [and]

[and]: Editorial

[(c) Whether to proceed according to the domestic regulatory framework of the Party of import, provided that the framework is consistent with this Protocol or according to the procedures provided for in Article 8 of this Protocol.] ^{16/}

This provision would allow for a decision by importing Party to permit the exporter to proceed either according to the AIA procedure, or by the domestic regulatory framework provided it is consistent with the Protocol.

3. Failure to acknowledge receipt of notification by the Party of import will not imply consent for transboundary movement.

ARTICLE 8 - DECISION PROCEDURE FOR AIA

^{16/} The concept considered in this paragraph can be covered in Article 5.

1. Decisions taken by the Party of import shall be [based on risk assessment] [in accordance with Article 14] [made on the basis of scientific principles,] [, the precautionary principle] [of the adverse effect on the conservation and sustainable use of biological diversity], [taking also into account risks to human health] [and social, economic and cultural criteria]. ^{17/}

[based on risk assessment] [in accordance with Article 14]: Requires that the decision must be based on a risk assessment. The second phrase requires that the decision be based on a risk assessment performed according to the specific provisions for risk assessment in Article 14.

[made on the basis of scientific principles]: This may not specify the general provision for a risk assessment unless the principles are stated.

[the precautionary principle]: See Article 1. It is unclear as to whether this applies to the decision or to the risk assessment. If retained the word “and” should be added.

[of the adverse effect on the conservation and sustainable use of biological diversity]

[taking also into account risks to human health]: See Article 1

[and social economic and cultural criteria]: See Article 1

[2. The Party of import shall within the period of time referred to in Article 7 inform the notifier whether:

(a) The intentional transboundary movement may proceed [after no less than ninety days] without a written consent; or

The decision must be reached in the period referred to in Article 7, that is within [ninety] days of receipt of the notification.

As worded, this provision requires the importing Party to reach a decision on whether the AIA process should continue or whether the export may proceed after [ninety] days without further written consent. Note that this decision can be concomitant with the acknowledgement of receipt of the notification..

[after no less than ninety days]: The period is identical to the period of time referred to in Article 7 and follows a decision to allow import without further written consent.

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

^{17/} Paragraph 1 should be revisited in light of the outcome of the discussions on Article 14.

3. Within [a reasonable period of time] [ninety] [one hundred and eighty] [days] from the acknowledgement of receipt of notification, the Party of import shall communicate its decision, in writing, to the notifier [and the Biosafety Clearing-House]:

[a reasonable period of time] [ninety] [one hundred and eighty] [days]: The term “a reasonable period of time” introduces legal uncertainty into the provision, especially when paragraph 3(d) permits an extension of the time period for reaching a decision. Ninety days following acknowledgement of the notification would provide a time of up to 180 days to reach a decision, 180 days following acknowledgement of receipt would provide a period of up to 270 days to reach a decision.

[and the Biosafety Clearing House]: May duplicate Article 20(3)(d) which requires that the Party of import shall notify the BCH of the decision.

(a) Approving the import, with or without condition, including how the decision applies to subsequent imports of the same LMO;

(b) Prohibiting the import; [or]

[or] should add "or" following option a. Editorial

[(c) [Requesting additional relevant information [in accordance with [its national legislation] [and] [or] Annexes I and II].] [When calculating the time for the Party of import to respond, the number of days for which the Party of import is waiting for additional relevant information shall not be taken into account]]; [or]

{in accordance with}[its national legislation] [and] [or] [Annexes I and II]: Identifies the basis for the request for additional information

[when calculating the time....into account]: Waiting for additional information stops the clock.

[(d) Informing the notifier that the period specified in this paragraph is extended by [a defined period no longer than ninety days] [as much time as is necessary to assess the information it has received from the [notifier] so as to enable it to reach an informed decision.]]

[a defined period of no longer than ninety days]: Makes the total period available to reach a decision starting from receipt of the notification a maximum of either 270 or 360 days,

[as much time as is necessary to assess the information it has received]: May introduce legal uncertainty, see Article 8(3).

[notifier]: The information is provided by the notifier, See Article 7(1), but this may be needed to make sense of the paragraph.

[...so as to enable it to reach an informed decision]: May be repetitious as it restates the purpose of the Article.

4. Decisions under paragraph 3 shall include the reasons for the decision [except in the case of unconditional approval.]

[except in the case...approval] : There may be no need for explanations for an unconditional approval.

[5. Lack of [sufficient information] [or] full scientific certainty or of scientific consensus to determine the potential adverse effects of an LMO shall not prevent the Party of import from prohibiting the import of the LMO in question.]

This may be an implementation of the precautionary principle as a provision of the protocol (See Article 1). .Scientific consensus may need to be defined.

[sufficient information][or]: Would allow a Party to prohibit import on the basis of insufficient information other than the information required under Annexes I and II, e.g. information requirements under national legislation or by advisory bodies.

[or] provides for more than one reason for prohibition

[6. The Parties shall co-operate with a view to deciding, as soon as possible, to what extent in relation to the procedures, and in which cases, to be specified in an annex, a transboundary movement cannot proceed without an explicit consent.]

This provision would require the development of an Annex. The provision enables the Parties to decide on transboundary movements that would always require an explicit consent under AIA.

[7. If the Party of import does not respond within the period specified under paragraph X [and it is not the case in which a movement shall not proceed without an explicit consent], [the exporter [may] [shall not] [should not] proceed with the transboundary movement] the Party of import shall be deemed to have [approved] [prohibited] import of the LMO concerned.]

[and it is not the case in which a movement shall not proceed without an explicit consent]: As identified in paragraph 6 of this Article.

[the exporter [may]]: “ May” means absence of a response in the specified period of time is taken as implicit approval. And requires [approved] in the next phrase.

[shall not]: Means there is no consent, but does not necessarily imply [prohibited] in the next phrase

[should not]: Is conditional and may require additional explanation of under what conditions should the exporter continue with the transboundary movement.

[8. The failure of the Party of import to communicate [its decision] [or] [substantial progress towards a decision] within [ninety] days after the acknowledgement of the receipt of notification [or, if there is no acknowledgement of receipt of notification within the period specified in Article 7,] shall not imply consent to the intentional transboundary movement of the LMO, but the Party of export shall have no [further] [consequent] obligation under [Articles X] with respect to that transboundary movement of the LMO.]

[its decision] [or] [substantial progress towards a decision]: Article 8(3) and Article 20(3)(d) call for the Party to communicate its decision to the notifier and to the Biosafety Clearing House

[ninety]: The time indicated should be the time indicated in Article 8(3) above.

[or, if there is no acknowledgement of receipt of notification within the period specified in Article 7,] :
This clause is already stated in Article 7(3)

The period specified in article 7 is ninety days

[further] [consequent]: May be synonymous in this context

[Articles X] Refers to the specific obligations of the Party of export as identified in Articles 6, 7, 8, 9, 11, 12 and 28.

[9. The Conference of the Parties shall at its first meeting decide upon appropriate procedures and mechanisms to facilitate the reaching of a decision by a Party of import.]

This paragraph needs additional clarity since the procedures for reaching a decision are in the text. It should be clarified if this paragraph refer to capacity building, to co-operation, to simplified processes or lack of response.

ARTICLE 9 - REVIEW OF DECISIONS [UNDER AIA]

1. A Party of import may at any time in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity [taking into account risks to human health] [and the precautionary principle], [unilaterally] review and change its decisions with regard to the transboundary movement of an LMO. In such a case, the Party must, within thirty days inform any notified who has previously notified movements, [Parties concerned], and the Biosafety Clearing-House and give full details of the reasons for its decision.

[under AIA]: Limits the review procedures to decisions reached under the AIA procedure and excludes review of decisions reached under the non-AIA applications of the protocol.

[taking into account risks to human health]: In this instance the restatement of the objectives may be appropriate. See Article 1.

[and the precautionary principle]: See Article 1 In this instance may allow for divergent interpretations of the precautionary principle.

[unilaterally]: Permits the Party of import to change its decision unilaterally.

[Parties concerned]: Could include Parties of transit nor others depending on the interpretation of “concerned”.

[2. A [[Party] [State] of export] [notifier] may request a Party of import to review a decision it has made in respect of it under Article 8 where the [[Party] [State] of export] [notifier] considers that:

[[Party][State] of export] [notifier]: “Party” would require government to make the request and would limit the review request only to Parties to the protocol. “State of export” broadens the scope to include non-Party exporters but limits the request to governments. “Notifier” is consistent with Article 7 , 8 and 9(1).

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

Add [or]: Editorial

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

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

[There is reasonable evidence...]: Calls for an assessment of reasonable. May link to Article 36

[socio-economic cultural or the precautionary....]: Socio-economic includes cultural. See also Article 1. Decisions are based on the risk assessment, the precautionary principle, may be taken into account in the decision making process. See also Article 9(3).

[...best available scientific evidence]: Calls for determination as to what is the best available scientific evidence

[3. Parties of import shall respond to such requests in writing, within [a reasonable period of time] [ninety days], and provide full details on the basis for their decision.]

[a reasonable period of time]: May add legal uncertainty to the process. See Article 8(3).

[ninety days]:

[4. Risk assessment for subsequent imports of an LMO [or products thereof] into the same Party of import may [be taken at the discretion of the Party of import] [only be required if:

This paragraph appears to be out of context in this Article. The paragraph does not refer to a review, but to an application of the AIA procedure or to the scope of a decision. It could be moved to Article 5 or Article 8 or Article 11.

[or products thereof]: See Article 4 paragraph 1

[be taken at the discretion of the Party of import]: If retained there is a need to inform the notifier that subsequent imports will require a risk assessment. The general application of this provision may not be consistent with the requirements under Article 8(3)(a).

[only be required if:] Specifies the criteria for requiring a risk assessment for subsequent imports.

(a) **There is a change in the intended use of the LMO [or products thereof];**

[or products thereof]: See Article 4 paragraph 1

(b) **There is a variation in the receiving environment;**

(c) **There is a change in the import volume of the LMO [or products thereof], where such a change were to increase the risk of adverse impacts on biological diversity through increased exposure into the receiving environment;**

[or products thereof]: See Article 4 paragraph 1

(d) **It is a condition of first import of the LMO [or products thereof] under Article 8; or**

[or products thereof]: See Article 4 paragraph 1

(e) **There are other relevant factors likely to affect the risk assessment or risk management of the LMO [or products thereof].]**

[or products thereof]: See Article 4 paragraph 1

ARTICLE 10 - NOTIFICATION OF TRANSIT

Because the elements addressed in this article are covered in the following: Article 6,^{18/} Article 7,^{19/} Article 8,^{20/} Article 18,^{21/} and Article 28,^{22/} this article should be deleted.

^{18/} Paragraph 1 of working paper 8 of Sub-Working Group I: [Where such notification is required, Parties shall provide information to the Biosafety Clearing-House on: (a) Details of the categories of living modified organisms [and products thereof] for which notification is required; and (b) information to be provided with the notification, [based on that set out in Annex Y].

Working paper 8 of SWG 1 -Attachment I

[ARTICLE 11 - SIMPLIFIED PROCEDURE]

This Article allows for Parties of import to identify exemptions from the AIA procedure and for simplified procedures for specified transboundary movements of LMO's. The Article could follow Article 5.

1. [Without prejudice to paragraph 5 of Article 8,] a Party of import may, [giving reasons,] [on the basis of the best available scientific knowledge and experience and any other relevant information] [provided that adequate measures are observed to ensure the safe transboundary movement of living modified organisms, in accordance with the objectives of this Protocol], specify in advance to the Biosafety Clearing-House:

[Without prejudice to paragraph 5 of Article 8,]: This provision may not be in an appropriate context, since Article 8 paragraph 5 refers to ability to prohibit import based on lack of scientific certainty

[giving reasons,]: Would require a Party to give reasons for selecting a simplified procedure.

[on the basis of the best available scientific knowledge and experience and any other relevant information]: Sets criteria for implementing the simplified procedure. May call for a definition of “best available”.

^{19/} Paragraph 1 of working paper 8 of Sub-Working Group I: [Parties may require notification, in writing, through their focal point of the intent to transit a living modified organism [or products thereof] through their territory].

^{20/} Paragraph 2 of working paper 8 of Sub-Working Group I: [The State of transit [shall] [may] [promptly] acknowledge the receipt of the notification to the notifier. It [shall] [may] subsequently respond to the notifier, in writing, within [x] [30] days: (a) consenting to the transit movement with [or without] conditions; (b) Denying permission for the movement; or (c) Requesting further information and/or an extended period of time to respond.]

Paragraph 3 of working paper 8 of Sub-Working Group I: [If the competent national authority of the Party of transit fails to notify the notifier within the specified time frame, implicit consent shall be assumed for the transit of the LMO.]

^{21/} Paragraph 4 of working paper 8 of Sub-Working Group I: [The handling and transport requirements including documentation for living modified organisms referred to in Article 18 shall be followed in all transit movements].

^{22/} Paragraph 1 of working paper 8 of Sub-Working Group I: [The Party of export shall assume responsibility for any cases of accidental release in those States].

[provided that adequate measures are observed to ensure the safe transboundary movement of living modified organisms, in accordance with the objectives of this Protocol]: Requires that the simplified procedure will still achieve the objectives of the protocol See Article 1.

[(a) Cases for which transboundary movement can take place at the same time as the movement is notified to the Party of import. Such notifications may apply to subsequent similar movements to the same Party;]

[(b) LMOs to be exempted from the AIA procedure.]

2. The information relating to a transboundary movement that is to be provided in the notification referred to above is the information specified in Annex I.] ^{23/}

This can only apply to Article 11(1)(a) since (b) does not require a notification.

ARTICLE 12 - SUBSEQUENT IMPORTS

The contents of Article 12 are amply covered in the revised Article 8, para. 3 (a), as contained in UNEP/CBD/BSWG/5/SWG.I/CRP.3 as well as in Articles 11 and 14, contained in working papers 11 and 4, respectively, of Sub-Working Group I. For this reason, this article should be deleted.

UNEP/CBD/BSWG/5/SWG.1/CRP.3 - Attachment II

[ARTICLE 13 - MULTILATERAL, BILATERAL AND REGIONAL AGREEMENTS [OR ARRANGEMENTS] [OTHER THAN THE PROTOCOL]

[OR ARRANGEMENTS]: Arrangements are a less binding form of agreement where the conditions are not formally identified and agreed to by the Parties. Provision for arrangements are found in other international instruments, for example, the Basel Convention on transboundary movement of hazardous substances.

[OTHER THAN THE PROTOCOL]

1. Parties may enter into bilateral, multilateral, or regional agreements [or arrangements] [with Parties] [or non-Parties] regarding [procedures or information exchange related to] transboundary movement of LMOs [and products thereof], [consistent with the objectives of this Protocol] [and obligations under international law] [and] [provided that such agreements [or arrangements] do not result in a lower level of protection than that provided for by the Protocol]. [Decisions taken under these agreements [and arrangements] shall be based on risk assessment, made on the basis of scientific principles.]

^{23/} This provision could be deleted depending on the outcome of Article 5 (Application of the AIA procedure).

[or arrangements]: See above.

[with Parties]: Limits the scope of the provision to Parties

[or non-Parties]: Permits agreements or arrangements with non-Parties.

[procedures or information exchange related to]: Identifies the basis of the agreement or arrangement, consistent with the objectives of the protocol.

[and products thereof]: See Article 4 (1)

[consistent with the objectives of this Protocol]: Requires that the agreements and or arrangements are consistent with the objectives of the protocol.

[and obligations under international law]: Refers to other instruments and is not germane to the Article, but may add clarity to the provision..

[and]: Requires that the agreements and or arrangements fulfil the following requirement,

[provided that.....provided for by the Protocol]: Requires that the agreements and or arrangements provide the same degree of protection afforded by the procedures under the protocol

[or arrangements] See above

[Decisions taken under these agreements [and arrangements] shall be based on risk assessment, made on the basis of scientific principles.]: Requires that the agreements and or arrangements include a provision for a risk assessment based on scientific principles. This is implicit in the requirement that the agreement and or arrangement provide the same degree of protection as the protocol, which requires a risk assessment.

[and arrangements] use or agreements for consistency.

2. Parties shall communicate to the Secretariat and to all Parties [via the Biosafety Clearing-House] any such bilateral, regional and multilateral agreements [or arrangements] entered into either before or after entry into force of this Protocol.

[via the Biosafety Clearing-House]: The term "and the Biosafety Clearing House" is used in other provisions.

[or arrangements]: See above

[3. The provisions of this Protocol shall not affect transboundary movements that take place pursuant to such agreements and/or arrangements as between the Parties to that agreement or arrangement.]

[4. Any Party may determine that its domestic regulations apply with respect to specific imports to it and shall notify the Secretariat and the Biosafety Clearing-House of its decision.] ^{24/}

This provision is related to Article 11(1)(b),

[5. A regional economic integration organization, which itself is a Contracting Party to the Protocol and has a specific legal framework for biosafety, may declare that the Protocol shall not apply to movements within its territory.] ^{24/}

ARTICLE 14 - RISK ASSESSMENT ^{25/}, ^{26/}

1. Risk assessment [under [Article X] [AIA procedures]] shall be undertaken [on a case-by-case basis] in a scientifically sound [and transparent] manner in accordance with Annex II ^{27/} [and taking into account appropriate risk assessment techniques developed by relevant international organizations] and be based [at a minimum] on information provided in accordance with Article 6, [the precautionary principle, socio-economic and cultural concerns and experience] [and other available scientific evidence] in order to identify and evaluate the possible adverse effects of LMOs [or products thereof] on [the environment of the Party of [import][transit] as regards] conservation and sustainable use of biological diversity, [taking into account the risks to [human health,] social, economic, cultural, ethical, agriculture, and animal health considerations]].

^{24/} This provision could be reflected elsewhere in the Protocol.

^{25/} Elements for consideration for inclusion in Article 22, as noted in UNEP/CBD/BSWG/5/Inf/1 on Article 14: "[The Party of import may request technical or financial assistance from the Party of export or the exporter with the carrying out of the risk assessment. Such requests [should] [shall] be met to the extent possible, especially in cases where the Party of import does not have sufficient experience of the LMO in question or lacks the financial and technical capacity to carry out the risk assessment. Parties should [,where appropriate,] collaborate with the State of import in carrying out risk assessment [through the sharing of information and expertise].]"

Paragraph 8, contained in Working Paper 4 of Sub-Working Group I, is also referred to Article 22 (Capacity-building) for future consideration:

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

^{26/} The Sub-Working Group agreed that paragraph 6 of the earlier draft of this Article ("[8. The [exporter] [importer] [notifier] is responsible for the reliability of the information provided.]") could be deleted, provided that paragraph 2 of draft Article 10 was retained.

^{27/} This phrase may need to be revisited, pending the outcome of negotiations on Annex II.

[under [Article X] [AIA procedures]]: Identifies the Articles, and or the risk assessment under the AIA procedures. If “AIA procedures” is retained this would limit the provision to risk assessment under AIA. See other Articles where the term “under AIA” is in the title, thereby restricting the application of the Article to actions under the AIA procedures.

[on a case-by-case basis]: Requires risk assessment on a case by case basis, does not allow the application of risk assessment to classes of LMO's.

[and transparent]: Would provide for the risk assessment to be made available to other Parties or to the public..

[and taking into account appropriate risk assessment techniques developed by relevant international organizations]: This provision would require Parties to consider in their risk assessment the techniques in risk assessment developed by international organizations, but would not require them to use the same methodologies.

[at a minimum]: Sets a lowest level of information used in the risk assessment as that provided under Article 6. Article 6 requires provision of a risk assessment in accordance with Annex II. This permits the use of information additional to that contained in Annex II, e.g. required under national legislation..

[the precautionary principle, socio-economic and cultural concerns and experience]: See Articles 1,8 and 9.

[and other available scientific evidence]: A general provision relevant to risk assessment.

[or products thereof]: See Article 4(1).

[the environment of the Party of [import][transit] as regards:] The environment thereof is not the expressed objective of the protocol, it may be better to retain the wording of the objective, i.e. the conservation and sustainable use of biological diversity, [taking into account the risks to [human health,]

[import] [transit]: Identifies the recipient of the risk assessment.

[social, economic, cultural, ethical, agriculture, and animal health considerations]]: Social economic, cultural and ethical considerations can all be encompassed in the term socio-economic.

[2. [The Party of import shall be responsible for ensuring that a risk assessment is carried out as necessary for a decision taken under Article 8.] [Risk assessment [shall] [may] [be required to] be undertaken by [[as the responsibility of the] [the competent authority of] [the Party of [import][export]].] [The Party of import may [require] [ask] the exporter/Party of export to carry out the risk assessment.]]

[The Party of import.....Article 8]: Article 6 and Annexes I and II require that a risk assessment be provided to the Party of import under the notification procedures for AIA. This is a requirement for the notifier. Article 8 requires that the Party of import provide a decision based on that risk assessment under AIA. Article 6 does not specify who performs the risk assessment. The provision here may not be consistent with Article 6 and Article 8. Absence of a risk assessment in the notification would mean that the notification was incomplete and that the transboundary movement could not proceed. Under Article 6 the notifier has the responsibility to provide the risk assessment.

[Risk assessment [shall] [may] [be required to] be undertaken by] : “Shall” requires the risk assessment, “may” is conditional and therefore may require the identifications of the conditions .

[[as the responsibility of the] [the competent authority of] [the Party of [import][export]].]: May not be consistent with Article 6(1) unless the Party of import/export is the notifier.

[The Party of import may [require] [ask] the exporter/Party of export to carry out the risk assessment.]: This provision may be superfluous since Article 6 requires the notifier to provide a risk assessment. Clarity in this provision is dependant on who is the notifier. See Article 6(1).

[3. The financial responsibility for risk assessment shall rest with the [Party of [export][import][importer][exporter][notifier]].]

The risk assessment is a requirement under Article 6, notification. It would appear therefore that the financial responsibility lies with the notifier.

[4. Parties shall ensure that risk-assessment and management processes of micro-organisms are conducted in contained conditions.] ^{28/}

It is assumed that this provision means that a risk assessment must be conducted as identified in Article 4(2) and Article 5(1)(d) and Article 5(2)(b) . The provision may need to be reviewed following finalization of Articles 4 and 5.

[ARTICLE 15 - RISK MANAGEMENT

As currently titled this Article identifies the requirements to be met by Parties for risk management of LMOs under the protocol and /or under the AIA procedures.

1. [[In accordance with] [To the extent required by] Article 8(g) of the Convention,] Parties [of import] shall establish and maintain appropriate mechanisms, measures and strategies to regulate and manage risks [[especially those] identified under the risk assessment provisions of the Protocol] associated with the [use, handling and] transboundary movement of LMOs [or products thereof].

[[In accordance with] [To the extent required by]: Article 8(g) of the Convention,] Article 8(g) requires that Parties shall, as far as possible and , as appropriate, establish means to regulate manage or control 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 taking also into account the risk to human health.

^{28/} This provision could be dealt with in connection with Annex II (Contact Group 1).

[of import]: Article 8(g) does not apply to only Parties of import. This would contravene the requirement under the Convention.

[especially those]: May not be consistent with Article 8(g) which does not identify special cases.

[use, handling and]: May not be consistent with Article 8(g).

[or products thereof]: See Article 4(1)

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

[products thereof]: See Article 4(1).

[..... set out in Annex X]: Requires an Annex to be developed.

[3. Measures based on risk assessment [and in particular on sound and scientific information] [shall] [may] be imposed [to the extent necessary] to prevent adverse effects of the LMO [or products thereof] on the conservation and sustainable use of biological diversity [, [human health and socio-economic considerations] within the territory of the State of import]. [Lack of full scientific certainty or of scientific concern regarding the level of risk shall not be used as a reason for postponing measures to prevent harm.]]

[and in particular on sound and scientific information]: This is already a provision for the risk assessment, this may be repetitious.

[shall] [may]: “Shall “makes this a requirement, “may” is conditional. “May” may not be consistent with the objective of the Article.

[to the extent necessary]: This limits the risk management measures to the extent required to prevent adverse effects as identified in the objectives. It relates to the use of measures proportional to the identified risk.

[or products thereof] See Article 4(1)

[human health and socio-economic considerations]: See Article (1).

[...within the territory of the State of import]: Stipulating that the measures apply only to the regulation, management or control of the risks within the State(Party) of import could exclude measures for regulating, managing or controlling risks due to unintentional transboundary movement, or in transit and may not be consistent with Article 6(1) and Article 17(4)..

[Lack of full scientific certainty or of scientific concern regarding the level of risk shall not be used as a reason for postponing measures to prevent harm.]]: Application of the precautionary principle in applying risk management measures. See also Article 8(5).

[4. [If the Party of import lacks the financial and technical capacity to do so,] the Party of export [shall offer technical and financial assistance and] [shall] [is encouraged to] collaborate with the Party of import [for risk management].^{29/}]

[5. The type of risk management to be employed shall be appropriate to the LMOs [or products thereof] and activity in question and such risk-management strategies and measures shall [be commensurate with] [correspond to the results of] the risk assessment]

[or products thereof]: See Article 4(1).

[be commensurate with] [correspond to the results of] the risk assessment]: This is a restatement of Article 15(3).

[6. [Each Party shall take appropriate measures to prevent unintentional [transboundary movements of LMOs], [including requiring [as appropriate] risk assessments to be carried out prior to the first release of an LMO]].^{30/}

This provision is repeated in Article 17(1). Note that Articles 6 and 15(1) require that a risk assessment to be carried out prior to the first transboundary movement of an LMO subject to the protocol.

[7. Without prejudice to paragraph x above, each Party, in order to ensure genomic and trait stability in the environment, shall ensure that any LMO [or products thereof], whether imported or locally developed, undergo a period of observation commensurate with its life-cycle or generation time as the case may be before it is put to its intended use.]

[or products thereof]: See Article 4(1).

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

[or products thereof]: See Article 4(1)

.

^{29/} This paragraph will be redrafted to reflect the need for the Party of import to solicit financial and technical assistance, if necessary, from the Party of export to enable risk management capability to deal with the specific LMO [or products thereof] which is being imported.

^{30/} The text may need to be revisited, pending consultation with Sub-Working Group II.

[or human health.]: See Article 1.

[9. Parties shall require producers of LMOs [or products thereof] to phase out all antibiotic-resistance marker genes in LMOs by the year 2002.]]

[or products thereof]: See Article 4(1).

ARTICLE 16 - MINIMUM NATIONAL STANDARDS

The provisions of Article 16 have been sent verbatim, with the recommendation to Sub-Working Group II for inclusion in Article 2. For this reason, this Article should be deleted.]

ARTICLE 17 - UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

[1. Each Party shall take appropriate measures to prevent unintentional transboundary movements of LMOs [and products thereof].]^{31/}

[each Party shall.....products thereof]: This provision is also found in Article 15(6)

[and products thereof]: See Article 4(1).

2. Each Party shall take appropriate measures to notify affected or potentially affected Parties and, where appropriate, relevant international organizations, when it knows of an [unforeseen] [unintentional] occurrence [within an area] under its jurisdiction resulting in a release which [leads to or presents a significant likelihood of] [may lead to] transboundary movement of LMOs [and products thereof] that [is likely to] [may] have [significant] adverse effects on the conservation and sustainable use of biological diversity [taking also into account human health] in such Parties. The notification shall be provided as soon as the Party knows of the above situation. The Party providing notification shall also make available to the Biosafety Clearing-House a summary of that notification.

[unforeseen] [unintentional]: Potential inconsistency with the Article title.

[within an area]: Is consistent with concept of unintentional occurrence or transboundary movement from the territory of a Party.

[leads to or presents a significant likelihood of] [may lead to:] "leads to" requires that the transboundary movement will occur. "Presents a significant likelihood" is more stringent than "may lead to" .

[and products thereof]: See Article 4(1).

^{31/} This paragraph could be considered under Article 15 (Risk Management).

[is likely to] [may]: "is likely to" may impose a more precise condition than "may", and may call for a higher degree of certainty.

[significant]: This is a value term and may require definition.

[taking also into account human health]: See Article 1.

[3. Parties shall make available to the Biosafety Clearing-House [, through the Secretariat, as appropriate,] the relevant details of the point of contact, for the purposes of receiving notifications under this Article, no later than the date of entry into force of the Protocol for that Party.]

[, through the Secretariat, as appropriate,] : Usage in other Articles is "and the Secretariat".

4. Any notification arising from paragraph 2 above should include:

[(a) Available relevant information on the estimated quantities and relevant characteristics/traits of the LMOs [and products thereof];]

[and products thereof]: See Article 4(1)

[(b) A point of contact for further information;]

[(c) Information on the circumstances of the release, including the estimated date, as well as the use of the LMO in the originating Party;]

[(d) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity [taking also into account human health], as well as [available information about possible risk-management measures] [an assessment of the risks and methods for monitoring, control and mitigation or emergency measures, as appropriate];]

[taking also into account human health]: See Article 1.

[available information about possible risk-management measures]: Is set as an alternative to;

[an assessment of the risks and methods for monitoring, control and mitigation or emergency measures, as appropriate]

(e) Any other relevant information.

[5. Parties shall protect [, on the basis of national legislation,] the confidentiality of any information identified as confidential and provided under this Article.] ^{32/}

[, on the basis of national legislation,]: See Article 21. This provision for confidentiality in a notification under unintentional transboundary movement and emergency measures should be considered for Article 21.

[6. [Parties concerned] [Each Party, under whose jurisdiction the release of the LMO [and products thereof] referred to in paragraph 2 above originates,] shall immediately consult with [each other] [the affected Parties] to determine appropriate responses and initiate necessary action, including emergency measures, in order to minimise any negative impacts on the conservation and sustainable use of biological diversity [, taking also into account human health] [and socio-economic well being].]

[Parties concerned] [Each Party, under whose jurisdiction the release of the LMOabove originates,]: " Each Party" relates directly to Article 17(2)

[products thereof]: :See Article 4(1).

[each other] [the affected Parties]: This choice depends upon the choice between “Parties concerned” and “Each Party”.

[, taking also into account human health]: See Article 1.

[and socio-economic well being].] The term “socio-economic considerations” is used in several Articles. See Article 1.

^{32/} This paragraph may be deleted pending the outcome of Article 21 (Confidential information).

[ARTICLE 18 - HANDLING, TRANSPORT, PACKAGING [AND LABELLING] ^{33/}

1. Each Party [of export] shall [take] [promote] measures [as appropriate] to [ensure] [require] [provide] that LMOs [and products thereof] that are subject to intentional transboundary movement [within the scope of the Protocol] [under AIA] are:

[of export]: Assigns responsibility to the party of export.

[take] [promote]: "Take" places obligation on the government, "promote" places the onus on the exporter.

[as appropriate]:

[ensure] [require] [provide]: Use of the term "ensure" requires enforcement. Use of the term "require" requires legislation.

[and products thereof]: See Article 4(1).

[within the scope of the Protocol] Broader scope than those LMO's subject to AIA.

[under AIA] The provision would only apply to those LMO's under the AIA procedures.

(a) [Clearly identified [labelled],] [as appropriate,] handled, packaged and transported under conditions of safety [[no less stringent than those applied within the territory of the Party of export,] from the point of export in the Party of export [to the point of import into the Party of import]], [taking into consideration relevant international rules and standards] [in accordance with standards under this Protocol] in order to avoid adverse effects on the conservation and sustainable use of biodiversity[, taking also into account risks to human health];

[Clearly identified [labelled],] [as appropriate,]: The distinction between these is uncertain, either could necessitate decisions on appropriate content "as appropriate" is a value term.

[[no less stringent than those applied within the territory of the Party of export,]:

[to the point of import into the Party of import]]: Limits the application of the provision to transport between the Parties, it would not apply within the Party of import.,

[taking into consideration relevant international rules and standards]: See below.

[in accordance with standards under this Protocol]: The latter would require the development of standards under the protocol. The former could relate to existing standards under, for example :

UN/ECE Convention on Civil Liability for Damage Caused During Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels; or,

^{33/} Some delegations wish this entire article to be deleted.

IMO Draft International Convention on Liability and Compensation on Damage in Connection with the Carriage of Noxious and Hazard Substances by sea; or,
ECOSOC Recommendations on the Transport of Dangerous goods.

[, taking also into account risks to human health: See Article 1.

[(b) Clearly identified in accompanying documentation [[or] [and] labelling] [specifying] [containing: a statement as to] the presence, identity and relevant traits/characteristics; the requirements for safe handling, storage, transport and use; the name and address of the importer and exporter [or] [and] [the contact point] for further information; and a declaration that the movement is in conformity with the requirements of this Protocol, except that the Party of import may indicate that these requirements will not apply as to imports to it.]

[or][and]

[... labelling]: See above

[specifying] [containing: a statement as to]: The difference in these choices is unclear.

[or][and]:

[contact point]: This could vary depending on the LMO.

[2. The Conference of the Parties shall [consider the need for, and the modalities of, further developing] [develop] standards with regard to [identification,] handling, packaging and transport practices [under the Protocol] [after] [taking into consideration the results of] consultations with other international organizations.]]

[consider the need for....developing}

[develop] This would require the Conference or Meeting of the Parties to establish a process for developing standards.

[identification]

[under the protocol]

[after]

[taking into consideration the results of]

ARTICLE 19 - COMPETENT NATIONAL AUTHORITY/NATIONAL FOCAL POINT

1. Each Party shall designate one [or more] national focal point[s] to be responsible for liaison with the Secretariat on behalf of that Party, and one or more competent national authorities that shall be responsible for performing the administrative functions required by this Protocol and be authorised to act on its behalf with respect to those functions. A Party may designate a single agency to fulfil both the functions of focal point and competent national authority.

[or more] focal point[s]:

2. Each Party shall, no later than the date of entry into force of this Protocol for that Party, notify the name(s) and address(es) of its focal point[(s)] and competent national authority or authorities to the Secretariat. Where it designates more than one competent national authority, the Party shall convey to the Secretariat, with its notification, relevant information on the respective responsibilities of its competent national authorities to inform at a minimum, if applicable, a notifier which competent authority is responsible for which type of LMO. Each Party shall immediately notify the Secretariat of any changes in the designation of its national focal point[(s)] or in the name(s) and address(es) or responsibilities of its competent national authority or authorities.

[or more] focal point[s]:

3. The Secretariat shall forthwith inform the Parties of notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

ARTICLE 20 - INFORMATION SHARING/BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established ^{34/} [as part of the clearing-house mechanism under Article 18 , paragraph 3, of the Convention], in order to:

[as part of the clearing house mechanism...]: Provides the authority for establishing the Biosafety Clearing House. This phrase also defines that the Biosafety Clearing House is a component of the Clearing House Mechanism.

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs; and

(b) Assist Parties to implement the Protocol,

^{34/} Note: The extraordinary meeting of the Conference of the Parties that will adopt this Protocol should consider putting in place arrangements to ensure that the Biosafety Clearing-House is operational when the Protocol comes into force.

taking into account the special needs of developing countries, countries with economies in transition and small island developing States.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 and shall provide access to information made available by the Parties relevant to the implementation of the Protocol, as well as access, where possible, to existing international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House information required to be made available to it under this Protocol and:

(a) National laws, guidelines and/or regulations adopted for the implementation of the Protocol, including information required by the Parties for the AIA procedures;

(b) Any bilateral, regional and multilateral agreements [as well as unilateral declarations on the exemptions and/or the simplification of the AIA procedures];

[as well as ...AIA procedures]: Article 5 on the application of AIA and Article 11 on simplified procedure require that such exemptions and applications of a/the simplified procedures must be notified in advance to the Biosafety Clearing House..

(c) [Summaries of its risk assessments or environmental reviews of LMOs generated by its regulatory process [, and carried out in accordance with Article 14, including, when appropriate, relevant information regarding products of LMOs, not defined as LMOs, that contain genetic material resulting from the modification];]

[Summaries of its risk assessments..... regulatory process...]: As a stand alone item this would require Parties to provide to the Biosafety Clearing House information on risk assessments carried out under national legislation. When coupled with Article 14, this provision would add the requirement to provide information on assessments carried out under the protocol.

[....relevant information regarding products of LMOs not defined as LMOs... the modification]:

(d) Its final decisions regarding the importation or release of LMOs [new to its environment], [including the time taken for decisions to be made regarding the importation of LMOs];

[new to its environment]: Provides for information on both transboundary movement decisions and also for domestic decisions. Article 8(3) requires that the decision on importation is made available to the Biosafety Clearing House.

[including the time taken.....of LMOs]: This appears to relate to the period of time between receipt of notification and final decision.

(e) [Reports required under Article 35, including such reports on implementation of the AIA procedures.]

Reports to the Meeting of the Parties, as with reports to the Conference of the Parties, are commonly placed on the Secretariat web site, or in this case the Biosafety Clearing House.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Parties to this Protocol at their first meeting, and kept under review thereafter.

[ARTICLE 21 - CONFIDENTIAL INFORMATION]

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

2. The Party of import shall consult with the notifier if it believes that information identified by the notifier as confidential does not qualify for such treatment and shall inform the notifier of its decision providing reasons on request and an opportunity for consultation and for an internal review of the decision prior to disclosure.

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

[subject to national legislation]:

[Each Party.....information]: Establishes a requirement for Parties to have a process and legal framework to ensure confidentiality of information

[and shall protect....domestic LMO]:. Non discrimination.

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

5. If a notifier withdraws or has withdrawn a notification, a Party must respect the confidentiality of all information identified as confidential [, including information on which the competent authority and notifier disagree as to its confidentiality].

[including information on which....confidentiality]: This has the effect in most cases of the notifier determining confidentiality.

6. Without prejudice to paragraph 5 of this Article, the following information [should not generally] [in no case may] be considered confidential:

[should not generally]: Implies that there could be extraordinary circumstances warranting the release of confidential information.

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

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

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

[taking also into account human health]: See Article 1

ARTICLE 22 - CAPACITY-BUILDING

1. The Parties shall co-operate [in] [to promote] the development and/or strengthening of human resources and institutional capacities [in biosafety, including biotechnology to the extent that it relates to biosafety] ^{35/} [for the purpose of the effective implementation of this Protocol] in developing country Parties, in particular the least developed and small island developing States amongst them, and in Parties with economies in transition, including through existing international, regional, subregional, national institutions and organizations.

[in]: Requires Parties to co-operate and be involved in capacity building

[to promote]: Does not require active participation of Parties

[in biosafety, including..... biosafety]: This phrase may have the effect of broadening the elements for inclusion in biosafety capacity building.

^{35/} If this option is retained, biosafety would be defined by the legal drafting group (Contact Group 2).

[for the purpose of implementing...]: Identifies specific purpose of capacity building under the protocol and could be seen as an alternative to the preceding phrase.

[2. The needs of developing country Parties, in particular the least developed and small island developing States amongst them, [and Parties with economies in transition] [for financial resources, [and technical and scientific assistance,] and access to and transfer of technology and know-how] shall be taken fully into account in capacity-building for biosafety [, in accordance with the relevant provisions of the Convention], including technical and scientific co-operation and assistance in training and exchange of experts. [The needs of Parties with economies in transition shall likewise be taken fully into consideration in capacity-building for biosafety.]

[and Parties with economies in transition]: Provides consistency with Article 22(1).

[for financial resources]: Relates also to Article 29.

[and technical and scientific assistance]: Identifies specific aspects of capacity building

[access to and transfer of technology and know how]: In respect of biosafety.

[in accordance with the relevant provisions of the Convention]: The primary Articles of the Convention relating to this would be Articles 16 and 29.

[The needs of for biosafety]: Provides for the relationship to economies in transition.

3. Co-operation in capacity-building shall aim to enhance the technological and institutional capacities of developing country Parties, and Parties with economies in transition, in biosafety, [including] through training in science related to safety in the proper and safe [development and] management of biotechnology, and in the use of risk-assessment and risk-management techniques for biosafety.]

[including]: Implies priorities, but does not limit the provision.

[development and]: This relates also to Article 16 of the Convention.

[4. The needs of developing country Parties, in particular the least developed and small island developing States among them, and Parties with economies in transition in capacity-building for biosafety, including technical and scientific expertise and training related to the safe [development and] management of biotechnology and to the use of risk assessment and risk management techniques, shall be taken fully into account.]

This paragraph is an alternative to paragraph 2.

[development and]: See above.

[5. Parties shall endeavour to facilitate private sector involvement in capacity-building activities under this Protocol.]

ARTICLE 23 - PUBLIC AWARENESS AND PARTICIPATION

1. Parties shall promote and facilitate, as appropriate, public awareness and education on the safety in the transfer, handling and use of LMOs [and products thereof] in relation to the conservation and sustainable use of biological diversity [, taking into account human health]. In doing so, Parties shall co-operate, as appropriate, with other States and international organizations.

[and products thereof]: See Article 4 paragraph 1.

[taking into account human health]: See Article 1.

2. Parties [shall] [are encouraged to] [, in accordance with their national laws, regulations and administrative measures] [and where appropriate,] provide the public [with the opportunity for involvement in the decision-making process concerning the [release] [safe transfer, handling and use] of LMOs [and products thereof] and] with [information regarding] [the results of] the decision-making process [concerning the [release] [safe transfer, handling and use] of LMOs [and products thereof]] [, whilst respecting confidential information] [subject to Article 21].

[shall]/[are encouraged to]: “Shall” makes the provision binding, “are encouraged to” is voluntary.

[in accordance with their national laws regulations and administrative measures]:

[and where appropriate]:

[with the opportunity.....]and]: “shall” if retained with this phrase would require public involvement in the decision making process under the protocol.

[release]/[safe transfer, handling and use] : See Article 1.

[products thereof]: See Article 4 paragraph 1.

[information regarding]/[the results of]: Article 8 paragraph 3 may require the decision and the basis for that decision to be placed on the Biosafety Clearing house.

[whilst respecting confidential information]/[subject to Article 21]: Subject to Article 21 is more explicit.

3. Each Party shall endeavour to inform its public about the mode of public accessibility to the Biosafety Clearing-House.

[ARTICLE 24 - NON-PARTIES

[1. No Party shall export or import LMOs or products thereof to or from non-Parties.]

This provision prohibits trade with non-Parties.

[1. Parties shall [conduct their trade in LMOs with non-Parties on a basis consistent with the objectives] [not be restricted from trade in LMOs with non-Parties provided that such trade is carried out on the basis of the substantive provisions] of the Protocol. [Such trade could be the subject of bilateral, regional or multilateral agreements or arrangements with non-Parties [within Article 13], which should be made available through the Secretariat [and through the Biosafety Clearing-House].]]

[conduct their trade...]/[not be restricted.....]: Choice of the general(objectives) or the specific more explicit (provisions) obligation.

[Such trade could be.....Clearing House.]: Permits trade with non -parties through bilateral, regional or other agreements or arrangements (See also Article 13 on agreements and arrangements).

[within Article 13]: Within the provisions on multilateral bilateral or other arrangements.

[and through the Biosafety Clearing House]: Article 13 paragraph 2, if maintained, requires that details of all such arrangements, agreements to be available through the Biosafety Clearing House.

2. The Parties shall encourage non-Parties to adhere to this Protocol. The Parties shall encourage non-Parties to contribute appropriate information to the Biosafety Clearing-House on LMOs released in, and entering into trade to and from, their territory.]

[ARTICLE 25 - NON-DISCRIMINATION]

1. Parties shall ensure that measures to implement this Protocol, [including] [in particular in relation to] risk-assessment procedures, do not discriminate between or among foreign LMOs and LMOs of domestic origin.

[including]/[in particular in relation to]:

2. Parties shall also ensure that measures taken to implement this Protocol do not create unnecessary obstacles to, and/or constitute means of unjustified discrimination or disguised restrictions on, international trade.]

[ARTICLE 26 - ILLEGAL TRAFFIC ^{36/}

1. Each Party shall adopt appropriate domestic measures aimed at preventing and penalizing illegal traffic of LMOs [and products thereof].

[and products thereof]: See Article 4 paragraph 1.

2. [Where illegal traffic has been established the affected Party may request the Party of origin to dispose of the LMOs in question by repatriation or destruction, as appropriate, and at its own cost/expense.]

3. Each Party shall make available [appropriate] information concerning cases of illegal traffic [within that Party] to the Biosafety Clearing-House.]

[appropriate]: Requires judgement as to the relevance of the information.

[within that Party]: Limits the information to illegal traffic in a specific Party.

[ARTICLE 27 - SOCIO-ECONOMIC CONSIDERATIONS ^{37/}

[1. The Parties shall ensure that the socio-economic impacts of the introduction, transfer, handling or use of living modified organisms [and products thereof] on or within the [potential] Party of import and its environment, and strategies and measures to prevent or mitigate those impacts are appropriately considered during the [assessment and] management of risks, taking 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].]

[and products thereof]: See Article 4 paragraph 1.

[potential]: Refers to a future import.

^{36/} Contact Group 2 provided the following working definition: Illegal traffic means intentional transboundary movement of LMOs [or products thereof] carried out in contravention of the procedures [specified in Article [...]] of this Protocol.]. This may need to be revisited with a view to specifying the core elements of what would constitute illegal traffic and to revisit the phrase "intentional transboundary movement" after the definition of transboundary movement has been developed. This definition has also been transferred for consideration under Article 3 (Use of terms).

^{37/} One suggestion is to include reference to socio-economic considerations/social and economic values of biological diversity in the preamble to the Protocol.]

[assessment and]: Could include socio-economic impacts in the risk assessment.

[the long observation period....manifest]: This could relate to the times specified in Articles 6, 7 and 8.

[such adverse consequences.....farm products]: Specifies examples of particular impacts to be included in the socio-economic considerations.

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

[3. A Party that intends to produce, using a living modified organism, a hitherto imported commodity, shall notify the affected Party or the Party likely to be affected sufficiently in advance to enable the affected Party to undertake appropriate measures for conservation of potentially affected biological diversity. The Party substituting such import shall provide financial and technical assistance to the affected Party for undertaking these measures if the affected Party is a developing country.]]

[ARTICLE 28 - LIABILITY AND REDRESS

[1. The Parties shall [at their first meeting] [as soon as practicable] [on the basis of studies to be carried out] [without prejudice to their existing domestic legal systems] [examine [whether and] how] [adopt appropriate measures] [to establish procedures for developing appropriate rules and procedures] [to establish and develop rules and procedures] [in the field of [strict] liability and redress] [including restoration and compensation for damages resulting from transboundary movements of LMOs to biological diversity].]

[2. If harm, including transboundary harm, that proves detrimental to the environment, biological diversity, human or animal health or socio-economic welfare, arises as a consequence of living modified organisms or activities or products involving such organisms, the [operator in respect of production, handling, export and supply of those living modified organisms] [exporter] [Party of origin] shall be [strictly] liable for the harm, and the harm must be compensated. [If the [operator][exporter] is unable to [compensate] [discharge its obligations to redress,] the Party of origin shall be liable to [compensate to] the extent of the obligations not fulfilled by the [operator] [exporter].]

[operator.....] [exporter][Party of origin]: Identification of who is strictly liable

[strictly]:

[operator][exporter]:

3. If harm, including transboundary harm, occurs that proves detrimental to the environment, biological diversity, human or animal health or socio-economic welfare, the [State of origin] [operator] [exporter] shall meet the costs of restoring as far as possible the conditions that existed prior to the occurrence of the harm. Parties shall establish an [Emergency Fund] [Compensation Fund] [insurance scheme] [financial security], to provide [redress] [compensation] as necessary in the event of harm arising from the transboundary movement of living modified organisms.
[State of origin][operator][exporter]

[Emergency fund][Compensation Fund][insurance scheme][financial security]

[redress] [compensation]

4. Civil actions for compensation resulting from harm caused as a consequence of the transboundary movement, handling and use of LMOs [and products thereof] may only be brought within a Party at the courts of the place: (a) where the harmful event occurred; (b) where the damage was suffered; (c) in the Party where the defendant has his habitual residence.

[and products thereof]: See Article 4(1).

5. Parties shall, at their first meeting, initiate a process to further elaborate and adopt the details of the rules of liability and [redress] [compensation] [including] [and] the procedural rules [including the establishment of the [Emergency] [Compensation] Fund].

[redress][compensation]:

[including][and]:

[including.....Fund]:

[6. Each [Party] [or] [Party of origin] shall be liable for [[appreciable and significant] harm to the biological diversity of another Party resulting from the transboundary movement of LMOs under this Protocol] [harm, including transboundary harm, that proves detrimental to the environment, biological diversity, human or animal health or socio-economic welfare, arising as a consequence of the transboundary movement of living modified organisms] [which] [if such harm] occurs as a consequence of an action or omission that can be attributed to that [Party] [State] [under the provisions established by this Protocol]; [as a consequence [of] a conduct that constitutes a breach of an international obligation of the State under the terms of this Protocol; if the [operator] [exporter] is unable to discharge its liability, the State or States of origin shall be liable to the extent of the breach of due diligence obligation of the State of origin].

[Party] [or] [Party of origin]:

[[appreciable and significant]:

[harm to the.... Protocol]
 [harm, including.....modified organisms]
 [which]
 [if such harm]
 [Party][State]
 [under the provisions ...]
 [as a consequenceState of origin]
 [operator][exporter]

7. Each Party shall ensure that recourse is available in accordance with their legal systems for prompt and adequate compensation or other relief in respect of damage caused by the transboundary movement of living modified organisms by natural or juridical persons under their jurisdiction.] ^{38/}

ARTICLE 29 - FINANCIAL MECHANISM AND RESOURCES

[1. In considering financial resources for the implementation of this Protocol, Parties shall take into account the provisions of Article 20 of the Convention.]

General statement that would apply irrespective of its inclusion if paragraph 2 is maintained.

2. The financial mechanism established in Article 21 of the Convention shall be the financial mechanism for this Protocol.

[3. The financial mechanism referred to in paragraph 2 above, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island States amongst them, for capacity-building and for the promotion and safe use of biotechnology and, upon request, for the capacity to develop and implement programmes, particularly in the areas of risk assessment and risk management.]

Related to advice to the Financial Mechanism under a COP/MOP decision. See also Article 22 paragraph 2.

4. In the context of paragraph 1 above, Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island States amongst them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.

^{38/} Paragraphs 1, 6 and 7 may be read together.

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

ARTICLE 30 - CONFERENCE OF THE PARTIES

(Provisionally adopted)

1. The Conference of the Parties to the Convention shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and co-operation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Articles 35 of this protocol and, as well, reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are determined necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialised agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, which is qualified in matters covered by this Protocol and which has informed the Secretariat of its wish to be represented at a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

ARTICLE 31 - SUBSIDIARY BODIES AND MECHANISMS

(Provisionally adopted)

1. Any subsidiary body established by or under the Convention may, upon a decision by the meeting of the Parties, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the

Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by the Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the Bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

ARTICLE 32 SECRETARIAT

(Provisionally adopted)

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

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.

3. To the extent that these are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Meeting of the Parties to this Protocol shall decide at its first meeting the necessary budgetary arrangements to this end.

ARTICLE 33 - RELATIONSHIP WITH THE CONVENTION

(Provisionally adopted)

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.^{39/}

[ARTICLE 34 - RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS]

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

[except where the exercise.... biological diversity]: establishes a condition for primacy for the protocol.

^{39/} It was noted that it may be necessary to revisit this provision in the light of the outcome of the discussions on substantive articles which may have a bearing on issues such as settlement of disputes and adoption and amendment of annexes.

ARTICLE 35 - MONITORING AND REPORTING

(Provisionally adopted)

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the meeting of the Parties to this Protocol, report to the meeting of the Parties to this Protocol on measures taken to implement this Protocol.

[ARTICLE 36 COMPLIANCE]

The Parties shall at their first meeting consider and approve procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. Such procedures and mechanisms shall be separate from and without prejudice to the dispute-settlement procedure established under Article 27 of the Convention. They shall include provisions to offer advice or assistance, where appropriate.]

ARTICLE 37 - ASSESSMENT AND REVIEW OF THIS PROTOCOL

The Meeting of the Parties shall undertake, [five] years after the entry into force of this Protocol [and at least every five years thereafter], an evaluation of the effectiveness of this Protocol, including an assessment of the procedures and annexes.

[five]:

[and at least every 5 years thereafter]:

ARTICLE 38 SIGNATURE

(Provisionally adopted)

This proposal shall be open for signature at [] by all States and any regional economic integration organization from [] until [], and at the United Nations Headquarters in New York from [] to [].

ARTICLE 39 - ENTRY INTO FORCE

(Provisionally adopted)

- 1. This Protocol shall enter into force on the ninetieth day after the date of the deposit of the [] instrument of ratification, acceptance, approval or accession.**
- 2. This Protocol shall enter into force for a Party that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that Party deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that Party, whichever shall be the later.**
- 3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.**

[ARTICLE 40 - RESERVATIONS

No reservations may be made to this Protocol.]

ARTICLE 41 - WITHDRAWAL

(Provisionally adopted)

- 1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notifications to the Depository.**
- 2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depository, or on such later date as may be specified in the notification of the withdrawal.**

ARTICLE 42 - AUTHENTIC TEXTS

(Provisionally adopted)

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

The Annexes have not been annotated.

Annex I - INFORMATION REQUIRED IN NOTIFICATION FOR ADVANCE INFORMED AGREEMENT

- (a) Name and identity [and domestic classification of biosafety level, if any, in the exporting country] of the LMO(s) [or products thereof].**
- (b) Name, address and contact details of the [exporter] [applicant].**
- (c) Name, address and contact details of the [importer] [receiving company/institution/individual].**
- (d) Intended date[(s)] of the transboundary movement, if known.**
- (e) Taxonomic status, common name, point of collection or acquisition and characteristics of recipient or parental organism(s) related to biosafety.**
- (f) Centre(s) of origin/genetic diversity, if known, of the recipient and/or parental organism(s). [A description of the habitats where the organism may persist or proliferate.]**
- (g) Taxonomic status, common name, point of collection or acquisition and characteristics of donor organism(s) related to biosafety.**
- (h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the LMO [or products thereof].**
- (i) Intended use of the LMO [or products thereof].**
- (j) Quantity or volume of LMOs [or products thereof] to be transferred.**
- (k) [A [known and available] risk assessment report carried out in accordance with Annex II of the Protocol].**
- (l) Suggested methods for [safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures] [where appropriate].**
- (m) Regulatory status of the LMO [or product thereof] in question within the exporting state (e.g. whether it is prohibited in the state of export, whether there are other restrictions, or whether it has been approved for general release). If the LMO [or product thereof] is banned in the state of export, the reason(s) for such a ban.**
- (n) [The result of any notification to other Governments by the [exporter] [applicant] regarding the LMO [or product thereof] and the purpose thereof.]**
- (o) [Declaration] that the above-mentioned information is factually correct.**

Annex II^{40/} - RISK ASSESSMENT

Objective

The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects [of the transboundary movement] [, handling and use] of LMOs [or products thereof] on the conservation and sustainable use of biological diversity in the [potential] receiving environment [, taking also into account the risk to human health] [and socio-economic considerations].

Use of risk assessment

The results of risk assessment are used by, inter alia, competent authorities with respect to informed decision making on transboundary movement [, handling and use] of LMOs [or products thereof].

General principles

[The guiding principle of risk assessment is the precautionary approach]. [Based on the precautionary approach,] risk assessment should be carried out in a scientifically sound and transparent manner.

Lack of scientific knowledge or consensus may contribute to uncertainty regarding the level of risk. [This should not be interpreted as indicating [a risk,] an absence of risk, or an acceptable risk].

Risks associated with the transboundary movement [,handling and use] of the LMO [or products thereof] should be considered in the context of the risks posed by using the non-modified recipients or parental organisms in the [potential] receiving environment.

^{40/} Further discussion will take place in Contact Group 1 on the technical details pertaining to the contents in Annex II based on document UNEP/CBD/BSWG/5/Inf.1 and UNEP/CBD/BSWG/5/2. The result of the continuing technical discussion in Contact Group 1 at the fifth meeting of the open-ended ad hoc working group on biosafety will be contained in the report of the Co-chairs to the Plenary to be reflected in the final report of the open-ended working group at its fifth meeting.

Further discussion will take place in Contact Group 1 with consideration to amendment of the text by replacing all instances where should is used, by the term shall with a view to bringing the text of Annex II in line with the text of the relevant articles. In view of the fact that this aspect still has to be resolved it will be carried forward to the sixth meeting of the open-ended ad hoc working group on biosafety. This will also apply to the term are used in the first line of paragraph 2, page 1 (Use of risk assessment).

Risk assessment should be carried out on a case-by-case basis. This means that the required information may vary from case to case, depending on the LMOs concerned, their [intended] use and the [potential] receiving environment.

Methodology

To fulfil its objective, risk assessment entails, as appropriate, the following steps:

- 1. an identification of any characteristics associated with the [novel [base sequences of the genetic material] [compositions] [combinations]] of the LMO [or products thereof] that may have adverse effects on biological diversity in the [potential] receiving environment[, taking also into account the risk to human health][and socio-economic considerations];**
- 2. an evaluation of the likelihood of these adverse effects being realised, taking into account the level and kind of exposure of the receiving environment to the LMO [or products thereof];**
- 3. an evaluation of the consequences should these adverse effects be realised;**
- 4. an estimation of the overall risk posed by the LMO [or products thereof] based on the evaluation of the likelihood and consequences of the identified adverse effects; and**
- 5. a recommendation as to whether or not the risks are acceptable or manageable [, including, where necessary, identification of strategies to manage these risks and minimise the likelihood of adverse consequences].**

[Risk assessment can take into account expert scientific and technical advice [and guidelines developed by relevant international organizations]].

Risk assessment may require more specific information about individual topics, which may be identified and requested during the assessment process, while other topics may not be relevant in some instances.

Depending on the case, risk assessment therefore takes into account the relevant technical and scientific details regarding:

[Characteristics of recipient or parental organism(s)]

The biological, physiological, genetic and ecological characteristics of the recipient/parental organism [related to biosafety] [necessary to conduct the risk assessment].

[Characteristics of donor organism(s)]

The characteristics of the donor organism(s) [necessary to conduct the risk assessment] [including, in particular, pathogenicity and toxicity].

[Characteristics of the vector]

The characteristics of the vector, including its sources and host ranges.

[Characteristics of the inserts]

Characteristics of the nucleic acid or modification introduced.

[Characteristics of the LMO [or products thereof]]

The known differences between the LMO [or products thereof] and its recipient/parental organism [or products thereof] in any biological, physiological, genetic or ecological characteristic.

[Information relating to intended use]

Information relating to the [intended] use of the LMO [or products thereof], including new or changed use compared to the unmodified recipient or parental organism.

[Receiving environment]

Information on the location, geographical, climatic and ecological characteristics of the [potential] receiving environment.

[Resuscitated organism]

[Characteristics of resuscitated organism(s) and gene(s) and fossil DNA sequences.]

[Safety considerations for human and animal health]

[Information on the impact of the LMO on human and animal health]

[Socio -economic considerations]

[Socio-economic considerations] [Information on the potential impacts on the socio-economical patterns of the importing country, especially on traditional practices and national programs on sustainable agriculture.]

Attachment I

Sub-Working Group 1

Working Paper 8

19 August 1998

ARTICLE 8 - NOTIFICATION OF TRANSIT

Option Zero

No provision on notification of transit is necessary.

Option 1

1. Parties may require notification, in writing, through their focal point of the intent to transit a living modified organism [or products thereof] through their territory. [The Party of export shall assume responsibility for any cases of accidental release in those States]. Where such notification is required, Parties shall provide information to the Clearing-house on:

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

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

[2. The State of transit [shall] [may] [promptly] acknowledge the receipt of the notification to the notifier. It [shall] [may] subsequently respond to the notifier, in writing, within [x] [30] days:

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

(b) Denying permission for the movement; or

(c) Requesting further information and/or an extended period of time to respond. J

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

4. The handling and transport requirements including documentation for living modified organisms referred to in Article 17 shall be followed in all transit movements.

Attachment II

CONVENTION ON
BIOLOGICAL
DIVERSITY

UNEP/CBD/BSWG/5/SWG.I/CRP.3
21 August 1998
ORIGINAL: ENGLISH

OPEN~ENDED AD HOC WORKING
GROUP ON BIOSAFETY
Fifth meeting
Montreal, 17-28 August 1998
SUB-WORKING GROUP I

ARTICLE 6 (NEW ARTICLE 8) - DECISION PROCEDURE FOR AIA

Proposal submitted to Sub-Working Group I by the Co-Chairs

1. Decisions shall be based on risk assessment[, made on the basis of scientific principles,] [of the adverse effect on the conservation and sustainable use of biological diversity], [taking also into account risks to human health] [, the precautionary principle] [and social, economic and cultural criteria].
- [2. The Party of import shall within the period of time referred to in Article 8 inform the notifier that:
 - (a) The intentional transboundary movement may proceed [after x days] without a written consent, provided that the Party of import has not, [with justification] [giving reasons], requested additional information, imposed conditions, or prohibited the transboundary movement; or
 - (b) The intentional transboundary movement may proceed only after the Party of import has given its written consent.]
3. Within [a reasonable period of time] [90 days] from the acknowledgment of receipt of notification, the Party of import shall communicate its decision, in writing, to the notifier [and the clearing-house]:

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(a) Approving the import, with or without condition, including how the decision applies to subsequent imports of the same LMO; 1/

(b) Prohibiting the import; [or]

(c) Requesting additional relevant information [in accordance with Annexes I and II]. [When calculating the time for the Party of import to respond, the number of days for which the Party of import is waiting for additional relevant information shall not be taken into account]; [or]

[(d) Informing the notifier that the period specified in this paragraph is extended by a defined period no longer than 90 days] [as much time as is necessary to assess the information it has received from the [notifier] so as to enable it to reach an informed decision.]]

[4. Decisions under paragraph 2 shall include justification, except in the case of unconditional approval.]

[5. Lack of [sufficient information] or lack of full scientific certainty or of scientific consensus to determine the potential adverse effects of an LMO shall not prevent the Party of import from prohibiting the import of the LMO in question.]

[6. The Parties shall cooperate with a view to deciding, as soon as possible, to what extent in relation to the procedures, and in which cases, to be specified in an annex, a transboundary movement cannot proceed without an explicit consent.] 2/

[7. If the Party of import does not respond within the period specified under paragraph X [and it is not the case in which a movement shall not proceed without an explicit consent], [the exporter [may] [shall not] [should not] proceed with the transboundary movement] [the Party of export [import] shall not allow the exporter [importer] to commence with the proposed transfer until the AIA of the Party of import has been received] the Party of import shall be deemed to have [approved] [prohibited] import of the LMO concerned.]

OR

1/ The concept of subsequent imports should be retained since the deletion of Article 10 was based upon its retention.

2/ This paragraph will be given to Contact Group 2 for legal advice.

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[7. If the Party of import fails to communicate its final decision within IX] days of the receipt of the notification, the transboundary movement is no longer governed by the terms of this Protocol and the Party of export shall have no further obligations under this Protocol with respect to that transboundary movement.] 2/

[8. The Conference of the Parties shall at its first meeting decide upon appropriate procedures and mechanisms to facilitate the reaching of a decision by a Party of import which has not responded within the time period specified in paragraph 3 above.] 2/