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COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS

(Twentieth session,
Geneva, 7-16 December l998,
agenda item 5 (b))

PROGRAMME OF WORK

Programme of work for the 1999/2000 biennium and related proposals

Transport of Living Modified Organisms (LMO)

Note by the secretariat

Addendum 1

1. Reference is made to the proposal by the Expert from Germany in ST/SG/AC.10/1998/29.

2. The secretariat reproduces below the text of the draft Protocol on Biosafety, as transmitted by the secretariat of the Convention on Biological Diversity following the fifth session of the Open-ended Ad Hoc Working Group on Biosafety (Montréal, 17-28 August 1998).

3. This text should be considered again by the Open-ended Ad Hoc Working Group on Biosafety on its 6th and final meeting in Columbia in February 1999, which should be followed by an extraordinary meeting of the conference of the Parties to the Convention on Biological Diversity for adoption of the Protocol.

PREAMBLE

(Not considered by the Working Group at its fifth meeting)

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
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

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 socioeconomic imperatives]].

ARTICLE 1 bis - GENERAL OBLIGATIONS
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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

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

[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/

[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].]

[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 freedoms 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].

[ARTICLE 2 - USE OF TERMS
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

[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.

1/ This paragraph should be referred for consideration under Article 6, paragraph 9.

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.]

(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].

Export

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

Import

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

Exporter

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

Importer

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

Party of export

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

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.

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.]

ARTICLE 3 A - THE SCOPE OF THE PROTOCOL 4/
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

[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].]

[2. This Protocol shall not apply to:

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

[(b) Requirements for transport operations;]

[(c) Transit of LMOs and transboundary movements destined for contained use, except as regards Articles 1 bis (General obligations) and 15 (Unintentional transboundary movements).]] 6/

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

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 3 B, 17 and others.

ARTICLE 3 B - THE APPLICATION OF THE AIA PROCEDURE
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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/

[[(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];]

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

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

shall be subject to [an] AIA.

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

[(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

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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 4, 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.)

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.

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/

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

[(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];]

[(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 6, para. 3 (a).]]

ARTICLE 4 - NOTIFICATION
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

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 3 B. The notification shall contain at a minimum the information specified in Annex I. 15/

11/ This provision attempts to reflect a concept present in Article 9.

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.

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.

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 1 bis.

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

ARTICLE 5 - ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION [FOR AIA]
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

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

2. The acknowledgment shall state:

   a. The date of receipt of the notification;

   b. Whether the notification, prima facie, contains the information specified in Article 4; [and]

   [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 6 of this Protocol.] 16/

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

ARTICLE 6 - DECISION PROCEDURE FOR AIA
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

1. Decisions taken by the Party of import shall be [based on risk assessment] [in accordance with Article 12] [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/

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

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

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16/ The concept considered in this paragraph can be covered in Article 3 B.

17/ Paragraph 1 should be revisited in light of the outcome of the discussions on Article 12.

(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] [ninety] [one hundred and eighty] [days] from the acknowledgment of receipt of notification, the Party of import shall communicate its decision, in writing, to the notifier [and the Biosafety Clearing-House]:

(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]

[(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]

[(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.]]

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

[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.]

[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.]

[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 5,] 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.]

[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.]

ARTICLE 7 - REVIEW OF DECISIONS [UNDER AIA]
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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 notifier who has previously notified movements, [Parties concerned], and the Biosafety Clearing-House and give full details of the reasons for its decision.

[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 6 where the [[Party] [State] of export] [notifier] considers that:

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

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

[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.]

[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:

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

(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;

(d) It is a condition of first import of the LMO [or products thereof] under Article 6; or

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

ARTICLE 8 - NOTIFICATION OF TRANSIT
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

Because the elements addressed in this article are covered in the following: Article 4, 18/ Article 5, 19/ Article 6, 20/ Article 17, 21/ and Article 27, 22/ this article should be deleted.

[ARTICLE 9 - SIMPLIFIED PROCEDURE
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

1. [Without prejudice to paragraph 5 of Article 6,] 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:

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].

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 17 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].

[(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/

ARTICLE 10 - SUBSEQUENT IMPORTS
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

The contents of Article 10 are amply covered in the revised Article 6, para. 3 (a), as contained in UNEP/CBD/BSWG/5/SWG.I/CRP.3 as well as in Articles 9 and 12, contained in working papers 11 and 4, respectively, of Sub-Working Group I. For this reason, this article should be deleted.

[ARTICLE 11 - MULTILATERAL, BILATERAL AND REGIONAL AGREEMENTS [OR ARRANGEMENTS] [OTHER THAN THE PROTOCOL]
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

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.]

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.

[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.]

23/ This provision could be deleted depending on the outcome of Article 3 B (Application of the AIA procedure).

[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/

[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 12 - RISK ASSESSMENT 25/, 26/
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

1. Risk assessment [under [Articles (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 4, [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 21, as noted in UNEP/CBD/BSWG/5/INF/1 on Article 12: "[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 21 (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 ("[6. The [exporter] [importer] [notifier] is responsible for the reliability of the information provided.]") could be deleted, provided that paragraph 2 of draft Article 4 was retained.

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

[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 6.] [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.]]

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

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

[ARTICLE 13 - RISK MANAGEMENT
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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].

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

[3. 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.]]

[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/]

28/ This provision could be dealt with in connection with Annex II (Contact Group 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.

[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]

[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/

[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.]

[8. Parties shall cooperate 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.]

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

[ARTICLE 14 - MINIMUM NATIONAL STANDARDS 31/
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

The provisions of Article 14 have been sent verbatim, with the recommendation to Sub-Working Group II for inclusion in Article 1 bis. For this reason, this Article should be deleted.]

MERGER OF ARTICLE 15 AND ARTICLE 16 - UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

[1. Each Party shall take appropriate measures to prevent unintentional transboundary movements of LMOs [and products thereof].] 32/

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

31/ It was noted that Minimum National Standards should be linked to capacity-building.

32/ This paragraph could be considered under Article 13 (Risk management).

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.

[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.]

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];]

[(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];]

(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.] 33/

[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 minimize any negative impacts on the conservation and sustainable use of biological diversity [, taking also into account human health] [and socio-economic well being].]

33/ This paragraph may be deleted pending the outcome of Article 20 (Confidential information).

[ARTICLE 17 - HANDLING, TRANSPORT, PACKAGING [AND LABELLING] 34/
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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:

(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];

[(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.]

[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.]]

ARTICLE 18 - COMPETENT NATIONAL AUTHORITY/NATIONAL FOCAL POINT
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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 authorized 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.

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,

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34/ Some delegations wish this entire article to be deleted.

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.

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 19 - INFORMATION SHARING/BIOSAFETY CLEARING-HOUSE
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

1. A Biosafety Clearing-House is hereby established 35/ [as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention], in order to:

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

(b) Assist Parties to implement the Protocol,

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];

(c) [Summaries of its risk assessments or environmental reviews of LMOs generated by its regulatory process [, and carried out in accordance with Article 12, including, when

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35/ 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.

appropriate, relevant information regarding products of LMOs, not defined as LMOs, that contain genetic material resulting from 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];

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

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 20 - CONFIDENTIAL INFORMATION
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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].]

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].

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

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

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

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

ARTICLE 21 - CAPACITY-BUILDING
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

1. The Parties shall cooperate [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] 36/ [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.

[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 cooperation 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.]

3. Cooperation 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.]

[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.]

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

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

ARTICLE 22 - PUBLIC AWARENESS AND PARTICIPATION
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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 cooperate, as appropriate, with other States and international organizations.

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 20].

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

[ARTICLE 23 - NON-PARTIES
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

[1. No Party shall export or import LMOs or products thereof to or from 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 11], which should be made available through the Secretariat [and 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 24 - NON-DISCRIMINATION
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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.

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 25 - ILLEGAL TRAFFIC 37/
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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

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.]

[ARTICLE 26 - SOCIO-ECONOMIC CONSIDERATIONS 38/
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

[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].]

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.

37/ 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 2 (Use of terms).

[38/ One suggestion is to include reference to socio-economic considerations/social and economic values of biological diversity in the preamble to the Protocol.]

[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 27 - LIABILITY AND REDRESS
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

[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].

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.

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.

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].]

[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].

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.] 39/]

ARTICLE 28 - FINANCIAL MECHANISM AND RESOURCES
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

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

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.]

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.

39/ 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 29 - 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 cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

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

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

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

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

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

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

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

ARTICLE 30 - SUBSIDIARY BODIES AND MECHANISMS
(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 31 - 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 32 - JURISDICTIONAL SCOPE
(Deleted)

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. 40/

[ARTICLE 34 - RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS
(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)

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].]

40/ 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 35 bis - COMPLIANCE
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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 36 - ASSESSMENT AND REVIEW OF THIS PROTOCOL
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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.

ARTICLE 37 - 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 38 - RATIFICATION, ACCEPTANCE, OR APPROVAL
(Deleted)

ARTICLE 39 - ACCESSION
(Deleted)

ARTICLE 40 - 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 41 - RESERVATIONS
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

No reservations may be made to this Protocol.]

ARTICLE 42 - 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 Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

ARTICLE 43 - AUTHENTIC TEXTS
(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.

Annex I
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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 1/
(Approved for inclusion in the consolidated negotiating text
for the sixth meeting of the Working Group)

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].

1/ 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).

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.

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 realized, 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 realized;

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.]