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Chairman's Note On Articles 3-10 And 12-14

Please find enclosed a note in which items dealt with by sub-working group I of the Open Ended ad hoc Working Group on Biosafety have been reviewed with the intention of trying to assist the sub-working group by providing an improved basis for the group's discussions and negotiations.

The documents used for the preparation of the note are the Consolidated Text of Draft Articles annexed to the report of the last meeting Ad Hoc Working Group, draft articles 3-10 and 12-14, and the new submissions from Governments on these draft articles received after the third meeting of the Ad Hoc Working Group.

The criteria used in the preparation of this note have been to reduce the number of options without excluding any differences in intent or of substance. Where it seems that the only differences between options are in the phrasing, these options have been reduced to a single text with in some cases text in parenthesis to reflect alternatives. Where it seems logical, options have in some cases been organised in a different way than in the Consolidated Text. However, no attempts have been made to combine different options into "compromise options".

"Sub-headings" in italics in front of a line of options should be considered only as an aid to the reader and not as part of the text.

Standard terminology from draft article 2 of the Consolidated Text such as "Party of Import" or "Party of Export" has been introduced in parenthesis where such very frequently used concepts have been phrased differently in the various options.

Delegations will notice that the whole text of the note is placed in square brackets.

In spite of the efforts made, the text is still rather cumbersome and complicated. Aside the inherent complexity of the issues involved, this is mainly due to the fact that the overall principle used for the preparation of the note has been not deliberately to exclude any option differing in substance from any other option.

Veit Koester, Chairman of the ad hoc Working Group on Biosafety

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[ARTICLE 3 - APPLICATION OF THE AIA PROCEDURE1

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

OR

Option B : Each Party shall apply the Advance Informed Agreement procedure with respect to all living modified organisms defined in this Protocol.

No (intending country Party) (Party of export) shall (transfer, handle or use LMOs)(or products thereof) (shall allow the transboundary movement of LMOs)(or products thereof) to or within a (receiving (country) Party) (Party of import) (without first obtaining the receiving Party's consent) (without the Advanced Informed Agreement of the (importing country) (Party of import). Any Party exercising jurisdiction over an individual person or entity shall ensure that no such person or entity shall transfer, handle or use LMOs to or within (the receiving country Party) (Receiving Party) (Party of import)without first obtaining the receiving Party's consent, through the (receiving Party's) (Party of import's) National Competent Authority. (The State (Party) of export shall not allow the exporter to commence the transboundary transfer until it has received the AIA of the State (Party) of import.

OR

Option C: All initial transboundary movements of (LMOs) (a specific LMO)(for specific purposes or uses) (or products thereof) covered by the Protocol shall be subject to AIA. (The State of import)(Party of Import) may, however, declare that low-risk micro-organisms and other low-risk research organisms intended for contained use shall not be covered by the AIA procedure.)

(This article does not apply to :

1. LMOs imported into contained/confined facilities (imported for contained/confined use); or

2. LMOs subject to bilateral, multilateral or regional agreements or arrangements as provided in Article.)

OR

Option D: (All transboundary transfers of LMOs resulting from modern biotechnology, except those mentioned in paragraph 2, a to e below, shall be within the scope of the application of the AIA procedures) (Without prejudice to paragraph 2, e to h below (this Protocol)(these procedures))shall apply to transboundary movement of living modified organisms resulting from modern biotechnology (LMOs)).

2. (This protocol)(These procedures)(The AIA procedures) shall not apply to :

a)Organic materials which are components of LMOs but are not self-reproducible in the environment, such as DNA or RNA segments, plastids and peptides,

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1 Some options under Article 3 in the Consolidated Text of Draft Articles refer not only to the application of the AIA procedure but to the Protocol as such.

b) LMO products which do not contain live cells,

c) LMOs which are subject to any other international agreement related to transboundary transfer of LMOs,

d) LMOs requested to be imported by the competent authority of the (recipient Contracting Party) (Party of import) for the purpose of carrying out risk assessment as a process of the AIA procedures stipulated in this Protocol shall be excluded from the application of the AIA procedures,

e) LMOs to be used exclusively under confined conditions defined in this Protocol and if it is established by the Conference of the Parties to the Protocol that there does not exist any risk to the environment and human health by the use of those LMOs under the conditions so defined) (the transboundary movement of LMOs destined for subsequent contained use,)

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

g) transport operations.

h) the transit of LMOs, except as regards Articles (x) (on general provisions) and (y) (on unintentional transboundary movement).

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

(4. If it is established that there does not exist any risk by the use and release of certain LMOs on the basis of the best available scientific knowledge and experience, as well as relevant information, a recipient Contracting party by means of unilateral declaration or bilateral, regional or multilateral agreement or arrangement, may exempt such LMOs from the application of the AIA procedures, by which no explicit agreement by the competent authority of the recipient Contracting party is required.)

OR

Option E: (The LMOs to be included in the AIA procedure will be based on criteria listed in an annex.) (An LMO is subject to the AIA where:

a. The LMO is intended for field testing in the (importing country) (Party of import); or

b. The LMO has not been imported into the Party of Import and the LMO is not being produced in the Party of import, and

2. The LMO is one:
first) that is intended for first field growth in the Party of Import, including in particular first field growth in a centre of origin or genetic diversity for that product;

second) that has been banned or refused approval in the Party of export because of potential adverse effect on the conservation and sustainable use of biodiversity that were identified during the review process;

third) for which approval is in the process of being sought in the Party of export;

fourth) for which approval in the Party of export would have been required had the LMO been intended for domestic commercialisation, field testing, or field growth in the Party of export;

fifth) for which approval in the Party of export would have been required had the LMO been intended for domestic commercialisation or growth in the Party of export but for which an application or request for approval was withdrawn; or

c) The LMO has been imported into the Party of import, but subsequent to such import, the exporting Party has banned or refused approval of the LMO because of potential adverse effects on the conservation and sustainable use of biodiversity, and the Party of import has not approved the LMO for import or growth since such exporting Parity ban of refusal of approval.

Any Party may notify the Secretariat at any time that the advance informed agreement provisions shall not apply with respect to imports to such Party.

OR

Option F: Parties agree to establish an advance informed agreement procedure on Living Modified Organisms subject to international trade which may have adverse effects on human health and the environment. In their first meeting, the Parties will establish the scope, the documents and the mechanisms for the information and previous consent procedure and the criteria to select the living modified organisms which would be included in the previous fundamental consent procedure.

ARTICLES 4 - NOTIFICATION PROCEDURE FOR AIA

Notification

Option 1A: Each Party shall require the exporter) (The exporter)(The Party of export)(The State of export or, if requested the exporter) (or a natural or legal person under the jurisdiction of the Party of export)) (the designated (national) competent authority of the Party of origin) (to) (shall) notify (request) (by application) in writing (either through the channel of, or by providing a copy to the competent authority of the State of export) (through the channel of the competent authority of the State of export) (the information included in Annex I) (to the State (Party)of import)(the competent authority) (the focal point), prior to (the first) (any) intentional transboundary movement of LMOs) (subject to AIA). (One application or notification shall be sent to the (Parties concerned) (States concerned) and to the Biosafety Clearing House). (The State (Party) of export shall not allow the exporter to commence with the proposed transfer until the AIA of the State (Party) of import has been received).

OR

Option 1B: Each Party of import shall require notification to be given, by the Importer, to the Party of import of the first proposed transboundary movement of a living modified organism (LMO) subject to AIA before it is imported.

OR

Option 1C: Any Party who intends to transfer, handle or use any LMO to or within any (Receiving Party) (Party of Import) shall give prior notice, through its (National) Competent Authority, to the (National) Competent Authority of the (Receiving Party) (Party of Import), by application in writing of its intention to do so. Each Party shall ensure that any individual person or entity under its

jurisdiction who intends to undertake any transfer, handling or use of LMOs to or within any (Receiving Party) (Party of import) shall give prior notice to the (National) Competent Authority of the (Receiving Party (Party of import) by application in writing, of its intention to do so.

Information requirements

Option 2A : The (Party of)(origin) (export)(exporter)(importer)(intending Party) shall submit (a declaration and) (the information identified in Annex I), in writing,(all the information about the LMO necessary for implementation of adequate risk assessment) to (the Party of Import)(Receiving Party). The (information)(declaration) shall be written in a language acceptable to the (State of Import)(Party of Import).

OR

Option 2B: The information to be provided to the competent authorities of the (Party of Import) (recipient Contracting Party) for the implementation of the AIA procedures shall be specified and enumerated in a list by the Conference of the Parties to the Protocol. The list shall be reviewed, by the Conference of the Parties to the Protocol, periodically in the light of the most recent and best available scientific knowledge and experience, as well as other relevant information. The Conference of the Parties to the Protocol may establish a technical advisory body with the task of providing the Contracting Parties with scientific backgrounds for reviewing the list.

OR

Option 2C: The competent authority/focal point in the (State of Import)(Party of Import) shall provide information to the Exporter concerning its laws, regulations, guidelines, legal and administrative procedures and other requirements related to biosafety.

Accuracy of information

Option 3 zero: No provision on responsibility for the accuracy of the information is necessary.

OR

Option 3A: The (National) Competent Authority of the (Party of Export)(intending country Party) shall attest to the accuracy of the information stated above. The State (Party)of export shall, through its competent authority, examine the conformity of the notification under paragraphs x and y above with the requirements of this Protocol and the (Party) (State) of import, and shall stand surety for the accuracy and completeness of the information supplied by the exporter, on the basis of which the advance informed agreement is made.

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

OR

Option 3B: Each Party shall make its (exporter)(importer) responsible for the accuracy of the information provided in a notification and for any new information provided.

ARTICLE 5A - ACKNOWLEDGEMENT OF RECEIPT

Option zero: No acknowledgement is required.

OR

Option A: The Party of Import(by its competent authority) shall acknowledge the notification (under this Article)(to the Part of Export)(to the Importer), in writing, (within x days) (within a reasonable period of time) (in due time) (as soon as possible but not later than 180 days). (This acknowledgement (which does not limit the possibility to require further scientific information under Article x.) shall include:

(A) (confirmation that the notification contains prima facie the information described under Annex I);and/or

(B) (the date of receipt of the notification);and/or

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

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

OR

Option B: The designated national authority of the (Receiving Party) (Party of import) shall review the content of the request and, if found in order, shall within X days following notification, communicate such finding in writing to the designated (national) authority of the Party of origin.

In the event that the request is found not to be in order, the designated (national) competent authority of the Receiving Party may request within the period specified above, the missing information , in which case the deadlines specified for these purposes shall be suspended until the requested information is provided.

OR

Option C: The Party of Import shall (within the period referred to under paragraph x of this Article) (30 days of the date of receipt of the notification) inform the notified to proceed according to:

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

(B) or the procedure provided for in Article 4 (AIA).

ARTICLE 5B - RESPONSE TO AIA NOTIFICATION

Interim Response

Option 1 zero: No provision for interim response

OR

Option 1A: The response of the designated (national) competent authority of the receiving Party to a request for transboundary movement can take the following form;

An interim response which:
i) states the need to conduct a risk assessment;
ii) requests additional information.
iii) requests an extended period of time to(respond) (make a final decision)

Time frame

Option 2A: *(*The competent authority in the (State) (Party) of import) (The State (Party) of import) shall (take appropriate legislative and/or administrative measures to ensure response to the exporter and the Secretariat within X days after the date of acknowledging the receipt of notification) (communicate its decision with respect to importation of an LMO that is subject to the AIA (within 60 (x) days) (as soon as possible but not later than 180 days after transmission of the notification of an intention to export the LMO to the (competent authority of the Party of origin) (the Party of import.)

(Each receiving Party shall communicate its response to the Secretariat no later than x days after its notification to the Designated National (Competent) Authority of the country of origin.)

OR

Option 2B: The Party of import shall within the period referred to in Article 6 (30 days of the date of receipt of the notification) communicate to the exporter:

that, unless it has not, with justification, asked for additional information, imposed conditions or refused permission for the notified movement within 150 days after the date of receipt of the notification, the movement may proceed; or that the movement may proceed only after the Party of import has given its written consent, with or without conditions. The Party of import shall decide within 150 days after the date of receipt of the notification.

Extension of time frame for decision

Option 3A : The period for response should be extended by the period of time awaiting requested information; the period of time for conducting field trials; or by a request for additional time no longer than (60) (30)days.

OR

Option 3B: The Party of import may inform the notified with justification that this period (150 days) is extended by a defined period no longer than 60 days. When calculating the period of time for the Party of import to communicate its decision to the notified, the number of days for which the importing Party is

waiting for additional information which it has requested from the notified, shall not be taken into account.

OR

Option 3C: Notwithstanding paragraph 1 above, the (Receiving Party) (Party of import) shall be allowed as much time as is necessary to assess the information it has received from the (Party of export) (intending country Party) so as to enable it to reach an informed decision on the application and make its own risk assessment decisions on the transfer, handling or use of the LMO.

OR

Option 3D: Decisions regarding import should be made within a time frame agreed between the importing and exporting Parties.

OR

Option 3E: In the event that the request is found not to be in order, the Designated National (Competent) Authority of the receiving Party (Party of import) may request, within the period specified above, the missing information, in which event the deadlines specified herein shall be suspended until the requested information is provided

Consequences of failure to respond

Option 4A: If the Party of import fails to transmit a final decision or an interim response within the period of (60) (120) days) of receiving the application, (the living modified organism concerned shall not be exported without the explicit consent of the importing Contracting Party) (it shall be deemed to be a rejection of the application).

OR

Option 4B: Should competent authorities of the (recipient contracting Party) (Party of import) fail to reply to the Exporter (within the period mentioned in (X) above)(30 days), the competent authorities are deemed to have given to the Exporter (consent) (an implicit agreement) to the import of the LMOs concerned.

OR

Option 4C: If the importing Party fails to communicate its final decision to the notified within 180 days of the transmission of the notification of intention to export, the transboundary movements no longer governed by the terms of this Protocol and the exporting Party shall have no further obligations under this Protocol with respect to such transboundary movement.

ARTICLE 6 - DECISION BY THE PARTY OF IMPORT

Basis for the decision

Option 1: Decisions shall be based on (scientific principles and supported by the best available scientific evidence) (scientific risk assessment of the adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health) (risk assessment, socio-economic imperatives and social and ethical considerations) (scientific, social, economic and cultural criteria (considerations)).

Content of decisions

Option 2: Decisions shall (be in writing and) consist of either:

a) approval to import, without conditions, or

b) approval to import, with specified conditions, or

c)prohibition of import (absolutely or provisionally) (in which case the Party of origin shall only be able, through its Designated National Authority, to request the receiving Party to undertake the risk assessment with a view to reviewing its decision. In such a case, the receiving Party shall be able to require the Party of origin to cover some or all of the costs of the assessment;)

(The importing Party may request (from the importer) (from the competent authority of the exporting Party) further (scientific) (relevant technical) information before allowing or prohibiting the import.)

(In cases where the (State of import) (Part of Import) considers that the documentation provided by the state of export is not sufficient in order to determine the potential adverse effects of an LMO, the State of import has the right to prohibit import of the LMO in question.

(Should the importing Party impose conditions on the import, deny permission for the import, or request additional information, it shall state its reasons for doing so in the response).

(The State (Party) of Import shall not allow the transfer, use or release of an living modified organism unless risks can be minimised to an acceptable level.)

Information to be included

Option 3 zero: No specification in the Protocol of information to be included in the decision.

OR

Option 3A: The Party of Import shall provide full details to the Party of Export or Exporter, in writing, and the Clearing House on:

A. the basis for the decisions (to deny imports) including full details of risk assessments; (or)

B. whether the decision applies, either in whole or in part, to other potential imports of the same living modified organism; (and) (or)
C. whether notification is required for subsequent imports of the same living modified organism, in accordance with Article X.

OR

Option 3B: A final decision shall be accompanied by information describing the legislative and/or administrative measures on which the decision is based. The same conditions, if any, shall apply to the imported and domestic produced living modified organisms.

Obligations of the Party of export

Option 4: Each party of origin (Party of export) shall respect the conditions laid down in the response of the receiving Party no later than x days after the receipt of such communication;

ARTICLE 7 - REVIEW OF DECISIONS UNDER AIA

Option 1A: If, at any time before, during or after the intentional transboundary movement, the (Parties concerned) (State (Party) of Export)(or the State (Party)of Import)) (or the exporter)(as required by the Party of Export) (or the Importer as required by the Party of Import) becomes aware of relevant new information (on the LMOs in question) (about the (potential) adverse impacts of the LMO (and/or products thereof) (on the environment, biological diversity, human and animal health and agriculture) (on the conservation and sustainable use of biological diversity including within the Party of Import) (or of any new use of the LMO or products thereof) (new information on change in use, containment or conditions of use) which (may) (could) have (significant) consequences for the associated risks, Parties concerned (and the Secretariat and Clearing House) shall be informed (within 30 days) (immediately) (within a maximum of 15 days) of such information becoming available (and the (terms of) the AIA decision (may) be changed accordingly) (provided that the clearing house mechanism will be informed of the new requirement without delay).

(The Party of export will be responsible for the accuracy and adequacy of the information).

OR

Option 1B: Parties of export(exporters) may request Parties of import (through its designated (national) competent authority) (to review import decisions) (to conduct risk assessment with a view to reviewing its decision) in cases where Parties of Export consider that;

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

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

c) there is reasonable evidence that the decision has not been based on scientific principles and supported by the best available scientific evidence).

(In this case, the receiving Party (Party of import) shall be able to call for payment of all of the costs of the risk assessment.)

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

Importing Parties shall respond to such requests, in writing, within a reasonable period of time, and provide full details on the basis for their decision).

(In light of new scientific evidence and information made available to the receiving country Party, a new application may be submitted in respect of a previously rejected application.)

OR

Option 1C: If, subsequent to the intentional transboundary movement, the Party of export has gained new experience or has become aware of relevant new information that causes the Party of export to ban or refuse approval of the LMO because of the potential adverse effects on the conservation and sustainable use of biodiversity, and the Party of import has not approved the LMO for import or growth since such exporting Party ban or refusal of approval, the LMO will again be subject to the AIA, and the exporter will provide notice prior to export. New scientific information concerning the LMOs potential adverse impact on the conservation and sustainable use of biodiversity shall be submitted to the Clearing House within a reasonable time.

Safeguard clause

Option 2 zero: No provision regarding a safeguard clause is necessary.

OR

Option 2A: *(Safeguard clause 1)*If at any time a Party has reason to believe, taking into account available sci-
entific information, that LMOs for which an intentional transboundary movement may proceed on the basis of the Articles X to Y are likely to cause adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, that Party may then prohibit such and any such subsequent movements to its territory, or specify conditions under which all such subsequent movements have to take place. In such a case, that Party must promptly inform notifies who have previously notified movements of such LMOs in accordance with this Protocol with the reason of its decision.

OR

Option 2B: *(k7)*A (receiving Party) (Party of import) may at any time in light of new
information or evidence, unilaterally review its decisions on any transfer, handling or use of
LMOs into its country and employ any review mechanism established through its national
legislation or any other national procedures.

ARTICLE 8-NOTIFICATION OF TRANSIT

Option zero: No provision on notification of transit is necessary.

OR

Requirements

Option 1A: (Parties)(The State (Party)of Export) may require notification (by the exporter), in writing, (through their Focal point)(through the channel of the competent authority of the State of Export or by providing a copy to this

authority) of other Parties intent to transit (for the first time) a living modified organism (or products thereof) through their territory (for a specified use or purpose)..

. Where such notification is required, (Parties that require notification of intent to transit living modified organisms, or products thereof, through their territory)(the State of Export) (shall/should) (provide information /stipulate) (included in Annex X) (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)).

OR

Option 1B: The Party of export must obtain (the necessary permits)(written consent) from Party and non-party states through which the living modified organisms (and products thereof) will be in transit, (as well as assuming responsibility for any cases of accidental release in those states).

(All the requirements for labelling, packaging and transportation shall be met)

OR

Option 1C: Provided prior notification, consent and labelling is given, and subject to the national laws, regulations and procedures, each Party undertakes to facilitate the transit of living modified organisms through its territory.

For the purposes of this Article, «transit» shall mean the temporary stop over of an living modified organism which is on a continuous journey to another destination. For the avoidance of doubt, «transit» shall not mean the transfer to another Party of living modified organisms used for field testing, which are bound for another destination after the field testing.

Acknowledgement/response

Option 2A: The State of transit shall promptly acknowledge the receipt of the notification to the notified. It may subsequently respond to the notified, in writing , within 30 days:

(a) consenting to the transit movement with or without conditions;

(b) denying permission for the movement; or

(c) provide an interim response, that may contain a statement to import with or without specified conditions or prohibiting import during the interim period. This may include a statement that a final decision is under consideration and/or a request for further information and/or extended period of time to respond.

The State of transit may declare in writing whether or not a notification is required for subsequent transit movements of the same living modified organism and it shall inform the Secretariat and previous notifies of such decisions. The handling and transport requirements for living modified organisms referred to in Article 4 shall be followed in all transit movements.

OR

Option 2B: Upon receipt of this information/notification, the Party whose territory is to be transited shall inform the (Party of export)(or the

exporter)(and the Clearing-house), within a reasonable period time, of :

- (any provisions that may be require)

- (any transport, handling, packaging and labelling provisions for the transit of the living modified organisms or other requirements in addition to those specified in Article X).

The Party of transit shall be able, giving full reasons, to object to or to place conditions on the passage of the living modified organism through its territory.

Treatment

Option 3: The documentation provided for the transport of living modified organisms must specify the care needed during their transit.

ARTICLE 9-SIMPLIFIED PROCEDURE

Option zero: No provision for a simplified procedure in the Protocol

Simplified procedure initiated by the Party of export

Option 1: The State of Export may, subject to the written agreement of the States concerned, use, or allow the exporter to use, a (general) notification (procedure) (for the AIA procedure) (for living modified organisms having the same characteristics and which are transferred regularly to the same user (via the same customs office of exit of the State of Export and the same customs office of entry of the State of Import))..

Simplified Procedures initiated by the Party of Import

Option 2A: Without prejudice to Article X, a Party of Import can, with justification, specify in advance to other Parties cases:

(a) for which the intentional transboundary movement of living modified organisms to that Party may proceed according to its regulatory framework implementing Article 8(g) of the Convention on Biological Diversity, provided that the framework includes a control mechanism for transboundary movement consistent with the Protocol;

(b) for which the intentional transboundary movement can take place at the same time that the movement is notified to the relevant authority in the Party of Import. Such notifications may apply to subsequent similar movements to the same Party.

OR

Option 2B: If it is established, (on the basis of the best available scientific knowledge and experience and any other relevant information), that the use and release of certain living modified organisms does not pose any **(**significant) risk**,** a State (Party) of Import may, (by means of a unilateral declaration or a bilateral, regional or multilateral agreement or arrangement**)** (exempt such living modified organisms from the application of the AIA procedures set out in Article X , in which case no explicit agreement by the competent authority of the State of Import is required) (substitute the AIA procedure with a notification procedure). In such cases, the State (Party) of Import (may/shall) instead apply a notification procedure.

In cases where there is repeated transboundary transfer of an living modified organism, a State (Party) of Import may decide that the application of the AIA procedures be exempted or replaced by simple notification procedures provided for in paragraph 1 above) and shall communicate any such decision to the State of Export concerned.

OR

Option 2C: The State (Party) of import shall communicate in its response to the State (Party)of export whether an AIA procedure with explicit or implicit consent is required for subsequent imports of the same LMO or whether a simple notification in accordance with Article X shall be applied.

OR

Option 2D: Parties of import may introduce simplified procedures for Advance Informed Agreement for imports of living modified organisms, provided that any relevant international standards are applied and that adequate measures are observed to ensure the safe transboundary movement of living modified organisms resulting from modern biotechnology, in accordance with the objectives of this Protocol.

Information to be provided

Option 4A: Information to be provided in the notification is specified in Annex X.

OR

Option 4B: Notification of intent to export living modified organisms pursuant to this Article will contain the following information:

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

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

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

(d) Information on previous exports of the same living modified organisms to the recipient state;

(e) Date of the intended transfer, which will not be less than 30 days from the date of notification.

New information arising during the application of simplified procedures

Option 5: If at any time before during or after the transboundary transfer, the exporter becomes aware of relevant new information relating to the living modified organism which may have significant implications for the evaluation of associated risks, it must inform the competent authorities of the States concerned and the secretariat and Clearing-house within 30 days of the information becoming available.

Notification to the Secretariat or Clearing- house

Option 6: If a State of Import decides, pursuant to this Article, to exempt certain living modified organisms from the application of the AIA procedures or

to apply simple notification procedures to certain living modified organisms, it shall inform the Secretariat of the Protocol in writing accordingly. The Secretariat shall forthwith inform all Contracting Parties of such decisions.

ARTICLE 10-SUBSEQUENT IMPORTS

Option zero: No provision on subsequent imports is necessary.

Notification

Option 1A: Notification of subsequent imports of the same living modified organism into the same State (Party) of Import shall not be required unless specifically requested in writing by the State (Party) of Import in cases where there may be :

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

(b) variation in the receiving environment; or

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

Where notification for subsequent imports is specifically requested by the Importing Party full details regarding the information required (shall)(should) be provided, in writing, to exporting Parties or exporters and to the Clearing House. The information required (shall)(should) be based on that identified in (Annex I)(information required for notification of import of a living modified organism).

The Party of Import (shall) (should) acknowledge the notification in writing within a reasonable period of time. This acknowledgement shall include:

(a) confirmation that a risk assessment has been or is to be carried out in accordance with Article (13) (risk assessment); and

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

OR

Option 1B : Notification in writing is required for all subsequent imports of the same modified living modified organism into the same Party of Import.

The State of Import will acknowledge receipt of notification as quickly as possible and will inform the State of Export that:

(a) importation can proceed; or

(b) a new risk assessment procedure will be undertaken

OR

Option 1C: A single notification as well as a consent given in response to a notification may cover several similar including subsequent transboundary movements to the same Party of Import.

OR

Option 1D: A State of Import may at any time declare that subsequent imports of a specific LMO into its territory for specified uses or purposes, are exempted from

the requirement of AIA in Article X. Such an exemption (may)(shall) specify a procedure for a (simple) (prior) notification (indicating that the intentional transboundary movement can take place at the same time, that a specific movement is notified to the State of Import specifying the information to be contained in the notification and procedures for risk assessment and decision-making alternative to those established for the first import)..

The (State (Party) of Export/Import shall inform the Secretariat (clearing house mechanism) (of such declaration). (and previous notifies of any declaration that it has made pursuant to paragraph of the Article, and confirming that a risk assessment has been carried out in respect of earlier transboundary movement of the living modified organism concerned and including any requirements as to the movement, handling and use of the living modified organism concerned. Such a declaration may be withdrawn at any time by the Party concerned. The Secretariat and any notifies who have previously notified movements of such living modified organisms to that Party in accordance with this Protocol must be informed no later than 30 days prior to the withdrawal.

The (Secretariat) (clearing house mechanism) (shall) (must) (publish this information, including the kind of o living modified organisms for which the AIA procedure have been replaced by prior notification by a specific Party) (inform all Parties of information received pursuant to (these paragraphs). The Secretariat shall be responsible for transmitting this information for inclusion in the database established under Article X).

OR

Option 1E: Thirty days prior to subsequent transboundary movement of an LMO falling within the scope of this Protocol the Exporter shall notify the national focal point of the importing contracting party (Party of Import), if no response is received within this 30 day period, the exporter may proceed with the transboundary movement

When the conditions described in Annex X are fulfilled subsequent transboundary movements may proceed without notifying the focal point of the Party of Import. In this case, the exporter must ensure that appropriate relevant information is provided to the importer and or final user.

OR

Option 1F: The exporter must submit a new application for subsequent imports even though the competent authority may have given a positive clearance for the importation of a specific LMO.

OR

Option 1G: No application or any corresponding study shall be in any way influence by the existence of a prior acceptance of the same LMOs or products derived from them in the Party of Import or any other Party.

The import of an LMO or any of its products is permitted for a specific use; if the use changes a fresh application must be made to the competent national authority for a new clearance for the new use.

Regulations

Option 2: The regulations applied to imports shall be identical to those applied to living modified organisms produced in the State (Party) of Import.

ARTICLE 12-RISK ASSESSMENT

Option zero: No provision on risk assessment is necessary in the Protocol.

OR

Aim

Option 1A: Risk assessment should be undertaken (in a scientifically sound and transparent manner) to identify and evaluate the possible adverse effects of living modified organisms (and products thereof) on (the environment of the State of Import, as regards in particular) conservation and sustainable use of biological diversity, (agriculture, human and animal health) (taking also into account the risks to human health) (and ecological stability and socio-economic imperatives.)

Risk assessment as basis for decisions

Option 2A: Adequate risk assessment of the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity and adverse impacts on human health in the State of Import is the basis for AIA and is also a necessary requirement for decisions on handling, use and release of any living modified organism in that State.

OR

Option 2B: (Each Party shall ensure that appropriate decisions are taken based on the outcome of the risk assessment.**)**

OR

Option 2C: If the risk assessment shows that risks cannot be avoided or reduced to an acceptable level, the States concerned shall/may refuse authorisation to the import or transfer of that particular living modified organism.
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OR

Option 2D: The State of Import shall make all decisions on the basis of inter alia, risk assessment, socio-economic imperatives and social and ethical considerations.

Option 2E: Each Party shall ensure that appropriate decisions are taken based on the outcome of the ris assessment and on a case-by-case basis. If the assessment shows that risks cannot be avoided or reduced to an acceptable level, the States (Parties) concerned shall refuse authorizartion to the development, use release, import, export or transfer of that particular LMO or product thereof.

Application

Option 3: Risk assessment (as described in paragraph X of this Article) shall be undertaken (on a case by case basis (using a multidisciplinary approach)

a) (prior to the use, transboundary movement/transfer or handling of living modified organisms, as the case may, to or within the State (Party of Import/any Party;)

b) (prior to a first import);

c) (on receipt of a notification for the first import of a living modified organism);

d) (prior to any decision being taken under Articles x of this Protocol));

e) prior to undertaking a release into the environment);

(f) where applicable, at each stage of development including commercial use);

(g) for subsequent imports of the same living modified organisms into the same State of Import at the discretion of the State of Import (except for the following cases where risk assessment shall be required):

i) (where there is a change in the intended use of the living modified organism;)

ii) where there is a variation in the receiving environment; or

iii) where there are other factors likely to affect the risk assessment or risk management of the living modified organism.)

((h) for subsequent imports with alternative procedures for the risk assessment to those established for the first import);

Responsibility

Option 4 zero: No provision necessary.

OR

Option 4A: Risk assessment (as described in paragraph X of this Article) shall be undertaken (be required to be undertaken) by:

a) (the competent authority of) (the State (Party)of Import) (on the basis of information on the risk assessment provided to the competent authority/focal point);

b) (each Party);

c) any natural or legal person under its jurisdiction who intends to undertake a transfer or to handle or use a living modified organism as required by each Party);

d) (the State (Party) of export for risk assessment prepared by persons or entities under its jurisdiction)

(The exporter is responsible for the reliability of the information provided.)

Parameters

Option 5A: Risk assessments (as described in paragraphs X of this Article) (should/shall):

(be carried out in accordance with Annex X) (and any other relevant information)

(inter alia) take into account the following:

a) (as appropriate, existing guidelines relevant to biosafety;)

b) risk assessment techniques developed by relevant international organisations;

c) all relevant scientific evidence and experience;

d) relevant technical experience;

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

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

g) the characteristics of the receiving environment;

h) impact on centres of origin and areas with high genetic diversity relevant to the living modified organism;

(i) (the interaction between these);

j) information submitted by the country of origin (Party of export) ;

(k) the actual and/or potential effects on human health, the environment and agricultural production, including the population balance of the related organisms;

(l) social factors, socio-economic imperatives and ethical considerations.

(Further parameters for risk assessment can be adopted at the discretion of the State of Import).

OR

Option 5B: Each Party shall determine for itself, in accordance with its own legislation, the institutional arrangements for the conduct of risk assessments under this Protocol and for the preparation of technical findings in relation to requests for transboundary movement.

Information

(**Option 6A:** The person carrying out a risk assessment pursuant to this Protocol is entitled to refuse requests for information other than that required to be available by virtue of Annex X unless the State requesting the information/State (Party) of Import can show that the requested information is an essential part of the risk assessment in that specific case.

OR

Option 6B: The competent authorities of the State of Import may request the exporter to provide additional relevant information if necessary.

Financial responsibility

Option 7 zero: No provisions necessary on financial responsibility for risk assessment.

OR

Option 7A The financial responsibility for risk assessment shall rest with the (intending country party)(Party_of Export)

Co-operation

Option 8A: (Parties) (the Parties of Export) should, (where appropriate) (where the State of Import lacks the financial and technical capacity to carry out risk assessment under this Protocol) assist (technically and financially) (and collaborate with) States of Import with the carrying out of risk assessment (through the sharing of information and expertise).

OR

Option 8B: The competent authorities of the State (Party) of Import may request assistance from the exporter or from the competent authorities of the State (Party)of export. Such requests should be met to the extent possible, especially in cases where the competent authorities of the State (Party) of Import do not have sufficient experience of the living modified organisms in question.

OR

Option 8C: The Contracting Parties shall, taking into account in particular the needs of developing countries and countries with economies in transition, cooperate in order to promote international harmonisation in risk assessment and risk management procedures.

Micro-organisms

Option 9: . Parties shall ensure that risk assessment and management processes of micro-organisms are conducted in contained conditions.

Import restrictive measures

Option 10: Import restrictive measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity within the territory of the State of Import.

ARTICLE 13-RISK MANAGEMENT

Option zero: No Article containing provisions concerning risk management

OR

Requirements

Option 1A: In accordance with Article 8(g) of the Convention, Parties intending to undertake any transfer, handling or use of living modified organisms to or within the (receiving country) (State (Party)of Import) shall establish and maintain (national means to regulate, manage or control risks) (appropriate risk management measures and strategies that may be implemented) in the (receiving country) (State of Import)(Party of Import) (or shall ensure it has appropriate domestic laws in place) for the management of (risks identified under the risk assessment provision of the protocol) (risks and harm associated with the transfer, handling and use of the living modified organism and the protection and mitigation of potential harm to the (receiving country party) (receiving country) (State (Party) of Import) and shall incorporate such measures and strategies with risk assessment under Article 12 (Risk Assessment) above) .

OR

Option 1B: The intending Party (Party of export) shall ensure that the risk management strategies and measures proposed for implementation by the receiving country (Party of Import) pursuant to Article 7 shall (correspond to the results of the assessment referred to in Article X) (be established for both confined and contained uses and semi- and commercial releases) incorporate strategies and measures that will minimise, (prevent or mitigate) risk in the management and use of the organisms under consideration) (the potential socio-economic effects and impacts within the receiving country) (Party of Import), (particularly where the introduction of living modified organisms into the environment of the receiving country (Party of Import) may entail a displacement of a particular agricultural or resource use system or the culture and livelihood of the local people.)

OR

Option 1C: The risk management strategies and measures shall consist of such measures and strategies applicable at all/any of the following stages: transfer; handling; release and/or use of the living modified organism to or within the receiving country(Party of Import))

(Risk management strategies shall:

(a) be established for (both confined and) contained uses and releases;

(b) contain a description of the type and class of containment (and confinement**)** of the organism under consideration.)

OR

Option 1D: The type of risk management to be employed shall be appropriate to the living modified organisms and activity in question and such risk management strategies and measures shall (be commensurate with) (correspond to the results of) the assessment of risk. The type of risk management and the (practices) (measures) set out in Annex X shall be employed as a minimum.

Co-operation

Option 2A : Parties of Import and export should, where appropriate, cooperate in the development of risk management procedures.

OR

Option 2B: *(15)*If the receiving country (Party of Import) lacks the financial and technical capacity to do so, the intending country Party) (Party of export) shall offer technical and financial assistance and shall collaborate with the receiving country Party (Party of Import)).

Observation period

Option 3: Without prejudice to paragraph x above, each contracting party in order to ensure genomic and trait stability in the environment, any LMO whether imported or locally developed shall undergo a period of observation commensurate with its life cycle or generation time as the case may be before it is put to its intended use. Risk management schemes shall take due account of of the different purposes or uses for which the living modified organisms or the products thereof are developed or produced.

Antibiotic resistance markers

Option 4: Parties shall require producers of living modified organisms to phase out all antibiotic resistance marker genes in living modified organisms by the year 2002.

ARTICLE 14-MINIMUM NATIONAL STANDARDS

Option zero: No provisions necessary

OR

Option A: Each Party shall ensure that appropriate legal, institutional and administrative measures concerning the safe research and development, manufacture, transfer, handling and use of living modified organisms are in place (upon the date of entry into force of this Protocol for that Party) (two years after the date of ratification of accession of this Protocol). In addition to establishing such measures at the national level, Parties shall also cooperate in establishing at the international or regional level, procedures to carry out risk assessment under Article X.

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

National measures shall, as a minimum, fulfil the requirements set out in this Protocol with regard to the safe transfer, handling and use of living modified organisms, including those relating to risk assessment under Article 12 and enforcement conditions or prohibitions under Article 13.

(Parties may impose more stringent or comprehensive requirements, based on scientific considerations.)

OR

Option B: The Conference/Meeting of the Parties to the Protocol shall establish a minimum standard of risk assessment of living modified organisms. The minimum standard shall be reviewed periodically by the Conference/Meeting of the Parties in the light of the most recent and best available scientific knowledge and experience, as well as other relevant information. The Conference/Meeting of the Parties to the Protocol may establish a technical advisory body for providing the Contracting Parties with scientific backgrounds for reviewing the standard.]

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