Consultation Paper

Proposed Legislation for the Implementation of the Biosafety Protocol

Purpose

This paper outlines the detailed proposal of a new legislation for the implementation of the Cartagena Protocol on Biosafety in Hong Kong for better protection of biological diversity by controlling the release of living modified organisms (GMOs) [Note 1], and seeks public views on the proposal.

Background

The Convention and the Protocol

2. The Convention on Biological Diversity (the Convention) was adopted in the 1992 Earth Summit on Sustainable Development and came into operation in 1993. It provides a comprehensive approach to the conservation of biological diversity, the sustainable use of biological diversity, and the sharing of the benefits arising from the use of genetic resources in a fair and equitable way. There are currently over 190 Parties to the Convention including China, but the Convention has yet to be extended to the Hong Kong Special Administrative Region.

3. Biosafety (i.e. minimizing the risks from the possible adverse effects of modern biotechnology and its products on humans and the environment) is one of the issues addressed by the Convention. In January 2000, Parties to the Convention adopted a Protocol, known as the Cartagena Protocol on Biosafety to the Convention (the Protocol). A copy of the Protocol text and annexes is at Appendix II.

4. The Protocol requires Parties to take necessary and appropriate

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Note 1 See paragraph 5 on what is a "GMO".

legal, administrative and other measures to ensure that the development, handling, transport, use, transfer and release of any GMO, especially focusing on transboundary movement, are undertaken in a manner that prevents or reduces the adverse impacts of GMOs on the conservation and sustainable use of biological diversity, taking also into account risks to human health [Note 2]. However, GMOs which are pharmaceuticals are excluded from the scope of the Protocol. The Protocol came into effect in September 2003. There are currently over 140 Parties to the Protocol including China, but the Protocol is not applicable to the Hong Kong Special Administrative Region. Parties meet about once every two years to consider and adopt decisions on matters necessary for the implementation of the Protocol.

5. The Protocol concerns GMOs. A "living organism" is defined as any biological entity capable of transferring or replicating genetic material, and GMOs are living organisms that possess new combination of genetic material obtained through the use of modern biotechnology that overcome natural reproductive barriers. Living organisms with genetical material altered through traditional breeding and selection techniques (e.g. Hybrid Rice and Golden Sweet Corn) are not GMOs. Non-living products (e.g. cotton fibre) or processed food (e.g. milled maize, canned bean, soy milk) also are not GMOs.

6. The Protocol prescribes an advance informed agreement (AIA) procedure to be followed, prior to the first transboundary movement of GMOs for intentional introduction into the environment of the Party of import. Under the AIA procedure, the exporter must provide a detailed, written notification (including a risk assessment report) of the GMOs to the importing Party in advance of the shipment. The importing Party has to acknowledge receipt of this notification within 90 days and then explicitly authorize the shipment within 270 days or state its reasons for rejecting it. The absence of a response, however, does not imply consent. The purpose of this procedure is to ensure that importing Parties have the opportunity to assess risks that may be associated with

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Note 2 See paragraph 21 below for an elaboration on the phase "adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health".

the GMO before its import.

7. A number of transboundary movements of GMOs are excluded from the AIA procedure. These include:

a) GMOs in transit;

b) GMOs destined for contained use;

c) GMOs intended for direct use as food or feed, or for processing.

The Meeting of the Parties to the Protocol may also identify GMOs as being not likely to have adverse effects on biological diversity and exempt them from the AIA procedure.

8. A Biosafety Clearing House is established by the Protocol Secretariat which contains information on existing laws for implementation of the Protocol in different Parties, summaries of risk assessment of GMOs, decisions regarding import or release of GMOs, etc. The purpose is to facilitate exchange of information on GMOs and assist Parties to implement the Protocol.

9. The Protocol can better ensure protection of our local biological diversity from possible adverse impacts of imported GMOs. The application of the Protocol to Hong Kong will demonstrate Hong Kong's commitment in cooperating with the international community to protect the natural environment. Hong Kong is expected to share similar international obligations relating to the protection of biological diversity. We also need to follow the Protocol's requirements on import and export of GMOs where our trading partners have joined the Protocol.

The Legislative Proposal

10. To implement the Protocol in Hong Kong, we need to enact a new piece of legislation. The following paragraphs summarize the main aspects of the legislative proposal.

Objective

11. The main objective of the proposal is to provide a regulatory

framework to restrict and control the release of GMOs into the local environment. It would enable Hong Kong to fulfill the requirements of the Protocol and other relevant decisions of the Meeting of the Parties to the Protocol, and contribute to ensuring an adequate level of protection against the potential adverse effects of the GMOs on the conservation and sustainable use of biological diversity. The proposed legislation will reflect the requirements of the Protocol and decisions of the Meetings of the Parties to the Protocol, with appropriate adaptation to the local administrative and legal situations.

Key Elements

12. The proposed legislation will have the following key elements: –

a) Define a number of terms used. Most of them would be adapted from the definitions used in the Protocol, in particular the meanings of "GMO" and "release into the environment".

b) Regulate the release of GMOs, and import of GMOs for the purpose of releasing them into the environment. No person should release any GMO, or import any GMO for the purpose of releasing it, into the environment unless it is an approved GMO listed in a register. This restriction would not apply to GMOs in transit, GMOs for direct use as food or feed, or for processing, and GMOs that are pharmaceuticals for humans.

c) Establish a regulatory mechanism for applying to the Agriculture, Fisheries and Conservation Department (AFCD) for approval of a GMO for release into the environment. Applications would need to be accompanied by a report on a risk assessment carried out on the adverse effects of the GMOs. A schedule to the proposed legislation would set out the detailed requirements of the risk assessment.

d) Require an exporter in Hong Kong to send a notification to the authority of the place of import and obtain its prior consent for exporting a GMO to the place for release into its environment. This requirement would not apply to GMOs in transit, GMOs for direct use as food or feed, or for processing, and GMOs that are pharmaceuticals for humans. It also would not apply if the place of import does not impose any notification or prior consent

requirement.

e) Provide penalties for violation of import, export or related enforcement provisions. The proposed maximum penalty is a fine at Level 6 ($100,000 at present) and imprisonment for one year in the case of releasing an unapproved GMO into the environment.

f) Establish a public register containing information on applications received, decisions made, exemptions granted, and any other information relating to the enforcement of the legislation, including the risk assessment reports received. Applicants may request AFCD not to enter certain submitted information (particularly confidential commercial and industrial information, including research and development information) in the register.

g) Provide authorized officers with appropriate powers for effective enforcement of the legislation such as powers to require information, inspect premises, take samples, carry out GMO tests and powers of seizure.

h) Provide AFCD with powers to dispose of things seized or forfeited under the ordinance, and to give directions for disposal of forfeited things or any GMO.

i) Empower the Secretary for the Environment (the Secretary) to make regulations with respect to the details of the control regime, such as documentation requirement.

j) Empower the Secretary to exempt any GMO, with or without conditions, from the approval requirement for its release into the environment following a decision of the Meeting of the Parties to the Protocol which identified the GMO as being not likely to have any adverse effect on biological diversity.

k) Provide transitional arrangements within a certain period of commencement of the legislation.

13. Upon enactment of the proposed legislation, the Secretary will make a regulation with respect to requirements of documentation accompanying import / export shipments. There are no labeling requirements for any GMOs under the proposed legislation except the

documentation during import / export shipments.

Operation

14. AFCD will deploy staff for:

a) processing applications for approval of GMOs for release into the environment;

b) conducting or reviewing risk assessments in relation to proposed release of GMOs into the environment;

c) liaising with the Protocol Secretariat and other relevant overseas authorities on matters related to the implementation of the Protocol in Hong Kong;

d) keeping information on applications received, decisions made, exemptions granted and any other information relating to the enforcement of the legislation, including the risk assessment reports received;

e) maintaining an internet-based database on the new legislation, the register and the Protocol;

f) promoting compliance and curbing irregularities through law enforcement. These will include random inspections of import shipments to check conformity to the documentation requirements, taking samples from import shipment to test for GMOs, etc.;

g) compiling information and making available such information to the Secretariat as required under the Protocol; and

h) conducting publicity and public education programmes.

15. Major issues related to the operation of the proposed legislation are elaborated in the following paragraphs.

Release into the Environment

16. The main purpose of the proposed legislation is to implement the Protocol by addressing the adverse effects that GMOs may have on biological diversity when released into the environment through regulating such releases. An GMO is defined as released into the

environment if it is not in "contained use". "Contained use" means any operation, undertaken within a facility, installation or other physical barrier, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment".

Decision Making Process

17. Applications for the release of GMOs into the environment will be considered in a transparent manner, and will take into account advice of relevant experts on the findings of the risk assessment. It is proposed that upon receipt of an application, AFCD will check if it contains, prima facie, the required information. If yes, information received, except confidential information, will be entered in the register for public inspection. The application will also be submitted to an expert group (see para. 23 below) for advice.

Risk Assessment

18. Risk assessment forms an important part in regulating, managing and controlling the risks associated with the release of GMOs. The intention is to identify and evaluate potential adverse impacts of a GMO on the conservation and sustainable use of biological diversity. It should be carried out on a case-by-case basis, and the nature and level of detail of required information may vary from case to case, depending on the GMO concerned, its intended use and the likely potential receiving environment.

19. A risk assessment should contain the following steps:

a) An identification of any novel genotypic and phenotypic characteristics associated with the GMO that may have adverse effects on biological diversity in the likely potential receiving environment.

b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the GMO.

c) An evaluation of the consequences should these adverse effects be

realized.

d) An estimation of the overall risk posed by the GMO based on the evaluation of the likelihood and consequences of the identified adverse effects being realized.

e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks.

f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the GMO in the receiving environment.

Risks to be Assessed

20. The objective of the Protocol is to contribute to ensuring adequate protection of "the conservation and sustainable use of biological diversity, taking also into account risks to human health". It is obvious that the possible effects of a GMO on biological diversity from the conservation and sustainable use angles would be the main part for consideration in the risk assessment. The effects of the GMO on other parts of the environment, such as air, noise, water, etc., would be outside the scope of the risk assessment of the Protocol.

21. As the Protocol is adopted under the Convention on Biological Diversity, according to *An Explanation Guide to the Cartagena Protocol on Biosafety* [Note 3], it is commonly accepted that "risks to human health" under the Protocol refers to the effects of GMOs on human health resulting from the effects on biological diversity. The effects of GMOs on human health caused by consumption of GMO food products would be outside the scope of the Protocol as it is being dealt with under other

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Note 3 Mackenzie, Ruth, Burhenne-Guilmin, Françoise, La Viña, Antonio G.M. and Werksman, Jacob D. in cooperation with Ascencio, Alfonso, Kinderlerer, Julian, Kummer, Katharina and Tapper, Richard (2003). *An Explanatory Guide to the Cartagena Protocol on Biosafety*. IUCN, Gland, Switzerland and Cambridge, UK. xvi + 295pp.

relevant international fora (e.g. Food and Agriculture Organization of the United Nations and Codex Alimentarius Commission).

22. It is proposed that the above interpretation be adopted in the proposed legislation, i.e. the risk assessment will cover the effects of GMOs on the conservation and sustainable use of biological diversity. Other effects on the environment would not be covered in the assessment. In addition, the effects of GMOs on human health caused by consumption of GMO food products would also not be considered in the proposed legislation.

Expert Group

23. It is proposed that an expert group be established to advise AFCD on matters related to the operation of the proposed legislation, including applications received and risk assessments conducted for GMOs. Members of the group would be appointed by the Director of Agriculture, Fisheries and Conservation and comprise experts from the academic field, industry and NGOs in different relevant fields, e.g. agriculture, biodiversity, biotechnology, risk assessment / management, etc. AFCD should take into account advice of the expert group in deciding whether an application for import / release of a GMO should be approved (with or without conditions).

The Register

24. The main purpose of keeping a register is to provide a centralized source of information necessary for the implementation of the proposed legislation and serving as a biosafety clearing house for Hong Kong. The register is proposed to be established and maintained in digital form and accessible by the public through the internet. It will contain:

a) applications and the supporting information (particularly the risk assessment reports) received;

b) status of the applications (e.g. processing, approved, rejected, etc.);

c) exemptions granted by the Secretary; and

d) any other information relating to the proposed legislation, the Protocol and biosafety;

but will not contain any confidential commercial and industrial information, including research and development information.

25. Copies of entries in the register may be obtained on payment of a prescribed fee.

Shipment Documentation

26. GMOs subject to import or export are required to be accompanied by documentation identifying the GMOs and providing a contact point for further information. Detailed requirements (Appendix I) will be specified in a subsidiary regulation made by the Secretary. These requirements may be revised to reflect, as appropriate, changes in the international requirements under the Protocol in future e.g. in a decision of the Meeting of the Parties to the Protocol.

Sampling and Testing

27. Identification of GMO requires complicated DNA tests using the Polymerase Chain Reaction technique under stringent laboratory conditions and protocols. In addition, it may take a few days before the results are available. It is proposed that AFCD officers be empowered to take samples for GMO testing. The samples will be sent to an accredited laboratory for testing and results may be used for law enforcement and prosecution purposes.

Adventitious Threshold

28. In commercial production and transportation of agriculture products, mixing from different sources is inevitable. GMO varieties may contaminate adventitiously the traditional varieties and shipped as non-GMO products. It is proposed that products with an adventitious presence of 5% or less GMO varieties in the traditional varieties imported for direct use as food or feed, or for processing would be exempted from the documentation requirements for GMOs for direct use as food, feed or

processing. The threshold for export would be in line with the requirement of the place of import in question. However, the documentation requirement for release or contained use would not be exempted if non-GMOs have been contaminated by GMOs.

Transitional Arrangements

29. It is proposed that transitional arrangements be in place for a certain period after the commencement of the proposed legislation (exact time period to be determined). In relation to unapproved GMOs that have been released into the environment before commencement of the proposed ordinance, owners of the GMOs may apply to AFCD for approval for releasing the GMOs into the environment, or report it to AFCD, within this timeframe. AFCD will then, as the case may be, process the application, arrange for the disposal of the GMOs, or direct the owners to dispose of the GMOs in a manner as AFCD thinks fit. During the grace period, GMO shipments may also be imported / exported without the required documentation, and GMOs may be exported without prior notification to and approval from the place of import. However, the import into a place of import has to be in accordance with the import requirements of the place of import.

Implementation Plan

30. We are consulting stakeholders, including food trade associations, relevant importers / traders, environmental groups and academics, and concerned advisory committees such as the Advisory Council on the Environment, on the detailed proposal. The consultation is being announced on AFCD's website and the Business Consultation e-Platform under the GovHK website, and the consultation document has been mailed to stakeholders known to AFCD. Taking into account comments received from the consultation, we plan to finalize the proposed legislation for introduction into the Legislative Council in mid 2009.

31. We have obtained the agreement-in-principle of the Central People's Government (CPG) to extend the application of both the Convention and the Protocol to Hong Kong. We will formally request the CPG to complete the formalities on the extension upon enactment of

the new legislation for implementing the Protocol and completion of the other required preparatory work. The extension is expected to take place in about 2010/2011, taking into account the time required for carrying out consultation with the relevant parties, finalizing the proposed legislation and going through the legislative process.

Advice Sought

32. You are invited to send your views by letter, facsimile or e-mail to the Agriculture, Fisheries and Conservation Department at the following address on or before 31 August 2009:

Biodiversity Conservation Division
Agriculture, Fisheries and Conservation Department
6/F, Cheung Sha Wan Government Offices,
303 Cheung Sha Wan Road, Kowloon
Fax: 2314 2802
E-mail: biosafety@afcd.gov.hk

Agriculture, Fisheries and Conservation Department

Revised July 2009

Appendix I

Documentation Requirements for Shipment during the Import or Export of GMOs

Information Requirements

GMO that are intended for direct use as food or feed, or for processing, should clearly identify that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information.

2. The documentation should clearly indicate that:-

a) In cases where the identity of the GMOs is known, the shipment contains living modified organisms that are intended for direct use as food or feed, or for processing; or in cases where the identity of the GMOs is not known, the shipment may contain one or more living modified organisms that are intended for direct use as food or feed, or for processing;

b) The GMOs are not intended for intentional introduction into the environment;

c) The common name, scientific name and, where available, commercial names of the GMOs;

d) The transformation event code of the GMOs or, where available, as a key to accessing information in the Biosafety Clearing-House, its unique identifier code;

e) The internet address of the Biosafety Clearing-House for further information;

f) The details of a contact point for further information.

3. GMOs that are destined for contained use should clearly identify them as living modified organisms; and specify any requirements for the safe handling, storage, transport and use, and the contact point for further

information, including the name and address of the individual and institution to whom the GMOs are consigned.

4. The documentation should clearly indicate that: -

a) The shipment contains "living modified organisms", the common and scientific names of the GMOs and that the GMOs are "destined for contained use"

b) The name and address of the consignee, and exporter or importer, as appropriate, including contact details necessary to reach them as fast as possible in case of emergency;

c) Any requirements for the safe handling, storage, transport and use of the GMOs under applicable existing international instruments, domestic regulatory frameworks or under any agreements entered into by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;

d) The commercial names of the GMOs, if available, new or modified traits and characteristics such as event(s) of transformation, risk class, specification of use, as well as any unique identification, where available, as a key to accessing information in the Biosafety Clearing-House;

5. GMOs that are intended for intentional introduction into the environment of the place of import should clearly identify them as GMOs; specify the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use of GMOs, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contain a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

6. The document should clearly indicate that: -

a) The shipment contains GMOs for intentional introduction into the environment and a brief description of the GMOs, including their common and scientific names, relevant traits and genetic modification, including transgenic traits and characteristics such

as event(s) of transformation or, where available and applicable, a reference to a system of unique identification;

b) Any requirements for the safe handling, storage, transport and use of the GMOs as provided under applicable existing international requirements, domestic regulatory frameworks, or under any agreement entered into by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;
c) The name and address of the exporter and importer;
d) The details of the contact point for further information, including an individual or organization in possession of relevant information in case of emergency;
e) A declaration that the movement of the GMOs is in conformity with the requirements of the Protocol applicable to the exporter;
f) The commercial name, where available, risk class, and import approval for the first transboundary movement of GMOs.

Form of Documentation

7. There is no specific requirement regarding the form of documentation accompanying GMO shipments. The use of a commercial invoice or other documents required or utilized by existing documentation systems, or documentation as required by other local legislation and / or administrative frameworks is acceptable as documentation that should accompany the GMO shipments. Such documentation should include the information specified in the paragraphs above (as the case may be) and allow for easy recognition, transmission and effective integration of the information requirements. In addition to commercial invoices, other forms of documentation that are acceptable include import / export manifests, licences or certificates issued or required under other legislation e.g. phytosanitary certificates.

Appendix II

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

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

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

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

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

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

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

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

Article 1

OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 2

GENERAL PROVISIONS

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

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. 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.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3

USE OF TERMS

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f)"Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i)"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j)"Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4
SCOPE

This Protocol shall apply to the transboundary movement, transit, handling

and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 5

PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

Article 6

TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional

transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8
NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9
ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

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

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, prima facie, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10
DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article 11

PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The

Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and

capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12
REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

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

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

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13
SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be

provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14

BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article 15

RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16

RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage

and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. 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, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

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

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

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

Article 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

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

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

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

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

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

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

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

Article 21
CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted

under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

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

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

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

(d) Any methods and plans for emergency response.

Article 22
CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in

transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 23
PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

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

Article 24
NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with

non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25
ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 26
SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27
LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article 28

FINANCIAL MECHANISM AND RESOURCES

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

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

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

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

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

Article 29

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

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

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

3. When the Conference of the Parties serves as the meeting of the Parties to this

Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

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

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

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

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

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

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

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

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

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

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

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

Article 30
SUBSIDIARY BODIES

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

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

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

Article 31
SECRETARIAT

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

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat

shall apply, mutatis mutandis, to this Protocol.

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

Article 32

RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33

MONITORING AND REPORTING

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

Article 34

COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35

ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36

SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38

RESERVATIONS

No reservations may be made to this Protocol.

Article 39

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

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

Article 40

AUTHENTIC TEXTS

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

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS
UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

Annex II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

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

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable,

including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.
