



CBD



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~~OPEN-ENDED AD HOC WORKING~~

GROUP ON BIOSAFETY
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Chairman's Note On Articles 1, 1bis and 15-27

Please find enclosed a note in which items dealt with by sub-working group II 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 1, 1bis and 15-27, 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 1 - PRINCIPLES/OBJECTIVES

Option A

The objective of this Protocol, to be pursued together with the relevant objectives and provisions of the Convention, is to ensure the safe development, handling, transfer, use and release of LMOs and products thereof resulting from modern biotechnology so as to safeguard human and animal health, the environment, biological diversity, and socio-economic welfare.

Option B

The objective of this Protocol is to promote [shared responsibility and co-operative efforts among Parties to achieve] the safe transboundary movement of LMOs [and products thereof] resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity [, taking also into account the risks to human health] [including through exchange of information and a scientifically-based and transparent system of advance informed agreement].

Option C

The objective of the Protocol is to ensure safe transfer, handling and use of LMOs (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity taking into account the risks to human health. [The objective is also to ensure that these activities take into account human and animal health, and take place in accordance with the principle of sustainable development and in a socially and [ethically] [economically] justifiable way.]

Option D

The Protocol shall apply to the safe transfer, handling and use of LMOs resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

Option E

The objective of this Protocol is to ensure that transboundary movements of LMOs take place in conditions that are safe for the conservation and sustainable use of biological diversity and human health; to mitigate the harmful effects of unintentional transboundary movement; as well as to strengthen the capacities of developing countries and countries with economies in transition, *inter alia*, through adequate financing; to control transboundary movement; and for the environmentally sound management of the organisms subject to this Protocol.

Option F

The objective of this Protocol, to be pursued in accordance with its provisions and those of the Convention on Biological Diversity, is, with a view to attaining the objectives of the Convention, to set out appropriate procedures, including, in particular, advance informed agreement (hereinafter referred to as "AIA"), in the field of the safe transfer, handling and use of any LMOs (hereinafter referred to as "LMOs") resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

ARTICLE 1bis - GENERAL OBLIGATIONS

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Option zero No provision necessary

OR

Option A

1. The Parties to the present Protocol undertake to implement the provisions of the Protocol and the Annexes hereto which shall constitute an integral part of the present Protocol.

2. Parties shall ensure that the development, handling, transport, use, transfer and release of any LMOs [or products thereof] are undertaken in a manner that prevents or reduces to [acceptable levels, risks] [the minimum possible risks, within an acceptable range] to human and animal health, biological diversity[,] [and] the environment [and socio-economic welfare of societies].

3. [Parties shall prohibit the export of LMOs or products thereof unless they obtain] [Subject to the provisions of Article [], Parties shall not approve or allow the export of LMOs until such time as they have obtained] an advance informed agreement in writing from the State of import for the specific import.

4. Parties shall prohibit the export of any LMOs or products thereof to the Parties which have prohibited the import of such organisms [or products]. Parties exercising their right to prohibit the import of LMOs [or products thereof] shall inform the Secretariat and the Biosafety Clearing House of their decision.

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

6. Parties shall cooperate among themselves in order to achieve an environmentally sound system of management of the potential risks of LMOs [and products thereof].

7. Each Party shall take the appropriate [legal, administrative and other] measures to:

(a) Ensure safety in biotechnology, especially in the transboundary transfer and [handling, use and] release of LMOs resulting from modern biotechnology;

(b) Ensure that persons involved in the development, handling, transfer, use or release of LMOs [and products thereof] take such steps as are necessary to avoid unacceptable risks to human and animal health, biological diversity [,] [and] the environment [and the socio-economic welfare of societies];

(c) Require that information about a proposed transboundary transfer of any LMOs [or products thereof] be provided to the States concerned according to the appropriate procedures of notification set out in Article [] of this Protocol;

(d) Prohibit the export of any LMOs [or products thereof] to a State, or group of States belonging to a regional economic integration organization that includes Parties, which has prohibited imports of such LMOs by its legislation[, or if it has reason to believe that the organisms or products in question will not be managed in an environmentally sound manner, according to criteria to be decided on by the Parties at their first meeting];

(e) Cooperate with other Parties and may involve interested organizations as appropriate, directly and through the Secretariat and the Biosafety

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Clearing House, with respect to the necessary measures for safety in biotechnology, including the dissemination of information on LMOs [or products thereof, in order to ensure the environmentally sound management of such organisms and products and to achieve the prevention of illegal traffic and unintended releases];

(f) Ensure that appropriate national authorization is required for all activities, including experimental, involving development, handling, use, transfer and release of LMOs [or products thereof];

(g) Require that LMOs [or products thereof] that are to be the subject of transfer or a transboundary transfer be packaged, labelled, and transported in conformity with the rules and requirements to be set out by the Secretariat and the competent authorities of the States concerned;

(h) Require that LMOs [and products thereof] be accompanied by a transfer document from the point at which a transfer and transboundary transfer commences to the point of use or release.

[9. The Parties agree that failure to provide all the necessary information available about the LMOs or products thereof and any illegal traffic are criminal.]

[10. Each Party shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Protocol, including measures to prevent and punish conduct in contravention of the Protocol.]

[11. The obligation under this Protocol of States in which the LMOs or products thereof have been developed and in which they have originated is to require that those organisms or products are managed in an environmentally sound manner and may not under any circumstances be transferred to the States of import.]

12. Nothing in this Protocol shall prevent a Party or group of Parties from imposing additional requirements that are consistent with the objective and provisions of this Protocol and are in accordance with the rules of international law[, in order to better protect human and animal health, biological diversity, the environment and the socio-economic welfare of societies].

OR

Option B

General

1. Parties shall take all [necessary] [appropriate legislative and/or administrative] measures to comply with the provisions set out in this Protocol for the safe transboundary movement of LMOs resulting from modern biotechnology[, and, in particular, measures to prevent transboundary transfer of LMOs not pursuant to the provisions of the Protocol].

AIA

Option 2A Parties shall introduce, as necessary, implement and enforce national provisions in order to ensure compliance with the advance informed agreement procedures set out in Articles 6-11 of this Protocol, and shall ensure that advance informed agreement measures for the import of a LMO are implemented in a transparent manner, based on scientific principles and supported by the best available scientific evidence.

or

Option 2B Each Party shall apply the AIA procedure provided under Article (AIA) with regard to the transboundary movement of any LMO and shall ensure that any LMO leaving its territory shall be furnished with due authorization of the

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designated national authority of the receiving Party.

Information exchange

Option 3 zero No provision on information exchange in this Article.

or

Option 3A The Parties shall, in accordance with this Protocol, exchange information on LMOs in order to contribute to the environmentally sound management of biotechnology.

Cooperation

Option 4 zero No provision on Cooperation in this Article.

Option 4A Each Party shall cooperate with other Parties for the internationally harmonized implementation of the provisions of the Protocol.

Disguised restriction on trade

Option 5 zero No provision on disguised restrictions on trade in this Article.

or

Option 5A The Parties shall ensure that measures taken for the oversight of transboundary movement of LMOs do not create unnecessary obstacles to, and/or constitute a means of arbitrary or unjustifiable discrimination or disguised restrictions on international trade.

or

Option 5B Parties shall ensure that AIA measures for the import of a LMO are not more restrictive than measures applied to the same LMO produced domestically or imported from other Parties and are applied in a manner which does not constitute a disguised restriction on international trade.

Confidentiality

Option 6 zero No provision on confidentiality in this Article

or

Option 6A Parties which receive information and notifications of transboundary movements under the present Protocol shall ensure the confidentiality of the information of that nature which they have received.

Additional requirements

Option 7 zero No provision on additional requirements in this Article

or

Option 7A Parties may impose additional requirements for the safe transboundary movement of LMOs resulting from modern biotechnology, provided that they are consistent with the provisions of this Protocol and accord with other relevant international agreements.

Transport of LMOs

Option 8 zero No provision on transport of LMOs in this Article

or

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Option 8A Without prejudice to compliance with relevant international requirements for transport operations, the Parties shall, where appropriate, ensure that LMOs within the scope of this Protocol and subject to intentional transboundary movement are accompanied by relevant information on LMOs, as specified in Annex [], and that the exporter shall be able to prove that the movement is in conformity with the requirements of the Protocol. Transport of LMOs shall be carried out under safe conditions in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Territorial sea and EEZ

Option 9 zero No provision on territorial sea/EEZ in this Article

or

Option 9A 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.

OR

Option C

1. Each Party shall, in accordance with its particular conditions and capabilities:

(a) develop an institutional framework for the execution of the provisions set out in this Protocol;

(b) develop national strategies, plans or programmes for the provisions set out in this Protocol or adapt, for this purpose, existing strategies, plans or programmes;

(c) integrate, as far as possible and as appropriate, the provisions set out in this Protocol into relevant national strategies, plans or programmes.

2. Importing Parties may impose additional requirements, for the safe transboundary movement of LMOs, and products thereof, provided that they are:

(a) based on scientific principles and supported by the best available scientific evidence;

(b) detailed in national laws and regulations of the importing Party; and

(c) consistent with the provisions of this Protocol and in accord with other relevant international agreements.

OR

Option D

1. Each Party shall, in carrying out its obligations under this Protocol, develop or maintain an action plan that incorporates strategies to bring about an appropriate mix of public and private sector initiatives for the even development of biotechnology, in order to optimize benefits to society and to ensure safety in the development, transfer and use of LMOs.

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2. To avoid the undue build up of specific chemicals in the environment and possible perturbations to ecosystems, parties shall ensure that the design of transgenic organisms aimed at producing chemicals novel to the main parent organisms are incapable of independent existence outside of husbandry by humans.

OR

Option E

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

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

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

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

OR

Option F

1. Parties exercising their right to prohibit the import of LMOs shall inform the [Biosafety Clearing House] [clearing house mechanism] of their decision.

2. Parties shall prohibit or shall not permit export of LMOs or their products to the Parties which have prohibited the imports of such LMOs and products.

3. Each Party shall take appropriate measures to:

(a) Ensure that risk assessment and risk management procedures are strictly followed in handling, transport, use transfer and release of LMOs taking into account social, technological and economic aspects.

(b) Ensure that persons involved in the handling of LMOs take steps to ensure safety to environment, biological diversity and human health.

(c) Ensure that the transboundary movement of LMOs is conducted in a manner which will protect the environment, biological diversity and human health.

(d) Ensure that the information about the proposed transboundary movement of LMOs as per AIA is provided to the State of import by the State of export.

(e) Prevent the import of LMOs and their products if it has reason to believe that the LMOs in question will not be managed in an environmentally sound manner.

(f) Cooperate in activities with other Parties and interested organisations, directly and through the Secretariat, including the dissemination of information on the transboundary movement of LMOs, in order to improve the environmentally sound management of such LMOs to achieve the prevention of illegal traffic.

4. Nothing in this Protocol shall prevent a Party from imposing additional requirements that are consistent with the provisions of this Protocol, and are in accordance with the rules of international law, in order to better protect biological diversity, human health and the environment.

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

OR

Option G

The Parties to the present Protocol:

(a) Undertake, individually and collectively, to implement the provisions of the Protocol and the annexes thereto;

(b) Shall ensure that the development, handling, transport and use of LMOs do not have adverse effects on the conservation of biological diversity, the environment, as well as human health and the socio-economic welfare of populations;

(c) Shall ensure that AIA is obtained before any transfer of a LMO;

(d) Agree that all the information concerning the LMO shall be communicated to all the States concerned by the movement;

(e) Agree that any illegal traffic in LMOs is a crime that engages the responsibility of the perpetrator(s) and imposes on them the obligation to compensate the victim(s); and

(f) Shall consider and put in place adequate emergency plans to control and manage the risks associated with accidental or unintentional transboundary movements.

ARTICLE 15 - UNINTENTIONAL TRANSBOUNDARY MOVEMENTS

Option Zero No provisions necessary.

Option A

[1. The Parties shall take all possible precautions to prevent accidental and unintentional release and to reduce natural movements of intentionally released living modified organisms which may result in unintentional transboundary movements.]

[2. The Parties shall inform potentially affected states about any planned activities associated with LMOs within their territories that are likely to have transboundary effects. The potentially affected state(s) may request consultations between the concerned states.]

[3. The information supplied under paragraph 2 of this Article shall include, *inter alia*, the identity, relevant characteristics and numbers/volumes of the LMOs involved and any available information necessary to assess accident and emergency measures taken or needed to be taken, including measures identified under Article 14 (1) of the Convention.]

[4. Parties shall immediately notify affected Parties, potentially affected Parties and the Clearing House, in the event of known unintentional transboundary movements of living modified organisms, or of known domestic releases of living modified organisms which may result in unintentional transboundary movements.]

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Such notification shall include, *inter alia*:
 circumstances of the unintentional movement;
 a) the identity and quantities released;
 an assessment of the risks to the conservation and sustainable use of biological
 diversity and/or human health;
 emergency measures taken or needed to be taken;
 any available information regarding the handling of the organisms and related
 risk management measures to be applied;
 information specified in Annex I.]

[5. The Party which is the origin of the unintentional transboundary movement
 [which is likely to present a threat] shall take immediate action, in
 consultation with the affected Party, [to minimise adverse impact on the
 environment and] to prevent further release or transboundary movement of the
 living modified organism.]

[6. A Party which suspects that an unintentional transboundary movement has
 occurred into its territory shall inform the Party from which the unintentional
 movement is suspected to have originated. The Party from which the unintentional
 movement is suspected to have originated, shall immediately investigate this
 possibility and, if confirmed, trigger the mechanisms described paragraphs 4 and
 5 of this Article.]

[7. Each Party shall avoid any activity that may lead to accidental or
 unintended releases of aquatic living modified organisms to freshwater and marine
 ecosystems.]

[8. If necessary, the affected Party(ies) may request the Party from which the
 unintentional transboundary movement originates, to assist in emergency measures
 with the aim of minimising adverse effects on conservation and sustainable use of
 biological diversity and human health.]

[9. In the event of an unintentional release occurring during the international
 transport of a living modified organism subject to the article on Advance
 Informed Agreement [where such unintentional release is likely to present risks
 to the conservation and sustainable use of biodiversity], each Party shall,
 whenever it comes to its knowledge, [endeavour to] ensure that the national focal
 point of each potentially affected Party is immediately informed and provided
 with all available relevant information [, subject to the domestic legal
 requirements for the protection of confidential information and intellectual
 property rights in the Party providing such information]. For purposes of this
 Article, international transport refers to that portion of movement that occurs
 after the LMO has left the area under the national jurisdiction of the exporting
 Party and before it has entered the area under the national jurisdiction of the
 importing Party.]

Option C

[1. In the case that an unintentional transboundary movement of LMOs is likely
 to have significant adverse effects on the conservation and sustainable use of
 biological diversity, taking also into account risks to human health, the Party
 of origin of the unintentional movement shall ensure that any affected Party(ies)
 and non-Party(ies) [and the Clearing House] receives, as soon as possible, all
 relevant information concerning the unintentional transboundary movement and
 risks to the conservation and sustainable use of biological diversity, taking
 also into account risks to human health, and their management.

2. Information to be provided is specified in Annex I.]

3. The Party of origin of the unintentional transboundary movement shall, in
 consultation with the affected Party, immediately take appropriate actions to

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mitigate the adverse effects on human health, the environment and agricultural production, including the population balance of related species, and shall take appropriate actions and measures to prevent future unintentional transboundary movements and to minimise associated risks.

ARTICLE 16- EMERGENCY MEASURES

Option Zero No provisions necessary.

Option A

Option 1A

1. Each Party shall [endeavour to establish] [promote appropriate] national measures and procedures, including national contingency plans, related to emergencies or accidents involving LMOs which may present potential risks to its environment, and in particular, to the conservation and sustainable use of biological diversity, agricultural production, including the population balance of related species, and human health.

Option 1B

1. Each Party shall ensure that appropriate strategies and measures, including emergency plans, are incorporated in the risk management strategies and measures established under Article 13 to prevent, mitigate or rectify any potential risks in case of any accidental or emergency release of LMOs.

2. Each Party shall take the necessary measures to ensure that, in the event of an accident, the user shall be required to inform immediately the competent authorit[y][ies] of the State concerned. The information shall include, inter alia,

- a) the circumstances of the accident;
- b) other facts necessary to assess the effects of the accident on human and animal health, the environment, and the biological diversity;
- c) the emergency measures taken or needed to be taken together with any available information regarding the handling of the organisms; and
- d) any other information considered relevant.

3. Where information is provided under paragraph 2 above, the State concerned shall ensure that in any emergency, the necessary short, medium and long-term measures are taken, including the immediate notification of any other State which could be affected by the accident.

ARTICLE 17- HANDLING TRANSPORT PACKAGING AND LABELLING

Option A

[1. In order to maintain adequate safety levels during transport each exporting Party shall [establish appropriate,] [promote, as appropriate,] measures for the handling, transportation [,] [and] packaging [and transit] of LMOs [subject to Article (on AIA)] for transboundary movement.

2. The Parties shall [take into account] [ensure that LMOs to be exported are packaged and transported in accordance with] international conventions, standards and recommendations on classification, packaging, labelling and documentation related to transport established by appropriate international organizations, in particular the UN Recommendations on the Transport of Dangerous Goods, [and those elaborated under the auspices of the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO), and the International Airway Transport Association (IATA)].

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3. The Parties shall aim at developing standards with regard to packaging and transport practices under this Protocol.]

4. Exporting Parties shall:

ensure that shipments containing LMOs are clearly labelled, and identify on the label the type of LMO, the names and addresses of the exporter and importer, and contact details of national focal points of the exporting, importing and any transit Parties;

ensure that shipments containing LMOs are handled and packaged in such a way as to prevent accidental release of LMOs into the environment;

ensure that LMOs exported from their territories are subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export;]

require that LMOs be accompanied by a movement document from the point at which the transfer commences to the point of use.

5. The receiving Party shall have the right to impose terms and conditions on the packaging, labelling and transportation of a LMO to or within the receiving Party, for the protection of its environment [, in particular the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health and taking into account also such social and ethical matters it deems fit for national interest purposes].]

6. The Parties shall ensure that LMOs which have not been approved for use shall be handled and packaged in such a way as to ensure their complete isolation.

OR

Option B

1. The Secretariat shall cooperate with the World Customs Organisation with a view to assigning a universal identification code for products subject to this Protocol.

2. Each Party undertaking a transboundary movement of a LMO in accordance with [Article [] (on AIA)] shall ensure that the product is duly packaged, crated and labelled, including the corresponding Safety Information Sheet, which shall include the information specified in Annex [] .

3. The Parties shall ensure that the transboundary movement of LMOs from their territory is subject to packaging, crating and labelling requirements no less than those required by its national legislation.

4. The information on the Safety Information Sheet shall, to the extent possible, be in the language of the receiving Party.

OR

Option C

Each Party shall [establish appropriate] [promote, as appropriate] measures for the handling, transportation, packaging and transport of LMOs subject to transboundary movement [and subject to Article [] (on AIA)] [[in conformity with generally accepted and recognized international rules and standards in the field of packaging, labelling and transport, taking due account of relevant internationally recognized practices] [in accordance with standards to be elaborated under this Protocol]].

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OR

Option D

Transport of living modified organisms shall be carried out under safe conditions in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

ARTICLE 18- COMPETENT AUTHORITY/FOCAL POINT

Option A

[1. To facilitate the implementation of this Protocol, each Party shall designate or establish a national focal point and one or more competent authority(s) which shall receive applications and notifications and communicate decisions on living modified organisms in accordance with the Advance Informed Agreement procedure set out in Article 3, 4 and 5 and Annex I and II. Where a Party designates more than one competent authority, it shall specify the areas of responsibility for each

2. Each Party shall inform the Secretariat no later than the date of entry into force of the Protocol for that Party in question, which agencies have been designated as its focal point/competent authority(ies).

3. The Secretariat shall forthwith inform the Parties of notifications received under paragraph 2. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1, and 2 above for inclusion in the Database provided for in Article 19 on information exchange.

4. Parties shall inform the Secretariat and the Biosafety Clearing House within [] days of the date of decision, of any changes regarding the designation made by it under paragraphs 1 and 2 above.

5. The Competent Authority of each Party shall be the authoritative/decision-making body regarding any intended transfer, handling or use LMOs to or within the receiving country. The Competent Authority shall be provided with adequate [and timely] financial and technical assistance to establish and develop its infrastructure and human resources to carry out the responsibility assigned to it including as a minimum the responsibilities listed in Annex IV.

6. The Competent Authority of the receiving country Party may impose [au pays exporteur] such conditions and/or national procedures it deems fit regarding the transfer, handling or use of the LMO by the intending Party in order to protect its environment, in particular the conservation and sustainable use of biological diversity, and the [prévention des] risks to human health.]

Option B

[1. Each Party shall designate or establish competent authority/ies and/or focal point/s that shall be responsible for the administrative functions required by this Protocol and shall notify this to the [Secretariat] [Clearing House] [[no later than] [within three months of] the date of entry into force of this Protocol for it] [concurrently with the deposit of its instrument of ratification]. Any changes in the designation of competent authority/ies and/or focal point/s shall be notified to the [Secretariat] [Clearing House] [within one month] [immediately].

3. Each Party shall [strive to] ensure that its national focal point has sufficient resources to perform its task efficiently.]

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Option C

[1. Contracting Parties shall designate or establish one national focal point and one or more competent authorities for the implementation of the Protocol.

2. The national focal point shall perform the following tasks:

to provide other Contracting Parties, through the Secretariat of the Protocol, with general information on the implementation of the Protocol at the national level including, in particular, information on competent authorities responsible for the AIA procedures and/or for LMOs;
to collect information on the implementation of the protocol at its national level; and
to assist communication between foreign, regional or international institutions established for the implementation of the Protocol on the one hand and the national competent authorities on the other.

3. The competent authorities shall perform the following tasks:

to establish national guidelines and/or regulations for the implementation of the AIA procedures including detailed criteria for risk assessment within their competence;
to receive from exporters applications for the AIA procedures;
(a) to conduct risk assessment;
(b) to take a decision on result of the risk assessment;
(c) to inform the exporter with the result of the risk assessment; and
(d) to conduct, if necessary, additional trials, including field trials.]

**ARTICLE 19 - INFORMATION SHARING/
BIOSAFETY CLEARING HOUSE**

Option A

1. Subject to the national laws, regulations and procedures of each Party, and without prejudice to the obligation to provide information under the AIA procedure under Article 4, the Parties shall facilitate, through a clearing-house mechanism and/or national focal points of each Party, the exchange of information, relevant to [safety in biotechnology and the transfer, handling or use of LMOs and the impacts thereof, taking into account the special needs of developing countries] [the implementation of the Protocol]. Such information shall be transmitted to the Secretariat [, the Biosafety Clearing House] and other relevant bodies and Parties as the case may be.

2. Parties shall endeavour to co-operate with existing international agencies, organizations, mechanisms and regional networks for the dissemination of biosafety-related information [and standards applicable in other countries.

3. The Biosafety Clearing House shall serve as a body for information exchange, monitoring of implementation, and scientific and technical co-operation among Parties. It shall report regularly to the [Meeting of the Parties] [Conference of the Parties serving as the meeting of the Parties to this Protocol] on all aspects of its work and to the Secretariat regarding the implementation of procedures on notification and Advance Informed Agreement. The

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modalities of establishment of the Biosafety Clearing House shall be considered and decided upon by the Parties at their first meeting.

4. Each Party shall inform its public about the contents of, and mode of public accessibility to, the Biosafety Clearing House.

7. Without prejudice to Article 20 (Confidential Information), the Biosafety Clearing House shall contain and provide public access to information relevant to the implementation of the Protocol as follows;

- (e) [the information identified in Annex []]
- (f) information on risk assessments or environmental reviews generated by the regulatory process;
- (g) [information on decisions regarding the importation, field testing, or commercial use of any LMO;]
- (h) information concerning the development, use and transfer of LMOs;
- (i) available results relating to risk assessment and management;
- (j) national procedures for regulation, assessment and risk management;
- (k) [scientific references necessary to risk assessment and risk management;]
- (l) information on transboundary movement [of LMOs resulting from modern biotechnology which may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health];
- (m) information on unintentional movements according to Article 16;
- (n) general description of products consisting of or containing LMOs having received consent by a Party or Parties for placing on the market;
- (o) a summary of any methods and plans for monitoring LMOs;
- (p) the text of any decision on a notification of an intentional transboundary movement and the summary of the risk assessment;
- (q) information concerning its biosafety regulatory framework on LMOs;
- (r) a summary of any notified unintentional transboundary movements which are likely to have significant adverse effects in another Party or non-Party on the conservation and sustainable use of biological diversity, taking also into account risks to human health;
- (s) the text of decisions taken pursuant to Article [safeguard clause as referred to in BSWG 3/3/Add 1.]
- (t) information on risk assessments and import decisions relating to LMOs, including the time taken for import decisions to be made.

OR

Option B

1. The Parties shall facilitate the collection and exchange of publicly available [scientific, technical, environmental and legal] information on, and experience with, LMOs (LMOs) to enable Parties to make informed decisions related to Biosafety, taking into account the special needs of developing countries and the countries with economies in transition, through a [Biosafety Clearing House] [Biosafety Database].

2. A [Biosafety Clearing House] [Biosafety Database] should be established no later than the date of entry into force of this Protocol on the basis of existing international biosafety exchange mechanisms.

Option 3A

3. Each Party shall make available to the [Biosafety Clearing House][Biosafety Database]:

/...

- (a) its domestic laws, regulations, and guidelines applicable to the production, use, and handling of LMOs;
- (b) publicly available information on risk assessments or environmental reviews generated by the regulatory process.
- (c) publicly available information on its decisions regarding the importation, field testing, or commercial use of any LMO [, including any decisions to deny the importation of a LMO that has previously been imported by that Party].
- (d) whenever it comes to its knowledge, relevant publicly available information when an unintentional release of a LMO is likely to present risks to the conservation and sustainable use of biological diversity].

[4. Each Party shall provide transparent procedures for validation and verification of data which it makes available to the public and to the clearing-house.]

or

Option 3B

3. Without prejudice to Article 20 (Confidential Information), each Party shall ensure that the following information is provided to the Secretariat for inclusion in the [Biosafety Clearing House] [Biosafety Database]:
- (u) information on intentional movement having been subject to Advance Informed Agreement according to Article [] and related decision(s);
 - (v) information on unintentional movements according to Article 16 .

OR

Option C

1. The mechanism for the exchange of information and cooperation under the Protocol shall be the clearing house mechanism established by the Convention in its Article 18, paragraph 3.

Option 2A The clearing house mechanism shall include:

- (a) Information on measures adopted under national legislation;
- (b) Information on decisions adopted by countries with regard to the transboundary movement of LMOs;
- (c) Information on accidental or unintended movements of LMOs, including contingency or mitigation plans to be used in such event;
- (d) Information relating to the appropriate assessment and management of risks;
- (e) Information on the implementation of the AIA procedure, including simplified procedures and bilateral, multilateral and regional agreements;
- (f) Updated information on the designated national authorities for the purposes of this Protocol.

or

Option 2B Each Party of Import shall make available to the clearing-house mechanism, subject to appropriate protection of confidential business information identified:

- (w) information to assist other Parties in decision-making under the Protocol with respect to national laws, regulations, guidelines, codes of practice and administrative procedures for the safe

/...

- transfer, handling and use of LMOs;
- (x) any other information regarding LMOs that the Party considers would be of benefit to other Parties and to the public, including information with respect to risk assessment and management, and other scientific information; and
- (y) a list of LMOs subject to advance informed agreement which have been assessed or import into or use in its territory at the time of coming into force of this Protocol for that Party and a description of any conditions attached to imports of such LMOs.

or

Option 2C Each Party shall ensure that timely information pertaining to biosafety is provided to the clearing house mechanism

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

OR

Option D

1. (a) The Parties shall provide the Secretariat of the Protocol with the following information:

(i) National regulatory framework for the implementation of the Protocol, including:

(a) names, addresses and telecommunication numbers of the national focal point and the competent authorities;

(b) national guidelines and/or regulations for the implementation of the Protocol, including information required for the AIA procedures and for risk assessment;

(c) if any bilateral, regional and multinational agreements or arrangements as well as unilateral declarations on the exemption and/or the simplification of the AIA procedures.

(i) Periodic reports on the implementation of the AIA procedures, including statistics.

(b) The Secretariat of the Protocol shall circulate the information received pursuant to (1) above to all Parties.

2. The Parties are encouraged to make available to all interested parties, including other Parties, regional and international institutions as well as individuals information on the implementation of the Protocol, not included in (1) above.

ARTICLE 20 - CONFIDENTIAL INFORMATION

Option A

Parties shall respect the need to protect commercial-in-confidence information relevant to living modified organisms.

Option B

1. Parties shall respect the need to protect intellectual proprietary rights

/...

and confidential information [relevant to living modified organisms] received under the procedures established under this Protocol. [However, all information requested by the [importing party] [competent authority] for the purpose of decision-making must be provided by the [exporting Party] [notifier]]. [Confidentiality and proprietary provisions shall not be so excessive or broad as to hinder information-sharing among Parties which would undermine the ability of the national competent authority to take informed decisions.]

2. The notifier [should] [may] indicate any information submitted under the procedures established under this Protocol that it considers to be confidential and/or subject to intellectual property protection. [Verifiable justification] [Due justification] [Justification] must be given in such cases [upon request].

3. The competent authority shall decide, after consultation with the notifier, which information is confidential and shall inform the notifier of its decision [prior to disclosing the information].

4. If, for whatever reason, including in cases where the competent authority and notifier disagree, a notifier withdraws a notification, the confidentiality of all the information supplied [and indicated as confidential] must be respected by the competent authorities and focal points, [subject to national legislation].

Option 5A

5. The information specified in Annex I shall not be regarded as confidential with respect to the Protocol.

Option 5B

5. Without prejudice to paragraph 4 of this Article, [in no case may the following information be kept confidential] [the following information should not generally be considered confidential]:

- a) the general description of the LMO or LMOs, the name and address of the notifier [, and the purpose of the transboundary movement];
- 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.

Option 5C

5. In no case may the following data be considered confidential:

- (a) The following information concerning the host organism:
 - (i) Pathogenicity, toxicity, allergenicity to humans and, if any, to other species;
 - (ii) Capacity to transfer genetic material and potential pathways;
 - (iii) Methods for detecting the organism in the environment and for detecting the effective insertion of donated nucleic acid; and
 - (iv) Potential of the organism to affect ecosystem relations;
- (b) A summary of the risk assessment on the effects on the conservation and sustainable use of biological diversity, including the effect on domesticated animals and human health;
- (c) Any contingency method or plan; and

/...

(d) Accident prevention or mitigation method.

Option 5D

No provision necessary on categories of information which may not be considered confidential.

6. [Competent authorities, focal points] [,Parties] [and the Secretariat] shall not divulge any confidential information received under this Protocol [without the prior written consent of the notifier and shall comply with such conditions regarding release that the notifier may prescribe] and [have the obligation to] [shall] protect intellectual property [and proprietary] rights relating to the [data] [information] received.

7. Any Party receiving confidential information shall establish appropriate internal procedures for the protection of information so received [, 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].

ARTICLE 21 - CAPACITY BUILDING

Option zero No provisions necessary.

OR

Option A

1. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety including where necessary, through the appropriate international and national institutions. They shall take due account of the needs of developing countries with respect to capacity building in order to promote the development and transfer of safe biotechnology and knowledge.

2. The Secretariat, in collaboration with the Biosafety Clearing House, shall develop and implement regional and global capacity building programmes based on the identified needs of the concerned Parties. The Secretariat and the Biosafety Clearing House shall, in particular, assist developing countries in their efforts to identify and plan their capacity building requirements and secure funds for the implementation of their capacity building programmes.

3. The Parties agree that, according to the specific needs of different regions and sub-regions, regional or sub-regional activities/centres for training and capacity building regarding the safe management of LMOs shall be established, with financial assistance provided through the financial mechanisms under the Convention on Biological Diversity (CBD).

4. The Parties shall promote [technical and scientific cooperation][capacity building], including the promotion of cooperation in the training of personnel and the exchange of experts, informational exchange and institutional capacity building in order to strengthen the ability of importing states to perform risk assessments and to develop and implement [decision making and] risk management procedures.

5. Capacity building programs should maximize the use of existing multilateral, regional and bilateral mechanisms [where possible, including those addressed under the Convention]. Technical assistance from the private sector

/...

should also be facilitated and encouraged.]

6. Such capacity-building shall aim to ensure:

- (a) that Parties develop and strengthen their capacities to implement this Protocol;
- (b) that national legislation, frameworks and guidelines related to biosafety are developed;
- (c) that States involved in the transfer, handling and use of LMOs and or products thereof are aware of any associated risks and have the means to assess and manage the risks;
- (d) that States are able to achieve safety through proper risk assessment and management when certain LMOs and or products thereof are transferred into and/or to be used in their territories and act adequately in cases of accidental release of LMOs;
- (e) the development of procedures for risk assessment and risk management of LMOs.

7. Any Party to this Protocol or any of its signatories may make scientific-technical cooperation requests to the Secretariat for the purpose of applying the Protocol or participating in it, in particular:

- (f) preparing or evaluating risk assessment reports or impact statements;
- (g) developing or evaluating risk management schemes and appropriate monitoring programmes, procedures and standards;
- (h) preparing emergency plans and other safety measures;
- (i) transmitting requests for assistance and relevant information in the event of accidents;
- (j) providing information that may be relevant to the settlement of disputes.

8. The developed country Parties shall establish effective measures for strengthening and/or development of human resources and institutional capacities in biotechnology and biosafety in developing country Parties, encompassing technical, financial and institutional provisions.

9. The developed country Parties shall establish such measures to enhance the capacity of developing country Parties to acquire and/or develop relevant biotechnology, and its proper and safe management, and the building up of their local, technological and institutional competence, thereby contributing to the distribution of benefits from the potentials of biotechnology. through training in science related to safety in biotechnology and in the use of risk assessment and risk management techniques and the transfer of relevant knowledge, in biotechnology and biosafety on fair and most favourable terms including on concessional and preferential terms.

OR

Option B

1. The Parties agree that measures for national capacity building are essential for the effective implementation of this Protocol.

Option 2A

2. [The Parties] [Each Party] shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities [in biotechnology and biosafety including where necessary, through the appropriate international and national institutions] [in

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order to facilitate effective implementation of the Protocol]. They shall take due account of the needs of developing countries with respect to capacity building in order to promote the development and transfer of safe biotechnology and knowledge.

or

Option 2B

Parties shall co-operate to build capacity for risk assessment, decision making and risk management. Capacity building may include technical assistance, information exchange, training, education and institutional strengthening. Technical assistance from the private sector should be facilitated and encouraged.

Option 3A

3. Such capacity-building shall aim to ensure:

- (k) that national legislation, frameworks and guidelines related to biosafety are developed;
- (l) that States involved in the transfer, handling and use of LMOs and or products thereof are aware of any associated risks and have the means to assess and manage the risks;
- (m) that states are able to achieve safety through proper risk assessment and management when certain LMOs and or products thereof are transferred into and/or to be used in their territories and act adequately in cases of accidental release of LMOs;
- (n) the development of procedures for risk assessment and risk management of LMOs.

or

Option 3B

3. The building of national capacity shall be achieved, *inter alia*, through:

- (a) New and additional financial resources;
- (b) Training and technical assistance; and
- (c) Technology transfer relevant to the scope of this Protocol.

Option 4A

4. Implementation of these measures is properly addressed in the general framework of the Convention and through programmes and activities under international organizations such as UNEP and UNIDO.

or

Option 4B

4. Capacity building programmes should maximise use of existing mechanisms where possible, including those addressed under the Convention, and should be particularly aimed at developing countries.

ARTICLE 22 - PUBLIC AWARENESS / PUBLIC PARTICIPATION

Option zero [No provision necessary] [Include reference in preamble]

Option A

1. Parties shall take appropriate measures to enhance [public awareness of]

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[adequate public information on] [and/or public participation in] the implementation of the Protocol.

Option B

1. Each Party shall take appropriate measures to ensure, to the extent practicable, that the public has appropriate access to information related to the implementation of this Protocol, whilst respecting [confidential commercial] [commercial-in-confidence] information.

2. Each Party shall promote and facilitate, as appropriate and in accordance with national laws and regulations, and within their respective capacities, the development of educational public awareness programmes on safety in biotechnology.

Option C

[1. Each Party shall, in accordance with its national laws and regulations, provide the public which is likely to be affected by any activity or product involving LMOs, an opportunity for public hearings in the process of approving the release, transfer or use, contained or otherwise, of such LMOs.]

[1/2]. While respecting the need to protect [commercial-in-confidence] [confidential] information, Parties shall:

a) promote and encourage understanding of the safe use, handling and management of LMOs in relation to transboundary movement, and the conservation and sustainable use of biological diversity, including human health;

b) make available to the public risk assessment results and decisions concerning the transboundary movement of LMOs.

[2/3]. The Parties shall cooperate as appropriate, with other States and international organizations in developing educational and public awareness programmes [with respect to any risks and benefits associated with] [on safety in] modern biotechnology.

Option D

1. The Parties shall ensure that adequate information on the safe transfer, handling and use of LMOs is provided to the public in accordance with Article 13 and Article 14(1) of the Convention. Parties are encouraged to facilitate public participation in [and access to information on] risk assessment decisions.

2. The Parties shall promote and facilitate, at the national, sub-regional and regional levels, as appropriate, and in accordance with national laws and regulations, and within their respective capacities, the development and implementation of educational, both formal and informal, and public awareness programmes on safety in biotechnology.

3. Each Party shall, in accordance with its national laws and regulations, provide the public which is likely to be affected by any activity or product involving LMOs, an opportunity for public hearings in the process of approving the release, transfer or use, contained or otherwise, of such LMOs.

4. While respecting the need to protect [commercial-in-confidence] [confidential] information, Parties shall:

c) promote and encourage understanding of the safe use, handling and

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management of living modified organisms in relation to the transboundary movements and the conservation and sustainable use of biological diversity, including human health;

d) make available to the public risk assessment results and decisions concerning the transboundary movement of living modified organisms;

5.. The Parties shall cooperate as appropriate, with other States and international organizations in developing educational and public awareness programmes [with respect to any risks and benefits associated with] [on safety in] modern biotechnology.

6. Subject to relevant national legislation, Parties shall endeavour to disclose or make available information on biotechnology, safety in biotechnology and the results and impacts of any releases or use of any LMO to the public.

ARTICLE 23 - NON PARTIES

Option zero No provision necessary

Option A

Non-Parties in compliance with the substantive provisions of the Protocol shall be treated on an equal basis with Parties.

Option B

Parties shall not be restricted from trade in LMOs with non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of LMOs resulting from modern biotechnology, in accordance with the objectives of this Protocol.

Option C

Parties may enter into bilateral, regional or multilateral agreements or arrangements regarding transboundary movements of LMOs with Parties or non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of LMOs resulting from modern biotechnology, in accordance with the objectives of this Protocol. The provisions of this Protocol shall not affect transboundary movements that take place pursuant to such agreements and arrangements as between the parties to that agreement or arrangement.

Option D

1.The Parties shall apply the AIA procedures to all intended transboundary transfers of LMOs, whether the LMOs in question are imported from a Party or from a non-Party. The recipient Party shall not prohibit any transboundary transfer of LMOs from a non-Party merely on the grounds that the LMOs are from a non-Party.

2.The Parties may enter into a bilateral, multilateral or regional agreement or arrangement compatible with this Protocol with a non-Party regarding transboundary movement of LMOs.

Option E

1. The transfer of LMOs with non-Party countries shall be subject to the prior signature of a bilateral agreement between the country party to the Protocol and

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the non-Party country.

2. Under such agreement, the non-Party country shall be bound to the strict observance of the provisions of the Protocol on the transfer of LMOs.

3. The country party that signs the bilateral agreement shall transmit a copy to the Secretariat of the Convention and to the clearing house mechanism under the Convention.

Option F

Parties shall be bound by the provisions of this Protocol in their relations with non-Parties.

Option G

Any transboundary movement of LMOs, their parts, products, subproducts and derivatives resulting from biotechnology, originating from the jurisdiction of non-Party States, shall be regulated in accordance with the national law of each Party.

Option H

3. Within five years of the date of entry into force of this Protocol, the Parties shall determine the feasibility of banning or restricting, the import from and export to States not Party to the Protocol of LMOs covered by this Protocol. If determined feasible, the Parties shall elaborate in an annex the measures and conditions that will be applicable in such circumstances.

4. Notwithstanding the provisions in paragraph (1), imports and exports of LMOs may be permitted from and to any State not Party to this Protocol, if that State has submitted data and is determined on the basis thereof by the [Meeting of the Parties] [Conference of the Parties serving as the meeting of the Parties to this Protocol] to be in full compliance with the provisions of this Protocol.

Option I

Each Party shall reserve the right to ensure that a non-Party shall not undertake any transfer, handling or use of LMOs to or within a receiving country Party. Each Party shall reserve the right to ensure that any person or entity under the jurisdiction of a non-Party shall not undertake any transfer, handling or use of LMOs to or within a receiving country.

Option J

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

ARTICLE 24 - NON-DISCRIMINATION

Option zero No provisions necessary.

Option A

Parties shall ensure that measures taken in relation to living modified organisms under the Protocol do not create unnecessary obstacles to trade and do

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not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade.

Option B

The importing Party shall ensure that its decisions and actions with respect to the import of an LMO are not more restrictive than with regard to the same LMO produced domestically or imported from any other country.

Option C

5. During the course of the AIA procedures, in particular the risk assessment procedures, the recipient Parties shall not treat LMOs of foreign origin that are imported from other Parties or non-Parties with which an agreement or arrangement mentioned in Article 23 has been concluded more restrictively than those of domestic origin merely on the grounds that the LMOs in question are of foreign origin.

6. The recipient Parties may impose specific conditions when LMOs of foreign origin are imported from non-Parties with which no agreement or arrangement mentioned in Article 23 has been concluded, to the extent that such conditions are not contrary to the provisions of this Protocol as well as of the non-discrimination provisions of the WTO Agreement.

Option D

7. The receiving country Party has the sovereign right and prerogative to make its own decisions on any transfer, handling or use of LMOs to or within the receiving country Party by the intending country Party (Party of Export) or any person or entity under its jurisdiction who intends to undertake any transfer, handling or use of LMOs to or within the receiving country Party. In making its decisions, the receiving country Party reserves the right to take into consideration any matter of national interest such as social and ethical matters and sensitivities of the culture and religion prevailing in the receiving country.

8. Previous decisions by the receiving country Party on the transfer, handling or use of any LMO to or within the receiving country Party by an intending country Party (Party of Export) or person or entity under that intending country Party's (Party of Export's) jurisdiction shall not affect the right of the receiving country party to make its decision on the transfer, handling or use of the same LMO to or within the receiving country Party by another intending country Party (Party of Export).

9. National treatment shall not apply to the intending country Party (Party of Export) in respect the transfer, handling or use of any LMO to or within the receiving country where the same LMOs are being developed, produced and released by the receiving country Party.

ARTICLE 25 - ILLEGAL TRAFFIC

Option zero No provision necessary.

Option A

Illegal traffic

Option 1A

1. Any transboundary transfer of LMOs without appropriate notification to, or advance informed agreement of, all States concerned, pursuant to and in

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accordance with the provisions of this Protocol, shall be deemed to be illegal traffic.

Option 1B

10. For the purposes of this Protocol, any [transboundary movement of an LMO] [transfer, handling or use of any LMO to or within the receiving country Party by the intending Party or person or entity under the jurisdiction of the intending Party] :

- a) without notification pursuant to the provisions of this Protocol to Parties under this Protocol; or
- b) without the advance informed agreement pursuant to the provisions of this Protocol of any Party concerned; or
- c) with advance informed agreement obtained from Parties concerned through falsification, misrepresentation or fraud ; or
- d) that does not conform in any material way with the information given under the AIA procedure; or
- e) that results in deliberate transfer, release, handling or use of LMOs in contravention of this Protocol and of general principles of international law

shall be deemed to be illegal traffic.

Option 1C

1. For the purposes of this Protocol, any transfer, handling or use of any LMO shall be deemed to be illegal traffic if it occurs:

- a) without compliance with the provisions regarding advance informed agreement and/or notification contained in the Protocol [except as provided under Article 11 on Bilateral, Regional and Multilateral Agreements]; or
- b) with approval which was obtained through falsification, misrepresentation or fraud or does not conform in a material way with documentation provided pursuant to the provisions of the Protocol; or
- c) in contravention of any provision of the national legislation applicable in the States concerned.

Consequences of illegal traffic

Option 2A

2. In the case of a transboundary movement of LMOs deemed to be illegal traffic, the State of import shall have the right to destroy or dispose of the organisms or products in question.

Option 2B

1. In the case of a transfer, handling or use of LMOs deemed to be illegal traffic, the receiving country Party shall have the right to destroy or dispose the LMO in question or where possible to require the [person responsible for the illegal traffic] [Party of origin] to remove the LMO from the environment of the receiving country Party at [his][its] own expense.

Option 2C

2. In cases where illegal traffic has occurred, the importing Party may:
- a) impound the living modified organisms, or:
 - b) require and direct the disposal or re-export of the living modified organisms.

Option 2D

/...

2. In the case of a repetition of the offence by illegal traffickers, no country Party to the Convention shall engage in trade in LMOs with such persons for a period of three years.

Liability for illegal traffic

Option 3A No provision in this Article on liability for illegal traffic

Option 3B

3. Exporting Parties shall be liable for any illegal transboundary movement of LMOs or products thereof, including unsafe packaging.

Option 3C

3. In the case of a transfer, handling or use of LMOs deemed to be illegal traffic, the consequences under Article 27 (Liability and Compensation) shall apply.

Option 3D

3. The country undertaking the illegal traffic shall be liable for the adverse effects caused by the transfer of the LMO into the territories of the affected countries.

National legislation

4. Each Party shall develop appropriate national legislation to prevent [and/or punish] illegal traffic. Parties shall co-operate in this respect , with a view to achieving the objective of this Protocol

Data/information on illegal traffic

Option 5A No provision on data/information in this Article

Option 5B

5. Parties shall transmit to all affected and non-affected Parties to the Protocol, as quickly and effectively as possible, all available information concerning the illegal movement and any related risks, through the information exchange mechanism.

Option 5C

5. Data concerning known cases of illegal traffic should be included in the information exchange mechanism established under Article 19.

Option 5D

1. 5. The illegal traffic shall be recorded, on the basis of reliable documentation by the importing country, the exporting country, the Secretariat or a third country.

ARTICLE 26 - SOCIO-ECONOMIC CONSIDERATIONS

Option zero No provision necessary

Option A

/...

1. Parties shall ensure that the socio-economic impacts of the introduction of LMOs and products thereof are appropriately considered during the assessment and management of risks. In particular, the user shall take due account of the long observation period that these socio-economic impacts may require to manifest such adverse consequences as genetic erosion and associated loss of income and dislocation of traditional farmers and farm products.

1. A Party that intends to produce, using a LMO, a hitherto imported commodity, shall notify the other Party or Parties whose export is to be affected long enough, and in no case less than seven years in advance, so as to enable them to diversify their production and to implement measures concerning the biodiversity that would be reduced following the disruption of production of the commodity in question. The Party substituting its import in such unnatural way shall, when the affected Party is a developing country, provide financial and technical assistance to the affected Party.

Option B

1. The Parties hereby agree that socio-economic imperatives must be taken into account at all levels, during the transfer, handling or use of LMOs. To this end, the intending country Party shall ensure that the risk assessment prepared by it or person or entity under its jurisdiction under Article 12 (Risk Assessment) shall incorporate specific assessments on the socio-economic effects and impacts of the transfer, handling or use of the LMO on or within the receiving country and its environment, in particular on the conservation and sustainable use of biological diversity, taking into account its human health, agriculture and welfare.

2. The risk assessment shall in particular include an assessment of whether introduction of LMOs in the environment of the receiving country may bring about a displacement of a particular agricultural and resource use system or the culture and livelihood of the local people.

1. The intending country Party shall ensure that the risk management strategies and measures proposed to be implemented by the receiving country Party under Article 13 (Risk Management) shall incorporate strategies and measures that will prevent, if not minimise or mitigate the potential socio-economic effects and impacts within the receiving country Party, in particular where the introduction of LMOs in the environment of the receiving country Party may bring about a displacement of a particular agricultural or resource use system or the culture and livelihood of the local people.

Option C

1. The Parties shall ensure that the socio-economic impacts specific and unique to the use of LMOs that may manifest adverse consequences are appropriately considered during the assessment and management of risks [taking into account the fact that socio-economic considerations will vary considerably from Party to Party]. [In particular, the importing country shall take into account 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.

Option D

The Parties shall ensure that the socio-economic impacts of the introduction, management and use of LMOs and products thereof are appropriately considered during risk assessment and management, by applying strategies and measures that

/...

minimise, prevent and counteract the potential socio-economic impacts and having users take into account that such impacts may require a long observation period to manifest themselves.

Option E

1. Each Party shall develop or maintain legislation or other regulatory provisions that protect the general public from a monopolistic manipulation of the biotechnological, seed, chemical and related industries by individual private sector entities.

2. Each Party shall ensure that activities involving LMOs by both public and private entities are adequately regulated in order to ensure a fair and effective implementation of the provisions of this Protocol and to protect the fundamental moral and socio-economic interests of the general public and the international community.

Option F

Each Party shall ensure that the socio-economic impacts that result or might result from the transfer, handling and use of LMOs are taken into consideration both at the time of risk assessment and throughout the risk management process.

Option G

1. Decision-making on the transfer of LMOs from an exporting country to an importing country shall, as appropriate, include socio-economic considerations.

2. The final decision on taking socio-economic considerations into account in the transfer shall rest with the competent authority of the importing country.

3. The modalities for taking account of socio-economic considerations in the transfer of a LMO shall be governed by the national legislation of each country Party.

ARTICLE 27 - LIABILITY AND COMPENSATION

Option zero No provision necessary.

Option A

The Parties to this Protocol shall, at their first meeting, examine how to establish procedures in accordance with Article 14(2) of the Convention, for developing appropriate rules and procedures in the field of liability and redress, including restoration and compensation for damage resulting from LMOs to biological diversity.

Option B

1. Parties are responsible for the fulfilment of their international obligations concerning the conservation and sustainable use of biological diversity and preservation of the environment. They shall be liable in accordance with international law.

2. Parties shall ensure that resources are available in accordance with their national legal systems for prompt and adequate compensation or other relief in respect of damage caused by the use, handling and transfer of LMOs by natural or

/...

juridical persons under their jurisdiction.

3. With the objective of assuring prompt and adequate compensation in respect of all damage caused by the use, handling and transfer of LMOs, Parties shall cooperate in the implementation of existing international law and the further development of international law relating to responsibility and liability for the assessment and compensation of damage and the settlement of related disputes, as well as, where appropriate, development of criteria and procedures for payment of adequate compensation, such as compulsory insurance and compensation funds.

Option C

1. The exporter shall be liable for and shall fully compensate any damage deriving from the transboundary movement of LMOs, in accordance with the provisions of the present Protocol.

Option D

3. If harm, including transboundary harm, arises as a consequence of LMOs or activities or products involving such organisms, the operator in respect of production, handling, export and supply of those LMOs shall be liable for the harm, and the harm must be compensated.

4. When the operator is unable to discharge its liability the State(s) of origin shall be liable to the extent of the breach of due diligence obligation of the state of origin.

5. If the harm, including the transboundary harm, proves detrimental to human or animal health, biological diversity and the environment:

a) The operator responsible for causing such a harm shall restore as far as possible, the conditions that existed prior to the occurrence of the harm. The nature and magnitude of harm is such that it is impossible to restore those conditions full by operator alone the state of origin shall endeavour to restore.

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

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

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

Option E

1. Parties to this Protocol, recognising the risk involved in the transboundary movement of LMOs as well as the Advanced Informed Agreement and Risk Assessment procedures, adopt within this Protocol liability of States for damage arising from the transboundary movement of LMOs, when they occur as:

- a) a consequence of an action or omission attributable to the State under the provisions established by this Protocol;
- b) conduct that constitutes a breach on an international obligation

/...

of the State under the terms of this Protocol.

2. States, through national legislation and procedures are sovereign to determine whether liability is deemed as an act of a public, civil or individual party under national jurisdiction.

3. Given a contingency in the transboundary movement of LMOs falling within paragraph 1 of this Article, the State of origin shall ensure that compensation is made for harm caused to receiving Parties. The State of origin shall bear the costs of the contingency plan to restore, as far as possible, the conditions that existed prior to the occurrence of the harm. If it is impossible to restore these conditions in full, agreement may be reached on compensation, monetary or otherwise, by the State of origin for the deterioration suffered.

4. Any reasonable measures aiming to reinstate or restore damage or destroyed components of the environment, or to introduce, where reasonable, the equivalent of this components into the environment. National Competent Authorities are entitled to take such measures.

5. Any proceedings in respect of liability under this Article shall lapse after a period of [] years from the date on which the affected Party learned, or could reasonably be expected to have learned, of the harm and of the identity of the State of origin of the transboundary movement of the LMO causing damage.

6. The Parties hereby decide to establish an emergency fund to fulfil requirements arising from contingencies in the transboundary movement of LMOs. This Fund will be constituted by contributions from all Parties.

7. There shall be no liability on the part of the State of origin if the harm was directly due to an act of war, hostilities, civil war, insurrection or a natural phenomenon of an exceptional, inevitable and irresistible character.

Option F

1. The provisions of paragraph 2 shall apply in the event of any transfer, handling or use of LMOs deemed to be illegal traffic under Article 25 (Illegal Traffic), or, where the intending country party or any person or entity under its jurisdiction :

a) fails to comply with the advance informed agreement procedure under Article [] (advance informed agreement) of this Protocol; and/or

b) fails to provide adequate risk assessment in accordance with Article 12 (Risk Assessment); and/or

c) fails to provide adequate risk management strategies and measures in accordance with Article 13 (Risk Management); and/or

d) breaches any of its obligations under this Protocol, resulting in any negative or adverse effects on the environment of the receiving country Party, in particular, the conservation and sustainable use of biological diversity, socio-economic imperatives, and the risks to agriculture and human health.

1. In the case of a breach by the intending country Party or any person or entity under its jurisdiction under paragraph 1 above the intending country Party shall :

a) reimburse the receiving country Party for any costs incurred by the receiving country Party to mitigate and/or

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eliminate any harm and/or adverse effect that has occurred to the environment of the receiving country Party, including the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health; and

b) where the receiving country Party considers appropriate, destroy, remove or dispose the LMO in question at the intending country Party's expense, or, reimburse the receiving country Party for any costs incurred by the receiving country Party in destroying, removing or disposing the LMO; and

c) pay fair and adequate compensation, in monetary form or otherwise, to the receiving country Party. Fair and adequate compensation means the provision of sufficient reparation to enable the receiving country Party to establish and implement measures to rehabilitate and overcome the adverse or negative effects that had occurred.

Option G

1. While importing Parties remain responsible for the use of LMOs, and products thereof, within their national territories, exporting Parties shall be liable for any negative or harmful effects of LMOs, or products thereof, which could not have reasonably been foreseen on the basis of the information provided at the time of the first import.

2. Exporting Parties shall also be liable for any negative or harmful effects produced as a result of any breach of the obligations under this Protocol.

3. Exporting Parties shall also be liable for all forms of transboundary movement of LMOs and products thereof deemed illegal traffic under Article 25 of this Protocol.

4. The Parties from which unintentional transboundary movements of LMOs originate shall pay any costs incurred as a result of the unintentional movements and shall be liable for any resulting negative or harmful effects.

5. All cases of proven liability shall result in the payment of fair and adequate compensation by the exporting Parties to Parties affected.

6. If necessary, the importing Parties may impound, destroy or re-export unauthorised LMOs, or products thereof, at the cost of the exporting Party.

Option H

1. If harm, including transboundary harm, arises as a consequence of LMOs or activities or products involving such organisms, the State or States of origin shall be bound to negotiate with the affected State or States to determine the legal consequences of the harm, and the State or States of origin shall be strictly liable and the harm must be fully compensated.

2. If the harm, including the transboundary harm, proves detrimental to human or animal health, biological diversity, the environment or the socio-economic welfare of the affected State:

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

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origin and the affected State for the deterioration suffered.

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

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

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

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

6. The preceding subparagraphs shall not prevent:

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

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

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

Option I

1. Where activities related to research, handling, production, commercialisation, use and release or introduction of LMOs result in damage to biological diversity, the environment or public health, the importing Party or any natural or legal person represented by the importing Party shall have grounds to initiate an investigation to determine the gravity of the damage caused, the degree of responsibility of the exporting Party or the natural or legal person represented by the Party causing the damage, as well as the compensation to the State affected by the damage caused.

2. All cases of proven liability shall result in the payment of fair and adequate compensation by the exporting Parties to the importing Parties affected.

3. The importing parties may, at the expense of the exporting Party, impound, destroy or re-export unauthorised LMOs or products thereof.

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