

Biosafety Regulation Sourcebook

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January 2006

Biosafety Regulation Sourcebook

Livre source de la réglementation de biosécurité

Libro de referencia de normativas sobre seguridad de la biotecnología

CONTENTS/CONTENU/CONTENIDOS

1. Authors' Introduction/Présentation des auteurs/Introducción del autor

The Authors' Introduction explains the basis for and the development, intended use and availability of the Model Act. It concludes with a summary of the Act.

La présentation des auteurs explique les bases pour et le développement, la visée de l'utilisation et la disponibilité de l'Acte Modèle. Elle conclut avec un résumé de l'Acte

En la introducción del autor se explican las bases que inspiran y sientan el desarrollo, utilización prevista y disponibilidad del Código Base. Incluye un resumen del Código.

2. Model Act/l'Acte Modèle/el Código Base

The Model Act provides proposed provisions for a transparent, effective and workable biosafety regulatory framework and explanation by the authors on key issues relating to interpretation of the Cartagena Protocol on Biosafety.

L'Acte Modèle fournit des propositions de dispositions pour une structure de réglementation de biosécurité qui soit transparente, effective et réalisable et l'explication par les auteurs des enjeux clés relatifs à l'interprétation du Protocole de Cartagena sur la biosécurité.

El Código Base proporciona una propuesta de disposiciones para un marco de trabajo transparente, efectivo y practicable y una explicación de los autores sobre los temas clave vinculados a la interpretación del Protocolo de Cartagena sobre la seguridad de la biotecnología.

3. Model Act - Questions and Answers/Acte Modèle - Questions et réponses/Código base - Preguntas y respuestas

The authors provide answers to questions that have been or may be raised about the Model Act.

Les auteurs fournissent les réponses aux questions qui ont été ou peuvent être posées à propos de l'Acte Modèle.

Los autores dan respuesta a preguntas que han surgido o que puedan surgir con respecto al Código.

4. Biosafety Implementation Toolkit/La trousse à outils de la mise en oeuvre de la biosécurité/Herramientas de aplicación de la seguridad de la biotecnología

The checklist adopted by the Parties to the Protocol is an extremely useful tool in analyzing whether existing or proposed legislation complies with the Biosafety Protocol.

La liste de contrôle adoptée par les Parties au Protocole est un outil extrêmement utile pour analyser si la législation existante ou proposée est conforme au Protocole de biosécurité.

La agenda adoptada por las Partes firmantes del Protocolo constituye una herramienta de gran utilidad a la hora de analizar si la legislación existente o la legislación propuesta cumplen con las exigencias del Protocolo de seguridad de la biotecnología.

5. Proposals for Addressing Key Issues of National Biosafety Legislation/Propositions pour aborder les questions clés de la législation nationale de biosécurité/Propuestas de acercamiento a temas clave de la legislación nacional en materia de seguridad de la biotecnología

This chart provides helpful tips and proposals on how to address certain important issues in biosafety regulatory systems.

Ce schéma montre des astuces et des propositions utiles qui pourraient aider à aborder certains enjeux importants dans les systèmes de réglementation de la biosécurité.

Este cuadro proporciona consejos y propuestas útiles sobre cómo afrontar determinadas cuestiones importantes relativas a los sistemas reguladores de la seguridad de la biotecnología.

6. Model Documentation Requirements for Living Modified Organisms for Food or Feed, or for Processing (LMO/FFPs)/Exigences de documentation modèle pour les Organismes Vivants Modifiés destinés à l'alimentation humaine, animale et à la transformation (OVM/FFPs)/Documentación básica requerida para los organismos vivos modificados para uso como alimento humano o animal o para su procesamiento

This document is based on the trilateral agreement among Mexico, Canada and the United States concerning documentation for Living Modified Organisms for Food, Feed or Processing and may serve as a helpful model for similar agreements among other countries.

Ce document est basé sur l'accord trilatéral entre le Mexique, le Canada, et les Etats-Unis concernant la documentation des organismes vivants modifiés pour l'alimentation humaine, animale ou pour la transformation et peut servir comme un modèle utile pour les accords similaires entre les autres pays.

Este documento se basa en el acuerdo trilateral suscrito por México, Canadá y Estados Unidos relativo a la documentación exigida para los organismos vivos modificados para uso como alimento humano o animal o para su procesamiento, y puede resultar útil como modelo para acuerdos similares entre otros países.

7. Implementing a WTO Consistent Biosafety Regulatory Framework/Application d'un cadre réglementaire de prévention des risques biotechnologiques en accord avec l'OMC/ Aplicación de un Marco Reglamentario de Seguridad de la Biotecnología Coherente con la OMC (Synopsis)

Countries that are Party to both the Protocol and Members of the WTO can implement the Protocol in a manner that complies with their WTO obligations.

Les pays qui sont Parties au Protocole et Membres de l'OMC peuvent appliquer le Protocole d'une manière parfaitement cohérente avec les obligations de l'OMC.

Para los países que son Partes del Protocolo y miembros de la OMC, es posible aplicar el Protocolo de manera totalmente coherente con las obligaciones de la OMC.

8. Implementing a WTO Consistent Biosafety Regulatory Framework/Application d'un cadre réglementaire de prévention des risques biotechnologiques en accord avec l'OMC/ Aplicación de un Marco Reglamentario de Seguridad de la Biotecnología Coherente con la OMC (Full Text)

9. Cartagena Protocol on Biosafety/ Protocole de Cartagena sur la prévention des risques biotechnologiques /Protocolo de Cartagena sobre seguridad de la biotecnología

A copy of the Protocol is included for easy reference.

Une copie du Protocole est jointe afin de faciliter toute recherche de référence.

Se incluye una copia del Protocolo con el fin de facilitar el acceso a las referencias.

Authors' Introduction

Arent Fox and International Environmental Resources are pleased to make this Biosafety Regulation Sourcebook freely available as a public service to all parties who are interested in the development of biosafety regulatory frameworks that implement the provisions of the Cartagena Protocol on Biosafety.

Included in this Sourcebook is a Model Act that sets forth proposed provisions for a transparent, effective and workable national biosafety regulatory framework. While there are other reference materials available, the Model Act is the only reference document currently available that was specifically designed to implement and ensure compliance with the Cartagena Protocol on Biosafety.

Basis for the Model Act

Scientists in all corners of the globe have mounted ambitious research programs that apply the techniques of modern biotechnology to the development of valuable new agricultural, industrial, health care and consumer products. National governments have been struggling to keep up with these new developments in order to ensure that, while their citizens are able to enjoy the benefits of this new technology, those benefits do not come at the expense of health, safety or the environment.

The Cartagena Protocol on Biosafety (Protocol)¹ was adopted in January 2000, pursuant to a mandate contained in the Convention on Biological Diversity (CBD). The stated objective of the 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.

Countries that have ratified or intend to ratify the Protocol must ensure that they have appropriate biosafety measures in place. Among other things, the Protocol provides a mechanism for “advanced informed agreement” by importing countries of “living modified organisms” intended for intentional introduction into the environment on the basis of scientific risk assessment. The Protocol took legal effect on 11 September 2003, and has now been ratified by more than 130 countries.

¹ The Protocol is included as part of this Sourcebook and is also available, along with additional information and other related materials, from the Secretariat of the Convention on Biological Diversity at www.biodiv.org.

Adoption of a national biosafety regulatory framework is essential in order for governments to respond to the challenges posed by a rapidly developing technology. The framework must ensure an adequate level of protection and, at the same time, provide sufficient flexibility in recognition of likely advances in scientific understanding.

Since the Biosafety Protocol was adopted, multiple programs have been initiated to build capacity in developing countries in the field of biosafety. These programs largely seek to share experience about existing approaches to biosafety in North America, Europe, Australia and elsewhere with government officials charged with developing their own national frameworks. Notwithstanding these important initiatives, however, government officials around the world still have little concrete guidance to assist them in drafting their national biosafety frameworks in line with CBD, Protocol and other international obligations.

Development of the Model Act

To contribute to this process of drafting national biosafety frameworks, two legal experts in the field of biosafety – Stanley H. Abramson, Esq., Arent Fox PLLC, U.S.A. and Laura van der Meer (*née* Reifschneider), International Environmental Resources *sprl*, Belgium - developed a Model Act that contains proposed provisions for a transparent, effective and workable national biosafety regulatory framework. Importantly, the Model Act is the only reference currently available that is compliant with the Biosafety Protocol.

The Model Act is an independent undertaking, unrelated to any other product or initiative, which was finalized and published in December 2002. The authors have not sought or requested endorsement or approval of the Model Act by any organization, government or company and remain solely and entirely responsible for its approach and content.

Peer Review Process

The Model Act was subject to independent peer review by two eminent international legal scholars with long standing involvement in the field of biosafety: Dr. Julian Kinderlerer, Law Department, University of Sheffield, United Kingdom, and Dr. Katharina Kummer Peiry, Kummer EcoConsult, Switzerland. To test the appropriateness of the proposed provisions, the peer reviewers were asked to provide an independent peer review of an initial draft of the model. These reviewers both found that the draft largely complied with the requirements of the Biosafety Protocol and they found it to be a useful contribution. They also offered numerous suggestions for amendments to ensure that the provisions would be fully compliant with the Protocol and address all of its obligations as well as many helpful comments to improve the quality and clarity of the

provisions. The vast majority of these comments and suggestions were incorporated into the Model Act.²

Intended Use of the Model Act

The Model Act is designed to assist developing countries that may need to introduce new administrative and legal frameworks for environmental safety with respect to the import, export and use of living modified organisms within their territories. It is based on provisions found in existing and well-functioning biosafety regulatory schemes around the world that have been amended and shaped in accordance with actual experience in the field. Several explanatory notes are provided at the end of the Act to aid the reader in understanding the relationship between the provisions of the Act and the Biosafety Protocol and to further explain drafting decisions made by the authors.

The authors caution that no matter how good the “model,” one should avoid the temptation to engage in a simple cut and paste exercise. Models – or well-functioning laws in existence in other countries – cannot and do not take into account the differing legal structures and traditions, the varying environmental conditions and concerns, and the societal and cultural uniqueness of each country. Furthermore, one should not necessarily assume that drafting a biosafety framework begins with a blank piece of paper. Often the place to start is with laws already in force that can be utilized or modified to cover biosafety. These might include phyto-sanitary measures; import and export regulations for agricultural produce or living organisms; controls over the use of herbicides and pesticides in agriculture; health and safety regulations; or environment protection laws. Whether new legislation is created or existing legislation is modified to serve the required biosafety function, care must be taken to ensure that the entire legal system is consistent and workable and that the relationship among the various components is clear.

The authors intend for this Model Act to provide a structure that can:

- Assist regulators, scientists and other stakeholders with initial efforts to prepare new national biosafety frameworks or to consider amendments that might be required to existing laws and regulations;
- Help governments review and test concepts and provisions under consideration in existing national legislative proposals; and
- Be readily adapted to suit local needs and adopted, in whole or in part, to meet national objectives.

² The original draft, the reviewers' comments and a document detailing how the comments were addressed in the Model Act are available upon request from the authors at ModelBiosafetyAct@arentfox.com.

The Model Act provides a regulatory framework that defines what is regulated and the key mechanisms for implementation. It is envisioned that secondary legislation, including regulations, guidance documents, handbooks, etc. would be created to provide additional details. This structure has been selected because it provides a good balance between certainty for the regulated community and flexibility for the regulators to make adjustments to the details as experience is gained and scientific understanding advances.

Availability of the Model Act

The Model Act and accompanying materials are available free of charge as a public service to all parties interested in the development of biosafety regulatory systems that implement the Biosafety Protocol. The Model Act may be downloaded at www.arentfox.com/modelbiosafetyact.pdf.

Since its publication on the Internet, it has been used, along with other biosafety implementation tools, in workshops hosted by various international organizations, such as the International Service for the Acquisition of Agricultural Applications (ISAAA). It also has been provided directly to those who have requested it.

Comments and inquiries regarding the Model Act or any of the other material in this Sourcebook are welcome and should be directed to ModelBiosafetyAct@arentfox.com. All comments will be considered in preparing future revisions of the Act and materials.

Summary of the Model Act

- Adoption of a national biosafety regulatory framework is essential in order for governments to comply with the Biosafety Protocol and respond to challenges posed by a rapidly developing technology:
 - Countries that have ratified or intend to ratify the Protocol must ensure that they have appropriate biosafety measures in place.
 - Regulatory frameworks must ensure an adequate level of protection and, at the same time, provide sufficient flexibility in recognition of likely advances in scientific understanding.

- The Model Act is designed to assist developing countries that may need to introduce new administrative and legal biosafety frameworks:
 - Provides a structure to assist with initial efforts to prepare new biosafety frameworks or consider amendments to existing laws.
 - Helps governments to review and test concepts and provisions under consideration in pending draft measures.
 - Can be readily adapted to suit local needs and adopted, in whole or in part, to meet national objectives.
 - Based on workable regulatory systems already in existence around the world.
 - Intended to foster development of efficient and effective regulatory systems based on sound scientific principles.

- The Model Act is the only reference currently available that is compliant with the Biosafety Protocol:
 - Uses Protocol terminology.
 - Implements Advanced Informed Agreement procedure.
 - Follows scientific approach to risk assessment.
 - Provides for precautionary approach to government action in face of scientific uncertainty.
 - Includes public awareness and participation provisions.
 - Allows for future amendments as experience and knowledge grow.

- The Model Act is an independent project of two legal experts in the field of biosafety:
 - Unrelated to any other product or initiative.
 - Peer reviewed by international biosafety experts.
 - Freely available to all interested parties.

MODEL ACT

PROPOSED PROVISIONS FOR A TRANSPARENT, EFFECTIVE AND WORKABLE BIOSAFETY REGULATORY FRAMEWORK

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January 2006*

* The Model Act was first published in December 2002 by Stanley Abramson and Laura van der Meer (*née* Reifschneider) following independent peer review. In November 2004, the authors published a revised version, which included minor corrections to the original text for which the authors are solely responsible. This present version has been updated to ensure consistency with disciplines imposed by the World Trade Organization and its agreements.

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PREAMBLE

Authors' Note:

Depending on a country's legal traditions and requirements, a short preamble may be developed to briefly state the government's policy on biotechnology, mention its related international commitments (e.g., ratification of the Cartagena Protocol on Biosafety), and to state the legal authority under which the Act is created.

The preamble also may identify other legislation applicable to living modified organisms such as legislation and/or regulations governing food safety, pharmaceuticals, phytosanitary standards, seed registration, consumer protection, environmental protection, customs or other requirements. Careful consideration as to how a new biosafety framework act relates to and builds upon existing legislation and regulations will help to ensure a workable system without conflicts or overlap.

Where existing legislation and/or regulations in a country already exist, such legislation and/or regulations can be used in lieu of those suggested in this model law by simply including references to the existing legal provisions. Similarly, countries that already have codified relevant definitions or concepts such as the precautionary approach in other national laws in a manner that is consistent with the Cartagena Protocol may wish to refer to such legal provisions in the Preamble or text of the Act as appropriate so that the interpretation of the Act is clear and consistent with other laws.

Finally, reference to international bodies of which a country is a member, such as the World Trade Organization, and other relevant international agreements to which a country is party is useful to indicate that the Act has been developed in line with these applicable rights and obligations.ⁱ

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PART ONE: GENERAL PROVISIONS

Article 1. Objectives

- (a) In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Act is to ensure an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health;ⁱⁱ
- (b) To provide a transparent and predictable process for review and decision-making on such LMOs and related activities; and
- (c) To implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol).

Article 2. Definitions

- (a) "Applicant" means a person or country submitting an application, notification or petition pursuant to the provisions of this Act.ⁱⁱⁱ
- (b) "Biosafety Clearing House" means the information exchange mechanism established under Article 20 of the Cartagena Protocol.
- (c) "Cartagena Protocol" means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.
- (d) "Competent Authority" means the entity responsible for implementation of this Act.
- (e) "Contained use" means any operation or activity, undertaken within a facility, installation or other physical structure, which involves LMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment and the general population.
- (f) "Export" means the intentional transboundary movement from the area of national jurisdiction of [name of country] to the area of national jurisdiction of another country.

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- (g) "Import" means the intentional transboundary movement into the area of national jurisdiction of [name of country] from the area of national jurisdiction of another country.
- (h) "Living modified organism" (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
- (i) "Intentional introduction into the environment" means any deliberate use of LMOs subject to this Act that is not contained use, but does not include LMOs imported for direct use for food or feed or for processing.^{iv}
- (j) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.
- (k) "Modern biotechnology" means the application of:
 - (i) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
 - (ii) 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.
- (l) "National Focal Point" means the entity designated to be responsible on behalf of [name of country] for liaison with the Secretariat of the Cartagena Protocol.
- (m) "Operator" means any person conducting activities authorized or otherwise allowed under this Act.
- (n) "Person" means a juridical or natural person.
- (o) "Placing on the market" means action, other than pre-commercial licensing, which makes an LMO or LMOs available to third parties on a commercial basis.

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- (p) "Registry" means the compilation of LMOs or activities that are authorized, exempted or subject to simplified procedures in accordance with this Act and regularly published by the Competent Authority pursuant to Article 19.
- (q) "Risks to human health" means the potential impact on human beings as a direct result of an adverse effect on the conservation and sustainable use of biological diversity.^v
- (r) "Secretariat of the Cartagena Protocol" means the Secretariat established by Article 31 of the Cartagena Protocol.

Article 3. Scope

- (a) Subject to the exceptions set forth in this Act or provided for by regulation hereunder, this Act shall apply to the contained use, intentional introduction into the environment, and import and export of LMOs that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
- (b) This Act shall not apply to:
 - (i) LMOs that are pharmaceuticals for human use;^{vi}
 - (ii) LMOs in transit through but not destined for use in [name of country]; and
 - (iii) Any other LMOs or categories of LMOs that are exempted pursuant to Article 13 of this Act.

PART TWO: INSTITUTIONAL ARRANGEMENTS

Article 4. Establishment of Competent Authority

- (a) [Name of office or agency] shall be established as the Competent Authority for purposes of the administration of this Act and any regulations promulgated hereunder.
- (b) The primary functions of the Competent Authority are:
 - (i) To receive, respond to and make decisions on notifications pursuant to Article 6 and applications pursuant to Articles 7

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et seq. in consultation with the Scientific Advisory Committee and in conformity with the requirements of this Act;

- (ii) To establish administrative mechanisms to ensure the appropriate handling, dissemination, and storage of documents and data in connection with the processing of applications and notifications and other matters covered by this Act; and
 - (iii) To promote public awareness and education concerning the activities regulated under this Act, including through the publication of guidance and other materials that explain and elaborate on the risk assessment, risk management and authorization processes.
- (c) The Competent Authority shall also serve as the National Focal Point.^{vii}
- (d) The primary functions of the Competent Authority serving as the National Focal Point are:
- (i) To receive, process, and respond to information and notifications from the Secretariat of the Cartagena Protocol; and
 - (ii) To facilitate international information sharing as set forth in Article 21.

Article 5. Establishment of Scientific Advisory Committee

- (a) A Scientific Advisory Committee (SAC) shall be established by the Competent Authority for the purpose of conducting risk assessments and providing scientific and other technical advice and assistance to the Competent Authority. The responsibilities of the SAC shall include:
- (i) Conducting risk assessments;
 - (ii) Reviewing risk assessments provided in applications or notifications;
 - (iii) Reviewing risk management measures;

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- (iv) Recommending containment measures, limitations on the duration of authorizations, reporting mechanisms, remedial measures, monitoring procedures and other appropriate and scientifically sound conditions and risk management measures; and
 - (v) Providing such other expert advice and assistance as the Competent Authority may request.
- (b) The SAC shall consist of a core group of scientific experts appointed by the Competent Authority from the following fields:
- (i) Plant breeding and genetics;
 - (ii) Agronomy;
 - (iii) Weed science;
 - (iv) Plant pathology;
 - (v) Animal breeding and genetics;
 - (vi) Animal pathology;
 - (vii) Environmental toxicology;
 - (viii) Ecology;
 - (ix) Entomology;
 - (x) Virology; and
 - (xi) Microbiology.
- (c) The SAC may establish appropriate subcommittees and designate chairpersons of any such subcommittees, who shall be drawn from the members of the SAC. The SAC may appoint additional members to subcommittees as may be required. Members of the SAC and any subcommittees established hereunder shall be drawn from government agencies or independent institutions including research institutes and universities and other academic institutions.

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- (d) The SAC also may appoint temporary non-voting expert advisors from scientific disciplines not otherwise adequately represented on the SAC and its subcommittees.
- (e) All members of the SAC and its subcommittees and all advisors shall be required to disclose publicly any and all actual and potential conflicts of interest relating to any risk assessment or any other matter upon which the SAC or subcommittee may be consulted by the Competent Authority. An individual having an actual or potential conflict of interest with regard to a particular matter shall not participate in any risk assessment, discussions or deliberations concerning that matter and shall be removed from the SAC or subcommittee in cases where multiple actual or potential conflicts impair the individual's ability to serve in an independent or impartial manner.
- (f) Internal procedures for the operation of SAC and its subcommittees shall be proposed by the SAC and shall be approved by the Competent Authority and established by regulation. Such regulations shall provide for all matters necessary for the effective and transparent operation of the SAC and any subcommittees established hereunder but shall prescribe the terms of reference and competence of the SAC and shall include, at a minimum, mechanisms and procedures for:
 - (i) Designating members and chairpersons of the SAC and its subcommittees, appointing advisors and specifying rules of procedure for the SAC and its subcommittees, and for the participation of advisors in the SAC or its subcommittees;
 - (ii) Ensuring the absence of conflicts of interest among members of the SAC and its subcommittees and advisors to the SAC and its subcommittees in conformity with paragraph (e);
 - (iii) Providing appropriate remuneration for members of the SAC and its subcommittees and advisors to the SAC and its subcommittees; and
 - (iv) Ensuring the protection of confidential information as required by Article 9 of this Act, including a declaration that any information attained by virtue of membership in the SAC

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or a subcommittee, or appointment as an advisor to the SAC or a subcommittee, shall not be disclosed to others or used for any research, development or commercial purpose without the express written authorization of the Applicant identifying the information as confidential pursuant to Article 9.

PART THREE: NOTIFICATION AND AUTHORIZATION REQUIREMENTS

Article 6. Notification Requirements and Procedures for Contained Use Activities

- (a) No person shall conduct any contained use activities involving LMOs or import LMOs for such purposes without the prior submission of a notification to the Competent Authority as set forth in this Article, except as provided under Article 13(a).
- (b) A notification of intent to conduct activities with LMOs under contained use pursuant to paragraph (a) shall be submitted at least sixty (60) days before the activities covered by the notification are due to begin.
- (c) The notification shall include:
 - (i) The name and contact information for the Applicant;
 - (ii) The location where contained use activities will be undertaken;
 - (iii) The name and identity of the LMO or LMOs involved;
 - (iv) The nature and purpose of the activities, including such activities as storing, transporting, producing, culturing, processing, destroying, disposing, or using the LMOs in any other way;
 - (v) A description of the containment measures to be provided and the suitability of those measures for the LMOs and activities to be undertaken;
 - (vi) A description of any potential risks associated with the LMOs and activities to be undertaken; and

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- (vii) A description of remedial measures to be undertaken in the event of any unintentional introduction into the environment of the LMOs that may occur as a result of the activities to be conducted.
- (d) If the Applicant receives no response within sixty (60) days of the submission of the notification, the proposed activities may commence.
- (e) In response to the submission of a notification, the Competent Authority may, in consultation with the SAC, request additional information, including a risk assessment carried out in a scientifically sound manner, in accordance with Annex II and recognized risk assessment techniques. The Competent Authority shall inform the Applicant in writing of the additional information sought and the procedure the Competent Authority will follow in taking further action on the notification.
- (f) Where additional information is sought by the Competent Authority under paragraph (e), a final written decision as to whether the proposed activities may proceed shall be provided by the Competent Authority to the Applicant no later than sixty (60) days following receipt of the additional information. In the event the proposed activities are not permitted as requested in the notification, the Competent Authority shall include in its final written decision the reasons for the prohibition or any limitations or conditions that may be placed on the proposed activities.
- (g) Regulations governing the conduct of contained use activities, including relevant definitions, risk classifications, waste and disposal requirements and procedures, and requirements for risk assessments, shall be promulgated pursuant to Article 28 of this Act.^{viii}

Article 7. Authorization Requirements for Intentional Introduction into the Environment

- (a) The following activities are prohibited unless authorized by the Competent Authority in conformity with this Act:
 - (i) The intentional introduction into the environment of an LMO for purposes other than placing on the market; and

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- (ii) Placing on the market of an LMO.
- (b) No person shall import an LMO for activities subject to paragraph (a) without authorization under this Act.^{ix}
- (c) Persons proposing to export LMOs covered by this Act from [name of country] to another country party to the Cartagena Protocol shall:
 - (i) Notify the competent authority of the proposed party of import, in writing, prior to the first transboundary movement of an LMO for intentional introduction into the environment of the party of import by supplying, at a minimum, information specified in Annex I, in accordance with the Cartagena Protocol and any applicable domestic legislation;
 - (ii) Include a declaration that all information provided in such notification is factually correct; and
 - (iii) Prior to shipment, provide to the Competent Authority a copy of the authorization granted by the importing country where authorization is required under the Cartagena Protocol and/or the applicable laws of that country.^x

Article 8. Application Procedures for Intentional Introduction into the Environment

- (a) Any person proposing to intentionally introduce an LMO into the environment shall submit to the Competent Authority an application that complies with the requirements of this Article and describes the activity or activities for which authorization is sought, except as provided under Article 13.
- (b) Applicants shall include in their submissions:
 - (i) The information specified in Annex I relevant to assessment of the proposed activity,^{xi} with the exception of any information the Competent Authority identifies as unnecessary in pre-application consultations;
 - (ii) A risk assessment in conformity with Annex II,^{xii} and

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- (iii) Any additional information applicants deem relevant to an assessment of the potential risks and/or benefits of the requested activity.
- (c) All applications shall include a declaration that the information contained therein is factually correct.
- (d) An Applicant may withdraw its application at any time prior to the issuance of a final decision by the Competent Authority without prejudice.

Article 9. Confidential Information

- (a) The Competent Authority shall:
 - (i) Permit the Applicant to identify information provided to the Competent Authority in accordance with the requirements of this Act and any regulations promulgated hereunder, including information contained in notifications, applications and other written submissions, that is to be treated as confidential, with justification for claims of confidentiality to be provided upon request;
 - (ii) Decide whether it accepts as confidential the information designated by the Applicant;
 - (iii) Prior to any disclosure of information identified by the Applicant as confidential, inform the Applicant of its rejection of the claim of confidentiality, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure; and
 - (iv) In the event that an Applicant withdraws or has withdrawn an application, respect the Applicant's claims of confidentiality, including claims for that information on which the Competent Authority and the Applicant disagree as to its confidentiality.
- (b) The Competent Authority shall neither use nor permit the use of confidential information accepted as confidential under paragraph (a) for any purpose not specifically authorized under this Act except with the written consent of the Applicant and shall ensure that such

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information is protected by all persons involved in handling or reviewing applications or other written submissions under this Act.

- (c) Without prejudice to paragraph (a)(iv) above, the following information shall not be considered confidential:
 - (i) The name and address of the Applicant;
 - (ii) A general description of the LMO;
 - (iii) A summary of risk assessments performed on the LMO; and
 - (iv) Any methods and plans for emergency response.

- (d) In all cases, the Competent Authority shall ensure that natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices^{xiii} so long as such information:
 - (i) a secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
 - (ii) has commercial value because it is secret; and
 - (iii) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Article 10. Acknowledgment and Preliminary Response

- (a) Upon receipt of an application submitted under Article 8, the Competent Authority immediately shall refer the application to SAC for prompt screening for *prima facie* completeness.

- (b) As soon as possible and, in any event, within thirty (30) days of receipt of the application, based on information provided by SAC,

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the Competent Authority shall acknowledge receipt of the application and respond, in writing, to the Applicant.

- (c) The preliminary response shall include:
 - (i) The date of receipt of the application; and
 - (ii) Whether the application, *prima facie*, contains the required information or, if not, precisely what additional information within the scope of Annex I is required so that the Applicant may take corrective action.
- (d) If additional information is required, the number of days the Competent Authority must wait for the information shall not be included in calculating the timeframe for making a final decision under Article 12. Notwithstanding this provision, even when the application has deficiencies, the Competent Authority shall proceed as far as practicable with the procedure if the Applicant so requests.
- (e) Upon request, the Applicant shall be informed of the stage of the procedure, with any delay explained.^{xiv}

Article 11. Risk Assessment and Risk Management

- (a) The Competent Authority shall ensure that appropriate and adequate risk assessments are carried out for all activities that require authorization under Article 7.
- (b) Risk assessment, including the auditing of risk assessments, shall be carried out in a scientifically sound manner, in accordance with Annex II and recognized risk assessment techniques. Risk assessments shall take into account available information concerning any potential exposure to the LMO. Such risk assessments shall be based on the information included in the application and any other available scientific evidence.^{xv}

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- (c) The SAC shall audit risk assessments submitted by the Applicant and shall conduct or cause to be conducted any additional risk assessments as required on a case-by-case basis. In carrying out its risk assessment and auditing activities, the SAC shall take into account any risk management measures proposed by the Applicant.^{xvi} Where additional risk assessment is required, it may be undertaken by the Applicant, SAC or other experts at the discretion of the Competent Authority.^{xvii}
- (d) Upon conclusion of the risk assessment and auditing process, the SAC shall provide to the Competent Authority a risk assessment report that gives its opinion, with justifications, on the disposition of the application and indicate any additional risk management measures that may be necessary to minimize identified risks. The report should include a summary of the risk assessment that does not include any confidential information subject to protection under Article 9.
- (e) The Competent Authority shall ensure that appropriate mechanisms, measures or strategies are in place to regulate, manage or control risks identified during the risk assessment process and are imposed only to the extent necessary to protect human, animal or plant life or health.^{xviii}
- (f) The Competent Authority shall provide the risk assessment report described in paragraph (d) to the Applicant within three (3) days of receipt of the report from the SAC. The Applicant may submit comments on the SAC report in writing within thirty (30) days of its receipt of the report. Any such comments shall be provided to the SAC and shall be considered by the Competent Authority, in consultation with the SAC, in decision-making under Article 12(b).

Article 12. Decision-making and Communication of Decision

- (a) Following receipt of the risk assessment report, the Competent Authority shall make a final decision concerning the authorization requested in the application submitted under Article 8.
- (b) Any decision rendered under paragraph (a) shall be based upon:
 - (i) The information submitted by the Applicant under Article 8;

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- (ii) The risk assessment report prepared by the SAC in accordance with Article 11(d);
 - (iii) Any written comments provided by the Applicant in accordance with Article 11(f); and
 - (iv) Any relevant comments submitted by the public pursuant to Article 20.^{xix}
- (c) [In reaching a decision, the Competent Authority also may take into account, consistent with the international obligations of [name of country], socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.]^{xx}
- (d) 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, taking also into account risks to human health, shall not prevent the Competent Authority from making a decision, as appropriate, in order to avoid or minimize such potential adverse effects.^{xxi}
- (e) A decision on the basis of subsection (d) may be made where relevant scientific information is insufficient on the basis of available pertinent information, however, any decision shall be provisional and requires the Competent Authority:
- (i) To seek to obtain the additional information necessary for a more objective assessment of risk; and
 - (ii) To review the provisional decision in a reasonable period of time.^{xxii}
- (f) A final decision shall be made and communicated to the Applicant within one hundred-twenty (120) days of receipt of an application submitted for the intentional introduction into the environment of an LMO for purposes other than placing on the market, and within two hundred-seventy (270) days of receipt of an application submitted for the placing on the market of an LMO.^{xxiii}

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- (g) The final decision of the Competent Authority shall be recorded in a decision document that:
 - (i) Identifies the Applicant and summarizes the nature of the request;
 - (ii) Describes the procedure followed in reviewing the application;
 - (iii) Includes the summary of the risk assessment conducted by SAC;
 - (iv) States whether the requested activity is authorized, with or without conditions, or whether the requested activity is prohibited; and
 - (v) Provides the reasons for the decision.
- (h) Any specific conditions, limitations or requirements related to the authorization must be clear on the face of the decision document.
- (i) No person shall vary the purpose of the authorized activity as set forth in the decision document unless he obtains authorization from the Competent Authority.
- (j) LMOs or activities authorized under Article 7 et seq. shall be included in the registry to be established under Article 20.

Article 13. Simplified Application and Review Procedures

- (a) The Competent Authority may approve a facility, including an installation or other physical structure, for which no further notification is required under Article 6 for designated types or classes of contained use activities conducted in conformity with applicable laws, regulations and good laboratory practice standards. Procedures and requirements for this purpose shall be established by regulation under Article 28 of this Act.
- (b) The Competent Authority may exempt any LMOs or activities from the requirements of Articles 7 and 8 where it determines that sufficient experience or information exists to conclude that the LMOs or activities do not pose a significant risk to the conservation

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and sustainable use of biological diversity, taking also into account risks to human health.^{xxiv}

- (c) Where sufficient experience or information exists to conclude that LMOs or activities are not likely to pose a significant risk to the conservation and sustainable use of biological diversity, taking also into account risks to human health, but an exemption under paragraph (b) is not warranted, the Competent Authority may designate types or categories of LMOs or activities otherwise subject to Articles 7 and 8 that may proceed sixty (60) days after the submission of a notification conforming to paragraph (d).
- (d) A notification of intent to conduct an activity for which a designation has been made with respect to an activity or LMO under paragraph (c) shall be submitted to the Competent Authority at least sixty (60) days before the activity covered by the notification is due to begin and shall include:
 - (i) The name and contact information for the person submitting the notification;
 - (ii) The location(s) where the activity will be undertaken;
 - (iii) The name and identity of the LMO involved;
 - (iv) The nature and purpose of the activity;
 - (v) A description of any containment measures to be provided and the suitability of those measures for the LMO and activity to be undertaken; and
 - (vi) A description of remedial measures to be undertaken in the event of any unintentional introduction into the environment of the LMO that may occur as a result of the activity to be conducted.
- (e) If the Applicant subject to notification under paragraph (c) receives no response within sixty (60) days of the submission of the notification, the proposed activities may commence.
- (f) The Competent Authority shall publish notice of any proposal to exempt or apply simplified procedures to LMOs or activities under

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paragraphs (b) or (c) of this Article in accordance with Article 20 and transmit the proposal to the SAC for review.

- (g) The Competent Authority shall make a final decision on proposals under paragraphs (b) and (c) based upon the scientific review conducted by SAC and relevant comments submitted by the public. Any such exemptions or simplified procedures established under this Article shall apply equally to the designated LMOs or activities whether undertaken domestically or imported for such purposes.
- (h) The Competent Authority shall exempt from further regulation under this Act LMOs or categories of LMOs agreed pursuant to Article 7(4) of the Cartagena Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity.
- (i) In addition to or instead of the procedures set forth in this Article, the Competent Authority may enter into bi- or multi-lateral agreements to provide for simplified procedures for trade in specified LMOs.^{xxv}
- (j) LMOs or activities exempted or subject to simplified procedures under paragraphs (b), (c),(h) or (i) of this Article or as a result of a successful petition under Article 14 shall be included in the registry to be established under Article 20.

Article 14. Petition for Exemption or Simplified Procedures

- (a) Any person may petition the Competent Authority to exempt or to apply simplified procedures for LMOs or activities under Article 13(b) or (c) at any time.^{xxvi}
- (b) Petitions shall contain the following information:
 - (i) Name and address of the Applicant;
 - (ii) Name and description of the LMOs or types and classes of LMOs and/or activities for which exemption or simplified procedures are sought;
 - (iii) A comprehensive discussion of the scientific basis for the requested action accompanied by supporting documentation;

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- (iv) Any information known to the Applicant that would be unfavourable to the petition.
- (c) Within ten (10) days of receipt, the Competent Authority shall publish the petition in accordance with Article 20 and transmit the petition to the SAC for review.
- (d) The Competent Authority shall make a final decision on the petition based upon the scientific review conducted by SAC and relevant comments submitted by the public. The final decision may either approve or deny the petition in whole or in part and shall be communicated in writing to the Applicant within one hundred-twenty (120) days of receipt of the petition by the Competent Authority.

PART FOUR: REVIEW MECHANISMS

Article 15. Review of Decisions

- (a) The Competent Authority, in consultation with SAC, may review any decision under Article 6, Article 7 *et seq.* or Article 13(a), (b) or (c) at any time upon obtaining significant new scientific information indicating that the LMOs or activities involved may adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health. The Competent Authority shall inform the Applicant of its intent and reasons for initiating a review of the decision prior to undertaking the review.
- (b) Any Applicant may request the Competent Authority to review its decision under Article 6, Article 7 *et seq.* or Article 13(a), (b) or (c) with respect to an activity conducted or proposed to be conducted by the Applicant where the Applicant considers that:
 - (i) A change in circumstance has occurred that may have a material effect on the outcome of the risk assessment upon which the decision was based; or
 - (ii) Additional scientific or technical information has become available that may have a material effect on the decision including any conditions, limitations or requirements imposed under an authorization.

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- (c) If, upon review under paragraphs (a) or (b) in consultation with SAC, the Competent Authority finds that a change is warranted, it may issue an order changing the decision and/or the conditions in the authorization in a manner that is consistent with the validated scientific evidence or other accepted scientific methodology.
- (d) A written decision, pursuant to a review conducted under paragraph (a), shall be provided to the Applicant by the Competent Authority within ninety (90) days from the date the Applicant is notified of the review and shall set out the reasons for the decision.
- (e) A written decision, in response to a request for review under paragraph (b), shall be provided to the Applicant by the Competent Authority within ninety (90) days of the request and shall set out the reasons for the decision.

Article 16. Right of Appeal

- (a) Any Applicant who is aggrieved by any decision of the Competent Authority under this Act may appeal to [name of administrative appeals authority] on either procedural or substantive grounds.^{xxvii}
- (b) The [name of administrative appeals authority] shall decide on such appeals within a reasonable time, not to exceed sixty (60) days, and shall communicate its decision and the reasons therefore in writing to the Competent Authority and the Applicant.
- (c) An Applicant who remains aggrieved following an appeal under paragraph (a) or who does not receive a response within the timeframe stated in paragraph (b) shall have the right to appeal the decision of the Competent Authority to a competent court.

PART FIVE: SAFEGUARDS

Article 17. Monitoring and Submission of New Information

- (a) Operators shall monitor their activities to ensure that they comply with the requirements of this Act and any conditions or requirements imposed in connection with the authorization or allowance of activities under this Act.

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- (b) Operators that become aware of any significant new scientific information indicating that authorized activities with LMOs may adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health, or pose potential risks not previously known or considered, shall immediately advise the Competent Authority of the new information and newly identified risks and of the measures put in place to ensure the continued safe use of the LMOs.
- (c) Subject to the protection of confidential information in accordance with Article 9, Operators shall supply to the Competent Authority upon request and in accordance with regulations promulgated under the authority of this Act such information about their activities as is necessary for the Competent Authority to carry out its supervisory, monitoring or enforcement tasks under this Act or to deal with any emergency situations.

Article 18. Unintentional Introduction into the Environment

- (a) Any Operator with knowledge of an unintentional or unauthorized introduction into the environment of an LMO subject to this Act 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, shall, within 24 hours of when the Operator knew of the introduction, notify the Competent Authority of the occurrence.
- (b) A notification under paragraph (a) shall include the following:
 - (i) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the LMO;
 - (ii) Information on the circumstances and estimated date of the introduction;
 - (iii) Any available information about the possible adverse effect on the conservation and sustainable use of biological diversity, as well as available information about possible risk management measures;
 - (iv) Any other relevant information; and

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- (v) A point of contact for further information.
- (c) The Competent Authority, in consultation with SAC, shall consult with Operators providing notifications under paragraph (a) and determine whether any action is necessary to minimize any adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
- (d) Where it knows of an occurrence within its jurisdiction resulting in an introduction that leads or may lead to an unintentional transboundary movement of an LMO 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 another country, the Competent Authority shall notify affected or potentially affected countries, the Biosafety Clearing House, and, where appropriate, relevant international organizations.

Article 19. Cessation Orders

- (a) The Competent Authority may issue an order for the immediate cessation of any activity covered by an authorization or which has been the subject of a notification submitted under this Act or for the immediate imposition of additional risk management measures with respect to such activity, if the Competent Authority determines that there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking also into account risks to human health, on the basis of:
 - (i) One or more tests conducted and evaluated in a manner consistent with accepted scientific procedures, or
 - (ii) Other validated scientific evidence.
- (b) The Competent Authority also may issue a Cessation Order upon the failure of any Operator to demonstrate substantial compliance, after a reasonable period of time, with an order issued under Article 15(c) or, with respect to an authorization granted or notification submitted under this Act, when there exists a material infringement of any provision of the Act or regulations made hereunder.
- (c) An order issued pursuant to paragraph (a) or (b) shall be withdrawn once the Competent Authority determines that sufficient information

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exists to permit the activity to resume or to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of biological diversity, taking also into account risks to human health.

PART SIX: PUBLIC INFORMATION, AWARENESS AND PARTICIPATION

Article 20. Public Awareness and Participation

- (a) The Competent Authority shall promote awareness and education of the public and those conducting activities subject to the Act concerning biosafety matters through the publication and dissemination of this Act and regulations made hereunder, as well as guidance documents and other material aimed at improving understanding of biosafety and related authorization and notification requirements.
- (b) The Competent Authority shall publish, on a regular basis:
 - (i) Notices concerning proposals under Article 13(b) and (c);
and
 - (ii) Proposed decisions on applications and petitions filed pursuant to Articles 7 *et seq.* or 14 of the Act.
- (c) Upon request, the Competent Authority shall make available to any person portions of any application or petition subject to paragraph (b)(ii) that do not qualify as confidential information under Article 9, without prejudice to Article 9(a)(iv).
- (d) Any person may submit written comments on a proposed decision for any application for placing an LMO on the market or any petition for an exemption within sixty (60) days from the date the notice is posted. Such comments shall be considered as part of the decision-making process in accordance with Article 12(b). Any comments received by the Competent Authority and responses thereto also shall be made available to the public upon request.^{xxviii}
- (e) The Competent Authority shall publish notices of final decisions concerning all applications or petitions under Articles 7 *et seq.* and 14 of this Act and notices concerning the final resolution of any

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compliance matters under Articles 25 and 26 in cases involving non-compliance with material provisions of this Act.

- (f) The Competent Authority shall establish and maintain a registry of:
 - (i) LMOs for which authorization is granted under Article 7 *et seq.* of the Act, including whether the LMO has been authorized for placing on the market; and
 - (ii) LMOs and activities that are exempted or subject to simplified procedures in accordance with Article 13(b), (c) (h) or (i) of the Act.^{xxix}
- (g) Any regulations proposed under Article 28 of this Act must be published and a period of sixty (60) days allowed for the submission of written comments by any person. Such comments shall be considered as part of the regulatory process in accordance with Article 28(a). Any comments received by the Competent Authority and responses thereto also shall be made available to the public upon request.

Article 21. International Information Sharing

- (a) The Competent Authority shall notify the Biosafety Clearing House that its domestic regulations shall apply with respect to any imports of LMOs to the area of national jurisdiction of [name of country].
- (b) The Competent Authority shall provide to the Biosafety Clearing House:
 - (i) A copy of this Act, including any amendments, decisions pursuant to Articles 13(b) or (c), or regulations promulgated hereunder, and any other legislation or national guidelines of relevance to the implementation of the Cartagena Protocol or the management of LMOs;
 - (ii) Summaries of risk assessments generated pursuant to Article 11(d) of this Act;
 - (iii) Final decisions regarding the importation or intentional introduction into the environment of LMOs pursuant to Article 7 *et seq.*;

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- (iv) Reports concerning national implementation of the Cartagena Protocol in accordance with Article 33 of the Protocol;
 - (v) Within thirty (30) days of taking a decision under Article 15, a copy of the decision describing the changes to the previous decision and the reasons for the decision; and
 - (vi) Any other information required under the Cartagena Protocol or other international agreements concerning the subject matter addressed by this Act.
- (c) Where the Competent Authority renders a final decision regarding domestic use, including placing on the market, of an LMO that may be subject to export for direct use as food or feed or for processing, it shall ensure that information concerning the authorization of that LMO, as specified in Annex III, is provided to the Biosafety Clearing House established under the Cartagena Protocol within fifteen (15) days of making the decision.^{xxx}

PART SEVEN: IDENTIFICATION AND DOCUMENTATION^{xxxi}

Article 22. Documentation for LMOs Intended for Contained Use

- (a) LMOs that are imported into or exported from [name of country] for contained use shall be accompanied by documentation that:
 - (i) Clearly identifies them as LMOs;
 - (ii) Specifies any requirements for the safe handling, storage, transport and use; and
 - (iii) Provides a contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned.
- (b) Documentation accompanying LMOs for contained use under paragraph (a) shall remain available for inspection on the premises where the contained use activities are carried out.
- (c) Any additional documentation or identification requirements applicable to imports or exports subject to paragraph (a) and

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agreed upon under the Cartagena Protocol shall be addressed by regulation in accordance with Article 28 of this Act.^{xxxii}

Article 23. Documentation for LMOs for Direct Use as Food or Feed or for Processing

- (a) LMOs that are imported into or exported from [name of country] for direct use as food or feed, or for processing shall be accompanied during the transboundary movement and upon delivery to the port of entry by documentation that clearly identifies that the goods "may contain" LMOs and are not intended for intentional introduction into the environment.
- (b) The accompanying document shall also provide a contact point for further information.
- (c) Any additional documentation or identification requirements applicable to imports or exports subject to paragraph (a) and agreed upon under the Cartagena Protocol shall be addressed by regulation in accordance with Article 28 of this Act.^{xxxiii}

Article 24. Documentation for LMOs Intended for Intentional Introduction into the Environment

- (a) LMOs that are imported into or exported from [name of country] for intentional introduction into the environment must be accompanied by documentation that:
 - (i) Clearly identifies them as LMOs;
 - (ii) 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
 - (iii) Contains a declaration that the movement is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.
- (b) Any additional documentation or identification requirements applicable to imports or exports subject to paragraph (a) and

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agreed upon under the Cartagena Protocol shall be addressed by regulation in accordance with Article 28 of this Act.^{xxxiv}

PART EIGHT: ENFORCEMENT

Article 25. Enforcement

- (a) The Competent Authority may appoint as inspectors such number of persons appearing to him to be qualified for the purposes of ensuring compliance with the Act and its regulations.
- (b) The powers of an inspector are:
 - (i) at any reasonable time (or, in a situation in which in the inspector's opinion there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking also into account risks to human health, at any time):
 - (A) to enter premises, including but not limited to a facility, vessel or property, which the inspector has reason to believe it is necessary for him to enter and to take with him any person duly authorized by the Competent Authority; and
 - (B) to take with him any equipment or materials required for any purpose for which the power of entry is being exercised.
 - (ii) to carry out such tests and inspections (and to make such recordings), as may in any circumstances be necessary;
 - (iii) to direct that any, or any part of, premises which he has power to enter, or anything in or on such premises, shall be left undisturbed (whether generally or in particular respects) for so long as is reasonably necessary for the purpose of any test or inspection;
 - (iv) to take samples of any organisms, articles or substances found in or on any premises which he has power to enter, and of the air, water or land in, on, or in the vicinity of, the premises;

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- (v) in the case of anything found in or on any premises which he has power to enter, which appears to him to contain or to have contained LMOs which have adversely affected or are likely to adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health, to cause it to be dismantled or subjected to any process or test (but not so as to damage or destroy it unless this is necessary);
- (vi) in the case of anything mentioned in subparagraph (v) above or anything found on premises which he has power to enter which appears to be a LMO or to consist of or include LMOs, to take possession of it and detain it for so long as is necessary for all or any of the following purposes, namely:
 - (A) to examine it and do to it anything which he has power to do under that subparagraph;
 - (B) to ensure that it is not tampered with before his examination of it is completed; and
 - (C) to ensure that it is available for use as evidence in any proceedings for an offence under Article 26;
- (vii) to require the production of, or where the information is recorded in computerised form, the furnishing of extracts from, any records which are required to be kept under this Act or it is necessary for him to see for the purposes of any test or inspection under this Article and to inspect, and take copies of, or of any entry in, the records;
- (viii) to require any person to afford him such facilities and assistance with respect to any matters or things within that person's control or in relation to which that person has responsibilities as are necessary to enable the inspector to exercise any of the powers conferred on him by this Article;
- (ix) such other powers as may be necessary for the purposes mentioned in paragraph (a) above which is conferred by regulations made by the Competent Authority.

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- (c) Where goods are seized by an inspector without reasonable cause, the aggrieved person may bring an action in any competent court for appropriate relief, including an order for the return of the goods seized, and, if the claim prevails, shall be entitled to the costs of such proceedings.

Article 26. Offences and Penalties

- (a) Any person who violates a material provision of this Act or fails to comply with a Cessation Order or regulation issued pursuant to this Act shall be guilty of an offence and shall be liable, upon a conviction or finding of violation by a competent court of law or a duly appointed administrative body, for such fines as may be set by regulation, consistent with those established for violations of similar legislation or regulations, including additional penalties for each day that the offence is continued after legal service of a Cessation Order upon that person.
- (b) Any person who repeatedly and knowingly commits offences and is found to be in violation by a competent court of law or duly appointed administrative body under paragraph (a) for such offences may be prohibited from engaging in any further activities subject to this Act.

Article 27. Liability and Redress

Liability and redress for any damage that occurs as a result of activities subject to this Act shall be addressed by applicable laws.^{xxxv}

PART NINE: IMPLEMENTATION MEASURES

Article 28. Regulations

- (a) Consistent with the objective and scope of this Act, the Competent Authority shall propose and, after public notice and an opportunity for public comment pursuant to Article 20(g), finalize and publish such regulations as may be necessary for implementing the provisions of this Act.
- (b) The Competent Authority shall publish a schedule of fees to cover administrative costs of processing notifications, applications and petitions submitted under this Act.^{xxxvi}

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Article 29. Effective Date

This Act shall enter into force on [.....].

Article 30. Transitional Provisions

- (a) Any application pending at the date of the entry into force of this Act shall be subject to the provisions of this Act.
- (b) Activities that were ongoing at the date of the entry into force of this Act shall be permitted to continue but shall be subject to the review procedure set forth in Article 15.

Article 31. Review of Act

- (a) This Act and its regulations shall be reviewed in light of technical and scientific advances and for the purpose of improving the effectiveness of its operation every three years.
- (b) Review of the Act and its regulation shall include notice to the public of the review process and an opportunity for the public to comment on proposed changes.

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ANNEXES

- Annex I: Information Required in Applications
- Annex II: Risk Assessment
- Annex III: Information Requirements for Notices to the Biosafety Clearing House

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Annex I

Information Required in Applications

1. Name, address and contact details of the exporter.
2. Name, address and contact details of the importer.
3. 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.
4. Intended date or dates of the transboundary movement, if known.
5. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
6. 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.
7. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
8. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
9. 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.
10. Quantity or volume of the living modified organism to be transferred.
11. A previous and existing risk assessment report consistent with Annex II.
12. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

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13. 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.
14. Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
15. A declaration that the above-mentioned information is factually correct.

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Annex II

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.

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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:

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- (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.

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Annex III

Information Requirements for Notices to the Biosafety Clearing House

1. The name and contact details of the applicant for a decision for domestic use.
2. The name and contact details of the authority responsible for the decision.
3. Name and identity of the living modified organism.
4. Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
5. Any unique identification of the living modified organism.
6. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
7. 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.
8. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
9. Approved uses of the living modified organism.
10. A risk assessment report consistent with Annex III.
11. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

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Explanatory Notes

ⁱ **WTO Obligations:** The General Agreement on Tariffs and Trade ("GATT") is the basic body of law governing trade in goods under the WTO. The Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") explains the boundaries of the exception contained in GATT Article XX(b) for certain regulatory measures necessary to protect human, animal or plant life or health. The Agreement on Technical Barriers to Trade ("TBT Agreement") elaborates various GATT rules, in particular the Article III provisions regarding non-discrimination. More information on these agreements and WTO-consistent implementation of the Cartagena Protocol can be found in this Sourcebook in the document entitled "THE CARTAGENA PROTOCOL ON BIOSAFETY AND THE WORLD TRADE ORGANIZATION: Implementing a WTO-Consistent Biosafety Regulatory Framework GUIDELINES FOR BIOSAFETY REGULATORS."

ⁱⁱ **Meaning of "risks to human health":** Articles 1 and 3 of the Act track the objective and scope of the Cartagena Protocol by focusing on LMOs that may have an adverse effect on the conservation and sustainable use of biological diversity, "taking also into account risks to human health." The Protocol does not define the foregoing phrase. Because the Protocol was negotiated under the auspices of the Convention on Biological Diversity and is concerned with environmental protection, this phrase has been defined to clarify that the Act is concerned primarily with potential adverse effects on human health that result from adverse impacts on the conservation and sustainable use of biological diversity. See Art. 2(n).

While this Act remains firmly focused on the conservation and sustainable use of biological diversity, environmental risk assessment may include an assessment of potential impacts on human and animal health, such as allergenicity and toxicity, which may result from a release into the environment. More detailed assessments of potential impacts on human and animal health would be undertaken under other, complementary legislation, such as that addressing food and feed safety or pharmaceuticals that contain LMOs, when an LMO is proposed for such uses. In this case authorization under one or more other laws/regulations would be required.

ⁱⁱⁱ **Roles of Parties and Operators:** Protocol Article 8 requires exporting Parties either to provide the required AIA notification themselves or to ensure that their exporters (e.g. operators) notify the importing Party prior to the first shipment of LMOs for intentional introduction into the environment. An importing country could fulfill its obligations under the Protocol and avoid potential WTO problems by following normal practices for product approvals and allowing private parties to submit notifications.

^{iv} **Treatment of LMOs for Food, Feed or Processing:** Under the Protocol, LMOs intended for direct use as food or feed or for processing (LMO-FFPs) are not considered to be "introduced into the environment" and, therefore, are not subject to the Protocol's Advanced Informed Agreement provisions. Instead, Article 11 of the Protocol applies prior to the first transboundary movement of LMO-FFPs. See Biosafety Protocol, Art. 7(2)-(3).

Article 11 of the Protocol sets up a system in which countries that approve LMOs that may become or be used as LMO-FFPs must inform the Biosafety Clearing House within fifteen days of making the decision. This allows countries to have notice of what LMOs may be contained in LMO-FFP shipments from other countries. On the Biosafety Clearing House, importing countries can not only see what specific LMOs have been approved on a country by country basis, but can

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also access risk assessment and other information about the LMO. See Biosafety Protocol, Art. 11(1) and Annex II. In addition, any Party to the Protocol may request additional information from the governmental authority that approved the LMO(s) in question. See Biosafety Protocol, Art. 11(3). Alternatively, countries may regulate LMO-FFP shipments under their domestic regulatory system (but only if that system is consistent with the Protocol) or, in the absence of a domestic regulatory system, may make decisions on the first shipment of LMO-FFPs within a maximum of 270 days on the basis of a risk assessment undertaken in accordance with the Protocol. See Biosafety Protocol, Art. 11(6).

This Act follows the approach taken in the Protocol and excludes LMO-FFPs from regulatory approval requirements because they are not “intentionally introduced into the environment.” Countries that choose to take this approach will still need, however, to establish a formal process for monitoring approvals of LMOs placed on the Biosafety Clearing House and for assessing the information that is posted. This can be addressed in accompanying regulations. Article 23 of the Act contains the documentation requirements included in the Protocol for LMOs intended for direct use as food or feed or for processing.

^v See note ii.

^{vi} **Scope of the Act:** The exemptions to the Act set forth in Article 3(b)(i) and (ii) generally follow the exemptions to the Cartagena Protocol. See Biosafety Protocol, Art. 5 (Pharmaceuticals) and Art. 6 (Transit and Contained Use).

Pharmaceuticals: Under the Protocol, the exemption for pharmaceuticals is limited to LMOs that are pharmaceuticals for human use that are addressed by other international agreements and organizations. This approach was taken because of the Protocol’s primary focus on environmental safety, as opposed to human health. At the national level, countries must consider whether: (1) their participation in international organizations and/or schemes provides sufficient safeguards to exclude pharmaceuticals for human use from coverage under their biosafety framework act; and/or (2) domestic regulations governing the importation and use of pharmaceuticals are adequate for this purpose. Where domestic legislation governs both human and veterinary pharmaceutical products, an exemption of these items from coverage under this Act would be appropriate and a notification that such domestic legislation applies for imports of human and/or veterinary products should be provided to the Biosafety Clearing House.

Transit: With respect to transit, while countries may wish to follow the Protocol approach and exclude LMOs in transit from regulatory approval requirements, they may need to consider whether existing regulations on transport, containment, etc. are adequate to ensure that LMOs in transit are properly packaged and transported in accordance with international standards.

Contained Use: The Act covers contained use of LMOs, notwithstanding the exemption set forth in the Protocol concerning transboundary movements of LMOs destined for contained use, because of the importance of contained use as part of the regulatory structure at the national level. In addition, it should be noted that the contained use provisions set forth in Article 6 of this Act also would apply to LMOs used in containment for pharmaceutical development unless specifically stated otherwise. In effect, while separate specific legislation normally is used to deal with clinical trials, product approvals and import of pharmaceutical products, contained use

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regulations generally cover all laboratory work with LMOs, even if the substances will ultimately be used for pharmaceuticals products.

^{vii} **Relationship between Competent Authority and National Focal Point:** Parties to the Cartagena Protocol must designate a Competent Authority to implement Protocol requirements and a National Focal Point to serve as a liaison between the country and the Secretariat. These functions may be combined in one entity. If they are not combined, provision must be made to transmit information from the Competent Authority – which will implement the domestic biosafety legislation – to the National Focal Point for transmission to the Biosafety Clearing House in conformity with various time periods set forth in the Protocol. For simplicity, this Act takes the approach of combining the two functions such that the Competent Authority also serves as the National Focal Point.

^{viii} **Performance Standards for Contained Use:** Many countries already have in place detailed regulations for laboratories, etc. that would apply to contained use activities involving LMOs. If such regulations are not in place, they need to be created under this or any other framework act in accordance with international standards; many examples of such regulations are available for consideration. These same performance standards could be used as the criteria for approving any facility seeking to conduct activities involving LMOs under Article 13(a).

^{ix} **Implementation of the Protocol's AIA Procedures:** The requirements set forth in Articles 7-12 and related provisions implement the Advanced Informed Agreement procedures under the Biosafety Protocol for the importation of LMOs for intentional introduction into the environment and would be utilized in lieu of Protocol procedures. As reflected in Article 21(a), a country adopting such national legislation would need to inform other countries and potential exporters/importers through the Biosafety Clearing House that the domestic law applies with respect to any imports or exports of LMOs to or from the country.

^x **Notification to Exporting Country of Exports:** The Cartagena Protocol does not require notification to or approval by the country of export prior to exporting to another country. It does, however, require that exporting countries establish a legal requirement to ensure that exporters under their jurisdiction provide accurate information to other countries. The legal requirement for an exporter to obtain authorization in accordance with the legal requirements of the importing country and to provide accurate information is set forth in Article 7(c)(i) and (ii). An additional obligation to provide a copy of authorizations received from importing countries to the exporting country prior to shipment has been added in Article 7(c)(iii) simply to keep the exporting government informed of the activities of its exporters and to facilitate communication among governments. Obviously one can only export LMOs that were legally produced in accordance with authorizations under this Act.

^{xi} **Relevant Information:** For example, information about the quantity or volume of the LMO to be transferred (see Protocol Annex I, para. 10) is relevant only to experimental releases and should not generally be required in applications for placing on the market. Annex C(1)(c) of the SPS Agreement requires Members to ensure, *inter alia*, that “information requirements are limited to what is necessary for appropriate control, inspection and approval procedures.” Article 5.2.3 of the TBT Agreement restricts information requirements “to what is necessary to assess conformity” with technical regulations or standards. Asking for more information than has been

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agreed as necessary under the Protocol could create problems in complying with these SPS and TBT requirements.

^{xii} **Requirement for Submission of Risk Assessment:** Consistent with current practice and Article 15(2) of the Cartagena Protocol, the Act requires Applicants to submit risk assessments concerning proposed activities. These may be new risk assessments or previous and existing risk assessments but must, in either case, be consistent with Annex II. Requiring the exporter or the notifier to carry out the risk assessment, as provided for in Protocol Article 15.2, is permissible under WTO rules so long as the requirement is non-discriminatory – *i.e.*, all notifiers, foreign and domestic, are subject to the same requirement – and consistent with a country's approach to regulating similar risks.

^{xiii} **Honest Commercial Practices:** For the purpose of this provision, “a manner contrary to honest commercial practices’ shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.” See Article 39 of the *WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPs).

^{xiv} **Processing without Undue Delay:** All stages of the procedure should be completed within the time frames established by the Protocol which are likely to be viewed as reasonable for purposes of determining WTO compliance.

^{xv} **Content of Risk Assessment:** In an approach similar to that of Annex III of the Protocol, SPS Article 5.2 allows regulators to take into account relevant ecological and environmental conditions, which would include assessing the consequences both of authorizing the LMO/activity and not doing so (*i.e.*, continuing with the existing situation). A risk assessment carried out in accordance with the science-based Protocol requirements and the Annex III guidelines would in all likelihood meet the SPS Agreement standards.

^{xvi} **Responsibility for Risk Assessment:** While a risk assessment must be submitted by the Applicant as part of the application, it is up to the Competent Authority to decide if the work is sufficient, accurate, scientifically sound, etc. Article 11 of the Act makes clear that the Competent Authority retains the ultimate responsibility for risk assessment. The Competent Authority usually accomplishes this task by forwarding a copy of the submitted risk assessments to a scientific advisory body (under the Act, the SAC) which then “audits” the risk assessment. Where it is not satisfied or wishes to confirm certain aspects of the submitted risk assessments, the SAC may conduct additional risk assessment activities or, via the Competent Authority, request that the Applicant perform certain additional studies or tests. The scientific conclusions and recommendations of the SAC are then provided to the Competent Authority for ultimate decision-making. Applicants are normally given a chance to comment upon the conclusions and recommendations of the scientific advisory body before a decision on the application is made. This approach is followed in the Act.

^{xvii} **Consistency of Risk Assessment Requirements with WTO Obligations:** The risk assessment provisions in Article 15.1 and Annex III of the Protocol are broadly consistent with the rules of the SPS Agreement (see SPS Article 5.1).

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^{xviii} **Limitation of Risk Management Measures:** SPS Article 2.2 requires that measures be “applied only to the extent necessary to protect human, animal or plant life or health” (see also SPS 5.3 through 5.6).

^{xix} **Criteria for Decision-Making:** The Protocol explicitly requires that decisions are made in accordance with Article 15 (requiring scientifically sound risk assessment). Basing regulatory decisions solely on the scientific conclusions of the risk assessment process, which includes identifying risk management measures that can adequately address any identified risks, will be compatible with WTO disciplines.

^{xx} **Consideration of Socio-economic Aspects:** The language in Article 12(c) of the Act is taken from Article 26 of the Biosafety Protocol, which allows – but does not require – consideration of certain socio-economic aspects in decision-making. The Protocol places two limitations on the consideration of socio-economic aspects. First, it is not any socio-economic considerations that may be taken into account, but only those “arising from the impact of an LMO on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.” Second, any consideration of socio-economic aspects must be consistent with countries international obligations, including WTO obligations. However, there is no provision under the WTO agreements that would allow a Member to justify regulatory restrictions affecting imports on the basis of general socio-economic considerations. This paragraph is therefore bracketed with the suggestion that it not be included in the Act.

^{xxi} **Lack of Scientific Certainty:** The language in this provision of Article 12 of the Act is taken directly from Article 10 of the Biosafety Protocol. See Biosafety Protocol, Art.10(6).

^{xxii} **Obligations accompanying Provisional Decisions based on Uncertainty:** SPS Article 5.7 permits members to adopt – on a provisional basis only - measures in cases where information is incomplete. To ensure full compliance with WTO limits on the use of precautionary measures, countries party to both agreements should ensure that any measures or decisions taken in the face of scientific uncertainty are provisional and subject to obligations to seek additional information and review the measures or decisions in a reasonable period of time.

^{xxiii} **Time Frames for Decision-Making:** Requests for approval for “intentional introduction of LMOs into the environment” includes both applications for placing on the market or commercialisation of LMOs and applications for more limited activities involving LMOs, such as field trials. In the case of field trials, for example, the applicant is requesting to undertake a specific activity that is limited in scope and time and that will involve certain controls to limit interaction of the LMOs with the environment beyond the field trial itself. In this case, the government need only consider the precise activity requested. In contrast, when an applicant requests authorization for placing on the market, the applicant is asking permission for a general authorization in which not only the applicant but others may import, buy, sell, use, etc. the particular LMO. Because of these differences in scope and environmental exposure, most regulatory systems distinguish between these two types of environmental releases both in terms of information requirements and time frames for decision-making, with shorter time frames for more limited activities such as field trials and longer time frames for commercialisation. That approach has been taken in Article 12 of this Act, which provides a maximum of 270 days for decisions on applications for placing on the market and a maximum of 120 days for requests for field trails and other more limited types of intentional introductions into the environment. These

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periods are within the 270 day limit established by the Protocol. Even shorter periods established in a country may encourage additional research and trade in and with that country.

^{xxiv} **Exemptions and Simplified Notification Procedures:** Article 13 allows the Competent Authority, on its own initiative, to propose and decide, based on input from the SAC and public comments, to exempt (paragraph (b)) or apply simplified notification procedures (paragraph (c)) to LMOs based on experience gained, etc. This possibility is provided for in Article 13 of the Cartagena Protocol and can be a useful way to ensure productive use of limited regulatory resources. Such an approach might be taken, for example, for repetitive field trials where sufficient information and experience exists to conclude that the activities do not or are not likely to pose a significant risk. It should be noted that the standards for an exemption versus a simplified notification requirement differ. No time frame (other than those applicable to public participation) has been set for this procedure, which may be carried out at the discretion of the Competent Authority.

^{xxv} **Obligations related to Special Treatment:** If a Protocol Party that is a WTO member reaches an agreement under Article 14.1 to grant special treatment to another country, that Party is obliged under WTO rules to grant the same treatment to any other WTO member that can meet the same standard as the country to which special treatment has been granted.

^{xxvi} **Petition for Exemption or Simplified Procedures:** This provision allows Applicants to petition for an exemption or simplified procedures for certain LMOs or activities. The standards, consultation processes, and available outcomes are the same as under Article 13, but the petition process has the advantage of providing Applicants with a mechanism to trigger Competent Authority consideration of a proposed exemption or simplified procedure and offers a ready-made package for the Competent Authority. A timeframe of 120 days is established for the Competent Authority to consider such petitions.

^{xxvii} **Administrative Appeal:** Provision needs to be made for an administrative review of decisions by an entity that is independent of the Competent Authority. Resolution of administrative reviews is generally a prerequisite for filing a legal complaint in a court of law.

^{xxviii} **Public Awareness and Participation:** All countries party to the Cartagena Protocol are encouraged to promote and facilitate public awareness, education and participation concerning the safe transfer, handling, and use of LMOs in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. This Act takes the approach of promoting transparency, education and awareness through publication of final decisions on all intentional introductions into the environment, as well as any petitions for de-regulation of LMOs, and any compliance matters involving cases of material non-compliance. It allows for direct public participation in decision-making on any regulation proposed under the authority of this Act, any application for placing an LMO on the market, and any petition to exempt LMOs or activities from authorization requirements. Whether a country takes this or another approach to public participation will depend on a country's legal traditions and may well be governed by existing laws concerning legal administrative procedure. In some countries, for example, public participation concerning individual decisions is not permitted but is encouraged with respect to the formation of government policy, legislation or regulations. Other countries publish and invite comment throughout the regulatory process, including on risk assessment reports.

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^{xxix} **Registry:** A registry established and maintained by the Competent Authority allows the public and potential importers, applicants or users of LMOs to know what LMOs/activities already have been approved and whether these or other LMOs have been exempted or subject to simplified procedures for notification or authorization under the Act. The registry is critical in the case of authorizations for placing on the market because such authorizations generally grant approval for the LMO to be imported, grown, processed, placed on the market, etc. by any competent person – not just the Applicant – without further approval. In the case of authorizations for field trials, on the other hand, the approval – or permit – is specific to the Applicant and any other person wishing to conduct field trials with the same LMO would require authorization under this Act. In this case, the registry simply serves to provide information about past or existing approvals.

^{xxx} **Process for Monitoring and Assessing LMO-FFPs:** As noted in the Explanatory Note to Article 2(i) of this Act, means to monitor information posted by other countries concerning approvals of LMOs that may be subject to export for direct use as food, feed or for processing is appropriate. If a country decides to subject imported LMO-FFPs to advanced decision making as a stricter domestic measure, under the WTO, it must have a scientific basis for doing so. It is therefore recommended that countries limit advanced regulatory requirements to cases where scientifically justified based on the potential receiving environment.

^{xxxi} **Documentation:** Articles 22, 23 and 24 of this Act set forth the documentation requirements included in the Biosafety Protocol for transboundary shipments of LMOs destined for contained use (Art. 22), LMOs intended for direct use as food or feed or for processing (Art. 23), and LMOs intended for intentional introduction into the environment (Art. 24). By including these requirements in a domestic law, countries can ensure that their exporters comply with Protocol requirements applicable to other countries party to the Protocol and also can ensure that any imports are accompanied by documentation in compliance with the Protocol. Each Article also includes a provision that enables any future decisions agreed under the Protocol to be addressed by regulations as appropriate.

Because it focuses on environmental protection and applies only to LMOs (and not, for example, processed food products derived from LMOs), this Act does not address the topic of consumer labelling.

^{xxxii} **Additional Documentation Requirements:** Accompanying regulations can be used to implement additional documentation and identification requirements agreed by the Meeting of the Parties to the Protocol as appropriate.

^{xxxiii} *Ibid.*

^{xxxiv} *Ibid.*

^{xxxv} **Liability and Redress:** Legal frameworks existing in most countries today are comprised of a wide range of tools, including regulatory regimes and contractual and non-contractual liability systems. Together, they function to prevent damage, provide compensation, and – in some instances – to impose sanctions. These instruments are of general applicability, covering all activities and products, including those that are biotechnology-related. They can and should be

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relied upon should any actual damage occur in connection with activities involving LMOs under this Act.

Similarly, any additional legislation that may be created to promote environmental protection should be of general applicability rather than biotechnology-specific. This general approach effectively focuses on prevention and compensation in the event of environmental damage and avoids unwarranted discriminatory treatment.

A general approach to environmental liability also is justified by the scientific context. Scientifically speaking, the mere use of biotechnology does not create a technology-*specific* environmental risk. Rather, environmental safety of biotechnology products and activities is determined by the same parameters as those applicable to other products and activities. The risk an organism or related activity may pose to the environment depends on the organism's properties and resulting interaction with the environment. This is the case regardless of whether those properties are the result of breeding technologies - either traditional techniques, or biotechnology - or "natural" evolution. This fact has been and continues to be confirmed by leading international institutions including the OECD, FAO, and WHO.

^{xxxvi} **Uniformity of Fees Imposed:** Under WTO rules, any such fees may not exceed the cost of services rendered and must be equitable in relation to fees charged for similar services for like products of domestic origin (see SPS Annex C.1.f; TBT Article 5.2.5; GATT III.1 and II.2.c and VIII). If fees are to be charged, a uniform fee schedule for regulatory processes should be established in line with actual costs, published, and made applicable to all applicants equally.

MODEL ACT

PROPOSED PROVISIONS FOR A TRANSPARENT, EFFECTIVE AND WORKABLE BIOSAFETY REGULATORY FRAMEWORK

QUESTIONS AND ANSWERS

PURPOSE, SOURCE AND DISTRIBUTION

1. What is the Model Act?

The Model Act is a freely available document that contains proposed legal provisions for a transparent, effective and workable national biosafety regulatory framework consistent with the Cartagena Protocol on Biosafety (Protocol or Biosafety Protocol) and other international obligations.

The Model Act is designed to assist developing countries that may need to introduce new administrative and legal frameworks for environmental safety with respect to the import, export and use of living modified organisms (LMOs) within their territories. It is based on provisions found in existing and well-functioning biosafety regulatory schemes around the world that have been amended and shaped in accordance with actual experience in the field.

2. Who is behind this Model Act?

The Model Act was created, as an independent undertaking, by two legal experts in the field of biosafety, Stanley H. Abramson, Esq., Arent Fox PLLC, U.S.A., and Laura van der Meer, Esq. (née Laura Reifschneider), International Environmental Resources, Switzerland. A draft of the Model Act was subjected to independent peer review by two well-known and experienced international experts in this field, Dr. Julian Kinderlerer, Law Department, University of Sheffield, United Kingdom, and Dr. Katharina Kummer Peiry, Kummer EcoConsult, Switzerland. The authors have not sought or requested endorsement or approval of the Model Act by any organization, government or company and remain solely and entirely responsible for its content and approach. Funding for the preparation and distribution of the Model Act has been provided by Arent Fox PLLC, International Environmental Resources, and private corporations.

3. Why was the Model Act created?

Notwithstanding important capacity building initiatives that have gotten underway since the Biosafety Protocol's adoption in 2000, government officials around the world still have little concrete guidance to assist them in drafting national biosafety frameworks in a manner that will facilitate compliance with their obligations under the Biosafety Protocol and other international instruments.

4. How does this Model Act relate to other models and guidance on biosafety?

The Model Act is the only reference currently in circulation that would ensure compliance with the requirements of the Biosafety Protocol. It is unrelated to any

other existing or ongoing product or initiative. The authors have reviewed other such undertakings and believe that the wide range of products available contributes to a positive debate and well-informed consideration by government officials of the various, diverse approaches and options available to provide for biosafety regulation.

5. Does the Model Act comply with the Biosafety Protocol?

Yes. Using the Biosafety Protocol Implementation Tool Kit (UNEP) as a guide, the authors have made every effort to ensure that the provisions of the Model Act comply with the Protocol and that it addresses all obligations contained therein. Explanatory notes are provided at the end of the Act to aid the reader in understanding the relationship between the provisions of the Act and the Biosafety Protocol and to further explain certain drafting decisions made by the authors.

The authors also have included in the Model Act additional provisions concerning, for example, contained use, because while exempted from the Protocol's Advanced Informed Agreement procedures, oversight of activities involving the contained use of genetically modified organisms and micro-organisms is a critical regulatory activity at the national level.

6. Can the Model Act be copied in its entirety by countries wishing to implement the Biosafety Protocol?

It could be, but the authors do not advise it. No matter how good the "model," one should avoid the temptation to engage in a simple cut and paste exercise. Models – or well-functioning laws in existence in other countries – cannot and do not take into account the differing legal structures and traditions, the varying environmental conditions and concerns, and the societal and cultural uniqueness of each country.

One should not necessarily assume that drafting a biosafety framework begins with a blank piece of paper. Often the place to start is with laws already in force (phyto-sanitary measures; import and export regulations for agricultural produce or living organisms; controls over the use of herbicides and pesticides in agriculture; health and safety regulations; environment protection laws) that can be utilized or modified to cover biosafety.

7. Has the Model Act been distributed? Is anyone using it?

The Model Act is freely available to any interested person and may be accessed via the Internet at www.arentfox.com/modelbiosafetyact.pdf. Since its publication on the website, it has been used, along with other biosafety implementation tools, in workshops hosted by various international organizations and other parties, including the International Service for the Acquisition of Agricultural Applications (ISAAA). It also has been provided directly to all who have requested it.

SCOPE

8. Regulation of biotechnology-derived food and feed products is critical for the protection of human health. Why doesn't the Model Act directly address these products?

This Model Act, like the Biosafety Protocol, is firmly focused on living modified organisms (LMOs) that may have an effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health. Environmental

risk assessment therefore includes an assessment of potential impacts on human and animal health, such as allergenicity and toxicity, which may result from a release into the environment of LMOs. Subjecting “products thereof” to environmental safety legislation not only is unworkable but would not reflect a science-based approach since non-viable products such as cotton socks and vegetable oils are not likely to pose any risk to the environment.

The regulation of food and feed derived from products of biotechnology is important but should be addressed separately from regulations aimed at environmental safety. This is because the data required, the questions being asked and the risk assessment process are different for environmental versus food/feed safety issues and are typically undertaken by different governmental authorities. Authorization under each applicable law/regulation, which together create a comprehensive regulatory system, is required.

9. How are commodity shipments treated under the Model Act?

The Model Act follows the approach taken in the Protocol and excludes LMOs imported for food, feed or processing (LMO-FFPs) from regulatory approval requirements because these LMOs are not “intentionally introduced into the environment.”

Countries will have notice and information of LMO-FFPs that may be included in commodity shipments, however, through the Biosafety Clearing House. The authors recommend that countries that choose to take this approach establish a formal process for monitoring approvals of LMOs placed on the Clearing House and for assessing posted information.

Protocol Parties are obligated to provide information to the Clearing House within 15 days of any domestic approval of an LMO that may end up in the commodity stream. Parties to the Protocol also may request additional information from the governmental authority that approved the LMO(s) in question. The Protocol obligation concerning information supply on LMO-FFPs has been incorporated into the Model Act.

10. Why doesn't the Model Act apply to genetically modified organisms and micro-organisms?

It does. To ensure consistency with the Biosafety Protocol, the terminology used in the Biosafety Protocol has been adopted in the Model Act. “Living modified organisms” (LMOs) are simply another name for “genetically modified organisms” (GMOs), which also includes micro-organisms.

11. Why doesn't the Model Act include transit operations?

Transit of LMOs through a territory on their way to another is excluded from the procedures under the Biosafety Protocol because such shipments are not intended – and are unlikely – to be released into the environment. To the extent it is needed, protection is provided through safeguard clauses that deal with unintentional releases of LMOs. If regulated, shippers and traders will likely respond by simply avoiding that country because it is not economically feasible to undergo the lengthy and expensive regulatory approval process for movements through countries. For these reasons transit also has been excluded from the Model Act.

12. Why doesn't the Model Act provide for governmental approval for all exports of LMOs?

The Biosafety Protocol does not require notification to or approval by the country of export prior to exporting to another country. It does, however, require that exporting countries establish a legal requirement to ensure that exporters under their jurisdiction provide accurate information to other countries. These obligations are included in the Model Act. An additional provision requiring exporters to provide a copy of authorizations received from importing countries to the exporting country prior to shipment also has been included in the Model, even though not required by the Protocol, simply to keep the exporting government informed of the activities of its exporters and to facilitate communication among governments. Obviously one can only export LMOs that were legally produced in accordance with authorizations under this Act.

13. Why hasn't the Protocol's Advanced Informed Agreement requirement been included in the Model Act?

The requirements set forth in Articles 7-12 of the Model Act implement the Advanced Informed Agreement procedures under the Biosafety Protocol for the importation of LMOs for intentional introduction into the environment and would be utilized in lieu of Protocol procedures. A country adopting such national legislation would inform other countries and potential exporters/importers through the Biosafety Clearing House that domestic law applies to any imports/exports of LMOs to or from the country.

LIABILITY AND REDRESS

14. Why does the Model Act refer to existing laws rather than providing for liability and redress in the Model Act itself?

It is not necessary to include specific liability provisions in a national biosafety framework. Legal frameworks existing in most countries today are comprised of a wide range of tools, including regulatory regimes and contractual and non-contractual liability systems. Together, they function to prevent damage, provide compensation, and – in some instances – to impose sanctions. These instruments are of general applicability, covering all activities and products, including those that are biotechnology-related. They can and should be relied upon should any actual damage occur in connection with activities involving LMOs under this Act.

Similarly, any additional legislation that may be created to promote environmental protection should be of general applicability rather than biotechnology-specific. This general approach effectively focuses on prevention and compensation in the event of environmental damage and avoids unwarranted discriminatory treatment.

A general approach to environmental liability also is justified by the scientific context. Scientifically speaking, the mere use of biotechnology does not create a technology-specific environmental risk. Rather, environmental safety of biotechnology products and activities is determined by the same parameters as those applicable to other products and activities. The risk an organism or related activity may pose to the environment depends on the organism's properties and resulting interaction with the environment. This is the case regardless of whether those properties are the result of breeding technologies - either traditional techniques, or biotechnology - or "natural" evolution. This fact has been and continues to be confirmed by leading international institutions including the OECD, FAO, and WHO.

PRECAUTION AND SOCIO-ECONOMICS

15. Does the Model Act incorporate the precautionary principle?

There is no internationally defined or accepted “precautionary principle.” The precautionary approach as defined in Rio Principle 15, which does enjoy international consensus, is referenced in the opening article of the Model Act. Further, a provision concerning possible governmental action in the face of scientific uncertainty, which is taken directly from Article 10 of the Biosafety Protocol, has been included.

16. Does the Model Act allow for consideration of socio-economic aspects in governmental decision-making on LMOs?

Socio-economic considerations are addressed in the Act in the same manner as in the Protocol. This means that socio-economic considerations “arising from the impact of an LMO on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities” may be taken into account in decision-making but only in keeping with countries’ international obligations, including those under the WTO.

LABELLING AND TRACEABILITY

17. Why doesn’t the Model Act ensure labelling and traceability?

The Model Act includes the specific requirements that are contained in the Biosafety Protocol for transboundary shipments of LMOs destined for contained use, LMOs intended for direct use as food or feed or for processing, and LMOs intended for intentional introduction into the environment. This ensures that exporters comply with Protocol requirements applicable to other countries party to the Protocol and also that any imports are accompanied by documentation in compliance with the Protocol. The Model Act also includes a provision that enables any future requirement agreed under the Protocol to be addressed by regulation.

Because it focuses on environmental protection and applies only to LMOs (and not, for example, processed food products derived from LMOs), this Act does not address the topic of labelling of consumer products.

Where product labelling is required under food and feed legislation, labelling should provide information relevant to the safety and use of the product, and not to the technology used to produce it or other information related solely to issues of consumer choice. If a food product derived from an LMO is qualitatively the same as and scientifically as safe as conventional counterpart products already existing in the food supply, then the process by which the LMO or product was derived is not information that should be required on the product label as a matter of law. If, on the other hand, the safety (allergenicity or toxicity), nutritional quality or composition of the product is altered in any meaningful way, then product labelling would provide relevant and material information of value to the consumer and should be required. To the extent there is a desire on the part of consumers for products that are not biotechnology-derived, such products can be offered in the marketplace and labelled accordingly to facilitate consumer choice.

PUBLIC PARTICIPATION

18. Why doesn't the Model Act provide for public participation in decision-making on all applications?

Consistent with the Biosafety Protocol, the Model promotes and facilitates public awareness, education and participation concerning LMOs through publication of final decisions on all intentional introductions into the environment, as well as any petitions to exempt LMOs, and any notices concerning compliance matters involving cases of material non-compliance.

The Model also allows for direct public participation in decision-making on any regulation proposed under the authority of this Act, any application for placing an LMO on the market, and any petition to exempt LMOs or activities from authorization requirements. This approach – which may or may not be appropriate for individual countries, depending on legal traditions and the level of public participation under other laws concerning the environment – was taken to ensure public participation where public interest is the greatest.

TIME FRAMES FOR DECISION-MAKING

19. Why are there different time frames for decision-making instead of the 270 days provided by the Protocol?

Most biosafety regulations in existence today distinguish between requests to commercialise a GMO (including import, production, sale, etc.) and other activities more limited in scope, such as field trials. Requests to conduct field trials generally require less information to be submitted by the applicant and are decided more quickly than authorizations for commercialisation. This approach has been taken in the Model Act, which provides a maximum of 270 days for decisions on applications for placing on the market and a maximum of 120 days for requests for field trials and other more limited types of intentional introductions into the environment.

ADDITIONAL INFORMATION

20. Where can I get more information about the Model Act?

The Model Act can be viewed and downloaded at the following location: www.arentfox.com/modelbiosafetyact.pdf. Additional information can be obtained from the authors by writing to: ModelBiosafetyAct@arentfox.com.

21. I disagree with the approach taken in the Model Act. What can I do?

The authors welcome all points of view, comments and concerns. These may be addressed to the authors at: ModelBiosafetyAct@arentfox.com.

22. Can I get copies of the Peer Reviewers' comments?

The original draft, the reviewers' comments and a document detailing how the comments were addressed in the Model Act are available from the authors upon request to the following email address: ModelBiosafetyAct@arentfox.com.

*Annex III***IMPLEMENTATION TOOL KIT 1/**

This implementation tool kit provides a compilation, as a checklist, of obligations found in the Cartagena Protocol on Biosafety. These obligations are organized in the following categories:

- Administrative tasks (initial and future)
- Legal requirements and/or undertakings
- Procedural requirements (AIA and Article 11)

I. ADMINISTRATIVE TASKS

	<i>Tasks</i>	<i>Article</i>	✓
	<i>Initial actions</i>		
1.	Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19(1),(2)	
2.	Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(es) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19(1),(2)	
3.	Provide to the Biosafety Clearing-House: <ul style="list-style-type: none"> - any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMO-FFPs; and - any bilateral, regional or multilateral agreements or arrangements. 	20(3)(a)-(b), 11(5), 14(2)	
4.	Specify to the Biosafety Clearing-House cases in which import may take place at the same time as the movement is notified.	13(1)(a)	
5.	Specify to the Biosafety Clearing-House imports of LMOs exempted from the AIA procedures.	13(1)(b)	
6.	Notify the Biosafety Clearing-House if domestic regulations shall apply with respect to specific imports.	14(4)	
7.	Provide the Biosafety Clearing-House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17(2)	
8.	Notify the Secretariat if there is a lack of access to the Biosafety Clearing-House and hard copies of notifications to the Clearing House should be provided.	(e.g., 11(1))	

	Tasks	Article	✓
	Follow-up actions		
9.	Provide to the Biosafety Clearing-House: <ul style="list-style-type: none"> - Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Art. 15; - Final decisions concerning the import or release of LMOs; and - Article 33 reports. 	20(3)(c)-(e)	
10.	Make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements.	25(3)	
11.	Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33	
12.	Notify the Biosafety Clearing-House of any relevant changes to the information provided under part I above.		

II. LEGAL REQUIREMENTS AND/OR UNDERTAKINGS

	Tasks	Article	✓
1.	Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2(2)	
2.	Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMO-FFPs.	8(2) 11(2)	
3.	Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.	9(3)	
4.	Ensure that AIA decisions are taken in accordance with Article 15.	10(1)	
5.	Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15(1),(2)	
6.	Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.	16(1)	
7.	Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	16(3)	
8.	Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16(4)	
9.	Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17(1)	
10.	Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant	18(1)	

	Tasks	Article	✓
	international rules and standards.		
11.	Take measures to require that documentation accompanying LMO-FFPs <ul style="list-style-type: none"> - clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment; and - provides a contact point for further information. 	18(2)(a)	
12.	Take measures to require that documentation accompanying LMOs destined for contained use: <ul style="list-style-type: none"> - Clearly identifies them as LMOs; - Specifies any requirements for their safe handling, storage, transport and use; - Provides a contact point for further information; and - Provides the name and address of individuals or institutions to which they are consigned. 	18(2)(b)	
13.	Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol: <ul style="list-style-type: none"> - Clearly identifies them as LMOs - Specifies the identify and relevant traits and/or characteristics; - Provides any requirements for the safe handling, storage, transport and use; - Provides a contact point for further information; - Provides, 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 the Protocol. 	18(2)(c)	
14.	Provide for the designation of confidential information by notifiers, subject to the exclusions set forth in Article 21(6).	21(1),(6)	
15.	Ensure consultation with notifiers and review of decisions in the event of disagreement regarding claims of confidentiality.	21(2)	
16.	Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21(3),(5)	
17.	Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21(4)	
18.	Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23(1)(a)	
19.	Endeavor to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23(1)(b)	
20.	In accordance with relevant domestic laws, consult with the public in decision making under the Protocol, while respecting confidential information.	23(2)	
21.	Endeavor to inform the public about the means of public access to the Biosafety Clearing-House.	23(3)	
22.	Adopt appropriate measures aimed a preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25(1)	
23.	Dispose, at its expense, LMOs that have been the subject of an illegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25(2)	

III. PROCEDURAL REQUIREMENTS: ADVANCED INFORMED AGREEMENT

	Tasks	Article	✓
1.	Provide written acknowledgement of receipt of notification to notifier within 90 days, including:		
	- Date of receipt of notification;	9(2)(a)	
	- Whether notification meets requirements of Annex I;	9(2)(b)	
	- That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; OR - Whether the import may proceed after 90 days without further written consent.	10(2)(a), 9(2)(c) 10(2)(b)	
2.	Communicate in writing to the notifier, within 270 days of receipt of notification: - Approval of the import, with or without conditions; - Prohibition of the import; - A request for additional relevant information in accordance with domestic regulatory framework or Annex I; or - Extension of the 270 day period by a defined period of time; AND	10(3)(a)- (d)	
	Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time.	10(4)	
3.	Provide in writing to the Biosafety Clearing-House the decision communicated to the notifier.	10(3)	
4.	Respond in writing within 90 days to a request by an Exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12(2),(3)	

IV. PROCEDURAL REQUIREMENTS: LIVING MODIFIED ORGANISMS FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING

	<i>Tasks</i>	<i>Article</i>	✓
1.	Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing-House within 15 days of making that decision, including the information listed in Annex II.	11(1)	
2.	Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing-House.	11(1)	
3.	Provide additional information contained in paragraph (b) of Annex II about the decision to any Party that requests it.	11(3)	
4.	In response to the posting of a decision by another Party, a Party that decides to import may take a decision on the import of LMO-FFPs: <ul style="list-style-type: none"> - either as approved under the domestic regulatory framework consistent with the Protocol; OR - in the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House. 	11(4),(6)	

Proposals for Addressing Key Issues of National Biosafety Legislation

1. Cross-cutting issues

Issue	Description	Concern	Solution
Message and thrust of the legislation	Underlying or direct statements in the legislation about the value, potential, acceptability, and hazards of modern biotechnology (e.g. in the Preamble)	Inherently negative statements in the preamble or elsewhere will convey a corresponding message to persons or businesses dealing with modern biotechnology. While each government must adopt a policy on biotechnology that is appropriate for its unique culture and environment as well as its particular needs with regard to agricultural production and human health, it should be recognized that the policy adopted by the country – as reflected in its regulatory framework – will have a direct bearing on whether or not the country will be able to take advantage of the technology where and when it wishes. Put another way, biotechnology research and development activities, as well as the availability of commercial products of biotechnology, will take place in countries that recognize its potential and invite its use with appropriate policies and regulations in place to provide for biosafety.	In order to convey a neutral message, negative statements in the preamble or other parts of the legislation should be avoided. Preambular language referring to the value of modern biotechnology could be based on the preamble of the Cartagena Protocol on Biosafety (“Biosafety Protocol” or “Protocol” available at www.biodiv.org), which adopts a balanced approach.

Safety requirements	Authorization of an activity only if it is established that it poses no risk	A standard of “no” or “zero” risk is unattainable. Even the safest activity poses some risk, while the most dangerous activities, such as driving a car, are allowed when risks are balanced with the societal benefits, and reduced through management and mitigation by the imposition of safety regulations and the required use of seat belts and air bags. It is therefore unrealistic to require that an activity be “risk-free”.	Safety standards and requirements for biotechnology should not be higher than for other technologies.
Transparency and clarity of the legislation	Structure and wording of the legislation that makes it difficult to fully understand the obligations	Transparency and clarity of the regulatory process is important to the consuming public, to the regulated community and to the regulators. National legislation and policy provides the framework within which all these actors operate. In order to comply with the legislation, they must be able to fully understand what is required of them.	Fundamental to achieving transparent and clear legislation are: (a) a well-thought out, understandable and workable structure; (b) simply stated provisions concerning the objectives and scope of the legislation; (c) consistent use of defined terms; and (d) clear provisions concerning the processes, rights, duties and limitations for public notice, comment and participation. Procedures and decisions must be transparent, predictable, logical, workable and not overly restrictive. Applicants must be able to rely on consistent, fair and efficient regulation.
Sound science	Importance of sound science as basis and reference of the legislation	Quality science and data are essential to effective risk assessment and management. Sound science is the foundation of public confidence. The general public must be educated to understand this technology, and the underlying scientific concepts. That is the essence of what the public has a right to know.	All biosafety legislation and supporting ordinances should be based in sound science. This will help ensure that implementing policies and procedures and the resulting decisions will be science-based.

<p>Proper implementation of the Protocol</p>		<p>In order to properly implement the Biosafety Protocol, the legislation must be drafted in such a way that its provisions fully implement the Protocol, and are not beyond its scope or inconsistent with its provisions.</p>	<p>There are a number of resources that can be used to facilitate compliance with and implementation of the Protocol. One of these resources is a Model Act which was written by two legal scholars, peer reviewed by two eminent international legal experts, and drafted to allow a country to use all or some of the model provisions in its national biosafety legislation implementing the Protocol. That Model Act is available free of charge at www.arentfox.com/modelbiosafetyact.pdf. In addition, the Biosafety Implementation Toolkit (UNEP/CBD/ICCP/3/10 Annex III) can be used to review draft legislation for compliance with the Protocol.</p>
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2. Specific issues or provisions

Issue	Description	Concern	Solution
<p>Definitions</p>	<p>Terms that are defined for the specific purposes of the legislation, usually in the first part of the legislation</p>	<p>Consistency of terminology is necessary to ensure clarity. Definitions spread throughout the text, redundant definitions (e.g. terms that do not appear in the legislation, terms the everyday meaning of which is well understood), and inconsistent use of defined terms create confusion. Use of new definitions that are not consistent with the Biosafety Protocol and do not enjoy international consensus puts a country at risk of having legislation that does not properly implement the Protocol.</p>	<p>Use of the definitions of the Biosafety Protocol will ensure that the legislation conforms to the Protocol, and helps to promote international harmonization. Definitions should be grouped in one section at the beginning of the legal act. Only terms that have a special meaning in the context of the Protocol must be defined. Once defined, each term should be used consistently throughout the legislation. An example can be found in Article 2 of the Model Act.</p>

<p>Scope: inclusion of products of biotechnology</p>	<p>Applicability of the legislation not just to genetically modified organisms (GMOs), but also to products of biotechnology</p>	<p>Inclusion of products of biotechnology in the scope makes the legislation unworkable. Concerning products, a distinction must be drawn between legislation intended to regulate environmental safety, and legislation on food and feed safety. Environmental and biodiversity protection legislation, such as the Biosafety Protocol, is concerned with living genetically modified organisms that may interact with the environment. The products of genetically modified organisms will either be living modified organisms (e.g. seeds) and regulated as such under this legislation; or they will be intended and used for other purposes such as food, feed or clothing, and hence not interact with the environment. Article 11 of the Biosafety Protocol recognizes this difference and provides distinct treatment for commodities intended for processing, food or feed. Food and feed safety legislation, on the other hand, assesses and addresses potential impacts of both GMOs and derived products containing detectable genetically modified material on human and animal health. Subjecting all derived products to a country's environmental protection approval process largely will prevent the development, importation and use of products of modern biotechnology in that country.</p>	<p>It is highly recommended that products of biotechnology be excluded from the scope of legislation implementing the Biosafety Protocol, consistent with the proper implementation of the Protocol. Appropriate regulation of products of biotechnology for purposes of food and feed safety should be addressed separately. Under the recommended approach, anyone proposing to place a living modified organism on the market for human consumption, for example, would first have to obtain approval under the environmental safety legislation (for the import or release) but also would have to obtain food and feed safety approval for the crops and derived products. On the other hand, if processed soy oil derived from biotech soybeans or socks made from biotech cotton are imported, it makes no sense to require an approval under the environmental legislation.</p>
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<p>Scope: inclusion of transit movements</p>	<p>Applicability of procedures for notification and authorization also to GMOs in transit through the country</p>	<p>Transit is excluded from the procedures under the Biosafety Protocol because such shipments are not intended – and are extremely unlikely – to be released into the environment. While a country is free to regulate transit if it wishes, the practical results of doing so are that shippers and traders will likely avoid that country because it is not economically feasible to undergo the lengthy and expensive regulatory approval process for each brief movement through a country. Allowing transit of GMOs without regulatory scrutiny presents little or no risk to the environment. Should transit result in unintentional release, this is covered by the Protocol even if regulatory approval of the movement is not required under national legislation. Conversely, subjecting transit to regulatory approval may result in significant revenue losses for a country through decreased use of its ports and transport infrastructure.</p>	<p>It is recommended that the procedures of notification and authorization not be applicable to transit movements of GMOs.</p>
<p>Precaution</p>	<p>Reference to the “precautionary principle” or the “precautionary approach” as a guiding principle of the legislation</p>	<p>Invoking precaution in a way that would allow a decision to be taken or to be reversed without reference to objective science-based criteria, and thus eliminate predictability, will effectively prevent import, development and use of biotechnology in the country.</p>	<p>If reference to precaution is made, it should be in line with internationally agreed language such as Principle 15 of the Rio Declaration, Article 10 (6) of the Biosafety Protocol, or the 1995 SPS Agreement.</p>

<p>Notification and authorization requirements</p>	<p>Different requirements for the different types of regulated activities</p>	<p>There are three categories of regulated activities, namely contained use, experimental release (including field trials), and placing on the market (i.e. commercialization) of GMOs. Because of their different characteristics, there are different risk assessment and information requirements for each of these. By subjecting all types of regulated activities to the same notification and authorization requirements, it is not possible to take account of these differences.</p>	<p>There should be distinct procedures for the authorization of the different types of regulated activity, namely contained use and release into the environment. The latter category should be subdivided in placing on the market (i.e. commercialization), and release into the environment for purposes other than placing on the market (i.e. experimental release). This should be reflected in the legislation.</p>
<p>Confidential information</p>	<p>Insufficient protection of confidential business information and trade secrets, e.g. in the context of the authorization procedure and public information</p>	<p>The ability of entrepreneurs to develop new products and to compete depends in some large part on their ability to protect their intellectual property, confidential business information and trade secrets. Legislation that makes no provision for protection of the confidentiality of certain types of information under certain conditions will act as a deterrent to potential applicants.</p>	<p>The legislation needs to contain a procedure, such as that found in the Biosafety Protocol, for the applicant to designate confidential information and ensure that such information is kept confidential. In situations where the authorities disagree about a claim of confidentiality, a procedure is needed to require the applicant to justify the request and for the authorities to consider the justifications (see Biosafety Protocol, Art. 21). If the application is withdrawn, the confidentiality of the information must be respected. This ensures that the applicant may, as a last resort, protect the confidentiality of the information by withdrawing the application. The protection of confidential information must be ensured particularly in the context of public consultation and participation, in the authorization procedure, and in the composition and exercise of functions of authorities and bodies. An example can be found in Article 9 of the Model Act.</p>

<p>Consumer product labelling</p>	<p>Requirement for labelling GMOs and GMO products to identify them as such</p>	<p>Product labelling for consumers is an important regulatory activity, and should not be confused with general education on the nature of a technology. Labelling of GMOs and products should provide information relevant to the safety and use of the product, and not to the technology used to produce it. Labelling merely because a product is the result of the application of modern biotechnology has the potential to mislead, because it suggests that the process is relevant or significant per se.</p>	<p>Regardless of the process used, labelling should only be required if the nature, the allergenicity or the nutrition or composition of the product has been changed in some meaningful way.</p>
<p>Socio-economic impacts</p>	<p>Authorization to be denied unless the activity is proven to have no adverse socio-economic impacts</p>	<p>The inclusion of socio-economic considerations without further qualification is overly broad and is not consistent with the Biosafety Protocol. An application should be considered on the basis of scientific criteria. An important part of this is the risk assessment to be carried out by the applicant. Socio-economic considerations should not be a part of this assessment.</p>	<p>Socio-economic impacts may be considered separately from the risk assessment in reaching a decision on imports. However, as the Protocol states, only those considerations “arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity” may be taken into account and then only when consistent with a country’s other international obligations (see Biosafety Protocol, Art. 26).</p>

<p>Traditional and ethical values and sustainable development</p>	<p>Authorization to be denied unless the activity is proven to have no impacts on traditional and ethical values, and on sustainable development</p>	<p>Such requirements are highly unusual for biosafety regulation or, indeed, for the regulation of any technology or product. They are also outside of the scope of the Protocol. Increased crop yields, reduced pesticide inputs, decreased conversion of habitat to agricultural land, improved resistance to pests and disease, etc. all are in the public interest and clearly make a substantial contribution to sustainable development. The purpose of this legislation is to consider environmental safety.</p>	<p>Unless a requested activity presents a specific and scientifically significant risk to the conservation of biodiversity, taking also into account human health, the activity should be permitted to proceed, not as a replacement but alongside conventional agriculture, organic and subsistence farming. The greatest public good will be achieved by ensuring that all environmentally sound tools are available to those who wish to use them.</p>
<p>Public information and participation</p>	<p>Involving the public in a way that allows meaningful participation while avoiding overburdening of the process</p>	<p>Transparency of the regulatory process is important to the consuming public and to the regulated community. It must be done in a way that is both workable for the government and meaningful for the public. The processes, rights, duties and limitations for public notice, comment and participation must be clearly defined. Public participation should vitalize and inform the process, not disrupt and retard it. For example, it is not necessarily useful or practical for the government to make available entire applications to the public. This would place a heavy administrative burden on the government, and would not necessarily ensure better understanding of the issues by the public.</p>	<p>A common approach, by which this problem can be avoided, is for the government to determine a standard package of information it will release to the public that is informative yet not overwhelming. This generally would include information about the LMO, the activity requested and a summary of the risk assessment and risk management measures, if any. Often the information is not provided to the public until the government has conducted its risk assessment auditing activities and come to a draft decision on the application. Distinction often is also made in public participation between the various activities requested. Generally the public is most directly involved where it is most concerned, i.e., for applications for placing an LMO on the market. An example of a provision on risk assessment can be found in Article 20 of the Model Act.</p>

Risk assessment	Procedures for carrying out and auditing risk assessments in accordance with the Protocol	Scientific risk assessment is the fundamental basis of biosafety regulation. The procedure should be laid down in accordance with the requirements of the Biosafety Protocol and with standard practice. It should clearly state the roles of the applicant and the competent government authority. It must be based on sound science.	The legislation should provide for the following steps. The applicant should be required to submit a risk assessment in compliance with Annex III of the Protocol. This will include risk management measures to be undertaken by the applicant. The government is then responsible for auditing the risk assessment, including any proposed risk management measures, and for conducting, or requiring the applicant to conduct, any additional risk assessment deemed to be necessary on the basis of the scientific auditing process. There should be a provision for the applicant to comment on the audit. The risk assessment required should be specified separately for each relevant activity (e.g. placing on the market, experimental release). Examples of relevant provisions can be found in Articles 8 and 11 of the Model Act.
Liability and redress (general)	Incorporation in the legislation of provisions governing civil liability for harm caused by GMOs	If a biotechnology-specific liability regime is created separately from any existing liability legislation, this may lead to discrimination of biotechnology against other technologies, particularly where there is no scientific basis or use experience that would justify the establishment of such a regime. It would also create a strong disincentive for indigenous and foreign institutes, universities scientists, companies and others to engage in research and development to meet the needs of the country, or to invest in biotechnology in	It should first be established how liability – for traditional and environmental damage – is addressed under the law of the country. If the existing legislation does not address liability for environmental damage, attention should be given to establishing a general environmental liability regime that provides for measurement, valuation, restoration, etc. in the case of actual damage to the environment. Such a scheme would cover all activities that result in harm (the type of activities that are causing substantial damage to the environment

		the country.	are well-known and do not include biotechnology) and provides a more efficient system that is aimed at true environmental protection because of its universal coverage. In the biosafety legislation, reference could be made to existing legislation on liability, if any. An example is given in Article 27 of the Model Act.
Strict liability	Imposing liability regardless of fault	Strict liability generally is reserved for ultra-hazardous activities such as blasting and pile driving which can result in real and substantial physical harm. There is no scientific basis or use experience that would justify the classification of the highly regulated and governmentally approved use of modern biotechnology as such an ultra-hazardous activity.	It is recommended not to apply strict liability to modern biotechnology, whether in the biotechnology legislation or by reference to general liability legislation.
Sanctions and penalties	High prison sentences or fines even for minor procedural omissions	The imposition of extreme sanctions for even the most trivial unintentional harmless error, and penalties disproportionate to the activities and unrelated to any harm, would prevent any person or business from engaging in any activity governed by these provisions. Neither the risk manager of the company nor an insurer could accept the possibility of such extreme consequences of even minor infractions. The activity would be uninsurable and therefore not feasible.	Sanctions and penalties should be in line with those provided for comparable activities, as addressed in relevant laws of the country. An example can be found in Article 26 of the Model Act.

<p>Due process of law</p>	<p>Provision for adoption or reversal of decisions without giving the applicant the rights of due process of law</p>	<p>Due process of law is a critical underpinning of any regulatory system, and is manifested in a number of important ways. First, the regulated community must have a system that is dependable, consistently applied and efficient. In other words, the legal process must work and result in decisions in reasonable time frames. Second, final decisions as well as enforcement and penalties must be based on proper cause, and allow appropriate response and appeal.</p>	<p>In all decision-making processes, the applicant should receive fair notice and opportunity to be heard, where penalties, punishment, denials or forfeitures may be imposed. If such are imposed, the applicant should have clear rights for reconsideration and appeal of those decisions. The legislation should expressly afford the applicant the rights of due process of law and appeal generally available under the administrative, environmental, or licensing laws of the country.</p>
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Model Documentation Requirements for Living Modified Organisms for Food or Feed, or for Processing (LMO/FFPs)

1. Purpose and Objective.

The purpose of this document is to articulate an understanding among the Participants with respect to the documentation requirements of the Cartagena Protocol on Biosafety (Cartagena Protocol) pertaining to living modified organisms intended for direct use as food or feed, or for processing (LMO/FFPs). Specifically, the objective of this arrangement is to clarify documentation requirements such that they fulfill the objectives of the Cartagena Protocol without unnecessarily disrupting commodity trade.

2. Cartagena Protocol on Biosafety.

Article 18.2(a) of the Cartagena Protocol states:

“Each Party shall take measures to require that documentation accompanying 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.”

3. Documentation Required.

Article 18.2(a) of the Cartagena Protocol is to be implemented as follows:

- a. The “may contain” language, when required, should appear on the commercial invoice as provided by the exporter. The importer is responsible for receiving the invoice and maintaining it after entry.
- b. The “may contain” language, when required, should state:

“Cartagena Biosafety Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment.”
- c. The last exporter prior to the transboundary movement and the first importer after the transboundary movement named on the invoice are the contact points for further information.
- d. Applicability:

- i. The “may contain” documentation is required for all transboundary movements of commodities intended for food or feed, or for processing, where an LMO of that commodity species is authorized¹ in, or sold from, a country of export, except:
 - (A) Shipments for which the exporting country does not have in commerce any LMO of that species; or
 - (B) When the exporter and importer have contractually defined a “non-LMO shipment;” provided, that such a shipment achieves a minimum of 95 percent non-LMO content, and that such definition does not conflict with regulations of the importing country.
- ii. Adventitious presence of LMOs in a non-LMO shipment should not be considered a trigger for the “may contain” documentation.

4. Fulfillment of Objectives and Requirements.

The Participants affirm that exporters and importers trading commodities with documentation according to these provisions have fulfilled both the objectives and the current requirements of Article 18.2(a) of the Cartagena Protocol.

5. Scientific Information.

The Participants hereby intend to maintain a continuous exchange of scientific information and to address issues on agricultural biotechnology that may arise among the Participants utilizing the expertise of scientific personnel. The Participants may elaborate on the subjects and mechanisms for information exchange.

6. Decisions on Importation.

This arrangement does not affect a Participant’s decision on the import of LMO/FFPs under its domestic regulatory framework or according to a risk assessment, pursuant to Article 11 of the Cartagena Protocol.

7. Further Consultation.

Whenever, in the judgment of a Participant, issues of concern arise that would require further consultation on the interpretation or implementation of this document, including relevant decisions of the Meeting of Parties to the Cartagena Protocol, the Participants may mutually agree to make the necessary modifications and/or updates.

¹ NOTE: It may be appropriate to briefly clarify the nature of the authorization (e.g., “approved for unconfined release”) in each of the Participant countries, and to direct attention to the Biosafety Clearing-House established under Art. 20 of the Cartagena Protocol as an important source of information.

8. Participation of Non-Parties.

[FOR USE WHEN ONE OR MORE PARTICIPANTS ARE NON-PARTIES TO THE CARTAGENA PROTOCOL]

[NAME OF COUNTRY] is not a Party to the Cartagena Protocol at this time. However, Article 24 of the Cartagena Protocol states that transboundary movements of LMOs between Parties and non-Parties shall be consistent with the objectives of the Cartagena Protocol, and that Parties and non-Parties may enter into arrangements, such as this, regarding such transboundary movements. This arrangement also meets the requirements in Article 14 of the Cartagena Protocol to accommodate the eventuality of a non-Party becoming a Party to the Cartagena Protocol.

BIOSAFETY PROTOCOL AND WORLD TRADE ORGANIZATION: Implementing a WTO-Consistent Biosafety Regulatory Framework

4 January 2006

Most countries that are party to the Cartagena Protocol on Biosafety ("Protocol") also are members of the World Trade Organization ("WTO") or seeking membership. Since several WTO agreements contain disciplines that are relevant to trade in products of modern biotechnology, those countries will need to take both sets of obligations into account as they develop implementing legislation. **Fortunately for countries that are Protocol Parties and WTO members, it is possible to implement the Protocol in a manner that is fully consistent with WTO obligations.**

BACKGROUND ON RELEVANT WTO AGREEMENTS

The General Agreement on Tariffs and Trade ("GATT") is the basic body of law governing trade in goods under the WTO. Under GATT rules, a WTO Member is not allowed to impose new "terms, conditions or qualifications" that impair access to that Member's market. An exception to this rule permits the establishment of regulatory measures necessary to protect human, animal or plant life or health, provided that such measures are not applied in a manner that would constitute arbitrary or unjustifiable discrimination between countries or a restriction on trade. The GATT also requires Members, *inter alia*, to treat imported products no less favorably than like products of national origin in respect of all laws, regulations and requirements.

The Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") explains the boundaries of the GATT exception and applies to all sanitary and phytosanitary measures that may affect international trade. Under the SPS Agreement, WTO members must be sure that any measure is: a) applied only to the extent necessary to protect human, animal or plant life or health; b) based on scientific principles and risk assessment; c) not maintained without sufficient scientific evidence; and d) not arbitrary, discriminatory or a disguised restriction on trade.

The Agreement on Technical Barriers to Trade ("TBT Agreement") elaborates various GATT rules, focusing in particular on non-discrimination and applies to all technical regulations and standards that are not covered by the SPS Agreement. The TBT Agreement requires Members that adopt technical regulations or standards to ensure that they do not create unnecessary barriers to trade and are no more trade restrictive than necessary to fulfill a legitimate objective.

In general, the WTO requires that decisions taken under regulatory regimes established for biotechnology be justified on the basis of the characteristics of the end product, rather than solely because they are products of modern biotechnology. Proposed measures must be notified to the WTO to ensure conformity with WTO obligations.

HIGHLIGHTS OF GUIDE TO WTO-CONSISTENT IMPLEMENTATION OF THE PROTOCOL¹

Requirements relating to Advanced Informed Agreement (AIA)

Information Requirements: The SPS and TBT Agreements require Members to ensure, *inter alia*, that information requirements are limited to what is necessary for appropriate control, inspection and approval procedures and to assess conformity with technical regulations or standards. Further, WTO national treatment and non-discrimination disciplines suggest that the information requirements should be the same for similar LMOs and activities whether imported or produced domestically.

Risk Assessment: The Protocol's risk assessment provisions are broadly consistent with the SPS Agreement: both require a science-based approach and allow regulators to take into account relevant ecological and environmental conditions, including assessment of the consequences of not approving the requested activity.

¹ A complete version of this paper containing Guidelines for Biosafety Regulators authored by Craig Thorn and Kevin Brosch, Esq., DTB Associates, LLP is reproduced with permission of the authors in the Biosafety Regulation Sourcebook, available at www.arentfox.com/modelbiosafetyact.pdf

A risk assessment carried out in accordance with the science-based Protocol requirements and the Annex III guidelines would in all likelihood meet the SPS Agreement standards. Whether a country bases its decision on a risk assessment prepared by someone else or conducts its own, as permitted under the SPS Agreement, importing governments are responsible under the Protocol for ensuring that that risk assessment meets Protocol requirements.

Risk Management: Under the GATT and the SPS Agreement, risk management measures may be imposed only to the extent necessary to protect human, animal or plant life or health. Science-based risk management requirements for specific risks identified in the risk assessment process and which are necessary to protect human, animal or plant life or health should have no trouble conforming to both Protocol and WTO rules.

Socio-economic Considerations: The Protocol allows – but does not require – Parties to take into account certain socio-economic considerations in their decision-making “consistent with their international obligations.” No provision under the WTO agreements would allow a Member to justify regulatory restrictions affecting imports on the basis of socio-economic considerations since the GATT exception is limited to measures necessary to protect human, animal or plant life or health. WTO Members are required, on the other hand, to take into account certain economic factors in decision-making. When dealing with a pest that poses an economic risk, as opposed to a food safety or environmental risk, for example, Members are not to impose SPS trade barriers in cases where the risk of economic damage to the importing country is slight, or the cost of control or eradication is small. Since SPS measures must be related to risks to human, animal or plant life or health, socio-economic considerations alone could not be used to justify the imposition of a measure.

Time-frames for Decision-making: The SPS and TBT Agreements require WTO members to complete approval procedures without “undue delay” and as “expeditiously as possible” in conformity with standard processing periods. The timeframes established in the Protocol are highly likely to be viewed as important evidence of what should be considered a reasonable timeframe for acknowledgement and decision-making for purposes of determining WTO compliance.

Recommendations:

- Incorporate Protocol Annex I into national biosafety legislation, requiring domestic and foreign notifiers/applicants to submit the information contained in Protocol Annex I as appropriate for the specific application.
- Clarify in national biosafety legislation that decisions, including any risk management measures imposed in connection with an approval, must be based on scientifically sound risk assessment in conformity with Article 15.1 and Annex III of the Protocol.
- Base measures and decisions on scientific evidence rather than socio-economic considerations. If socio-economic issues arising from impacts on biodiversity exist, address these through policies or programs that do not inhibit trade.
- Incorporate in national biosafety legislation acknowledgement and decision-making timeframes within the maximum limits established by the Protocol, accompanied by SPS Annex C(1)(b) rights and obligations.

Procedure for Imports of LMOs for Food, Feed or Processing (LMO-FFPs)

If a Protocol Party decides to subject LMO-FFPs to advanced decision making as a stricter domestic measure, under the WTO, it must have a scientific basis for doing so. In addition, a measure must comply with the other requirements laid down in the SPS and TBT Agreements including sufficiency of scientific evidence; necessity, and non-discrimination.

Recommendation: Establish a mechanism to monitor BCH postings concerning approvals of LMO that may be subject to transboundary movement and limit advanced regulatory requirements to cases where scientifically justified based on the potential receiving environment.

Handling, Transport, Packaging and Identification

As indicated above, method of production is not a sufficient justification under the SPS Agreement for imposing restrictions on handling, packaging and transport of a product. Measures maintained for SPS-related purposes must be, *inter alia*, based on a proper risk assessment and supported by sufficient scientific evidence. Moreover, WTO rules do not permit members to discriminate between like products. If the LMOs in question have been examined and approved for use, and there is no scientific reason to restrict their use, and special handling, packaging and transport requirements would be inconsistent with WTO rules. The existing requirement under Protocol Article 18.2(a) for exporters to clearly identify that shipments of LMO-FFPs “may contain” LMOs is not likely to have a significant effect on trade and would therefore probably be considered WTO-consistent. However, imposing more onerous requirements, without a demonstrable scientific rationale based on the characteristics of the individual LMOs covered, would almost certainly be judged WTO-inconsistent.

Recommendation: Allow commodity imports to be accompanied by a “may contain” statement, and show flexibility regarding the type of document provided.

Liability and Redress

As discussed previously, WTO Members are permitted to impose regulatory measures, which include liability provisions, on imports only if those measures meet the requirements of the WTO agreements – e.g., GATT Article XX and the SPS or TBT Agreements. A liability regime imposed on LMOs solely because they are products of modern biotechnology, rather than because of the identification of risks posed by an individual product, would almost certainly violate these rules. Similarly, an across-the-board requirement for liability insurance for LMOs, one that is not related to the risks associated with a particular product, would almost certainly violate WTO rules. The SPS Agreement also requires Members to avoid “arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.” That means Members that adopt a liability regime for biotech products must be able to demonstrate that they impose similar requirements on other technologies or activities that pose a similar risk.

Recommendation: Enact a general environmental liability law at the national level that will provide redress in the case of harm to biodiversity whether caused by LMOs or activities far more likely to result in damage. Any international rules found to be necessary can be created under the Convention on Biological Diversity.

CONCLUSION

It is possible for countries party to both the Biosafety Protocol and the WTO to carry out their legal obligations in a way that is consistent with both instruments. It is clear, however, that neither persons responsible for biosafety nor those responsible for trade can do the job alone: the key to success will be the involvement of a multi-sectoral team of experts that can ensure that national biosafety measures are effective and workable as well as compliant with the WTO disciplines.

15 December 2005

THE CARTAGENA PROTOCOL ON BIOSAFETY AND
THE WORLD TRADE ORGANIZATION:

Implementing a WTO-Consistent Biosafety Regulatory Framework

GUIDELINES FOR BIOSAFETY REGULATORS

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Mr. Thorn is a partner at DTB Associates, LLP, a consulting and legal services firm that represents a number of clients on issues related to biotechnology and international trade. Before founding DTB Associates in 2000, Mr. Thorn spent over 15 years with the Foreign Agricultural Service at the U.S. Department of Agriculture dealing with trade policy and WTO issues, serving as Director of the Europe, Africa and Middle East Division; Counselor for Agriculture at the U.S. Mission to the World Trade Organization (WTO); Deputy Director of the Multilateral Trade Policy Affairs Division; and Agricultural Attaché at the U.S. Mission to the European Union in Brussels. In those positions he was actively involved in the negotiation and implementation of WTO rules governing trade in agricultural products. He also has extensive experience with WTO dispute settlement proceedings.

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Mr. Brosch is a partner at DTB Associates specializing in international and agricultural law and policy. Before founding DTB Associates, Mr. Brosch served as special advisor on international trade to the Senate Committee on Agriculture Nutrition and Forestry and its Chairman, Senator Dick Lugar of Indiana. From 1989 to 1998, Mr. Brosch served as Deputy Assistant General Counsel for International Trade in USDA's Office of the General Counsel. In that capacity, he supervised all aspects of the trade law practice in USDA's legal office. Mr. Brosch served as legal advisor to the U.S. teams negotiating the Agriculture and Sanitary and Phytosanitary Agreements in the WTO Uruguay Round. He also supervised and participated in the negotiation of the agricultural portions of the North American Free Trade Agreement. In 1998, Mr. Brosch left the General Counsel's office to become Special Senior Trade Advisor to the Director of Trade Policy, Foreign Agricultural Service. Before joining government service, Mr. Brosch practiced international trade and antitrust law for eight years with the Washington firm of Steptoe & Johnson.

Summary of Recommendations

The following highlights recommendations for biosafety regulators in implementing the Protocol consistent with WTO rights and obligations:

AIA Procedure for Intentional Introduction into the Environment:

Roles of the Parties and Operators: Ensure that regulations allow governments or operators to submit the required AIA notifications.

Information Requirements: Incorporate Protocol Annex I into national biosafety legislation, requiring domestic and foreign notifiers/applicants to submit the information contained in Protocol Annex I as appropriate for the specific application.

Risk Assessment and Risk Management: Ensure that decisions under biosafety legislation are taken on the basis of a scientific risk assessment which conforms to the requirements of Article 15.1 and Annex III of the Protocol and that any risk management measures are based on specific risks identified in the risk assessment process and imposed only to the extent necessary to protect human, animal or plant life or health.

Criteria for Decision-making: Clarify in national biosafety legislation that decisions, including any risk management measures imposed in connection with an approval, must be based on scientifically sound risk assessment in conformity with Article 15.1 and Annex III of the Protocol.

Socio-Economic Considerations: Base measures and decisions on scientific evidence rather than socio-economic considerations. If socio-economic issues arising from impacts on biodiversity exist, address these through policies or programs that do not inhibit trade.

The Role of Precaution: Ensure that national biosafety legislation allows for provisional decisions in the face of scientific uncertainty by incorporating Protocol precaution language accompanied by an obligation on the governmental authority to seek to obtain additional information necessary for a more objective assessment of risk and to review the decision within a reasonable period of time.

Assigning Costs: If fees are to be charged, establish and publish a uniform fee schedule for regulatory processes in line with actual costs and make applicable to all applicants equally.

Timeframe for Decision-making: Incorporate in national biosafety legislation acknowledgement and decision-making timeframes within the maximum limits established by the Protocol, accompanied by SPS Annex C(1)(b) rights and obligations.

Procedure for Imports for Food, Feed or Processing: Establish a mechanism to monitor BCH postings concerning approvals of LMO that may be subject to transboundary movement and limit advanced regulatory requirements to cases where scientifically justified based on the potential receiving environment.

Confidential Information: Incorporate all Protocol obligations, enhanced by TRIPs agreement protections, into national biosafety legislation.

Handling, Transport, Packaging and Identification: Allow commodity imports to be accompanied by a “may contain” statement, and show flexibility regarding the type of document provided. Avoid mandatory requirements for food labeling for LMO products.

Bilateral, Regional and Multilateral Agreements: Ensure that the content of any arrangement under Article 14(1) can be duplicated with any other country that is a member of the WTO.

Liability and Redress: Enact a general environmental liability law at the national level that will provide redress in the case of harm to biodiversity whether caused by LMOs or activities far more likely to result in damage. Any international rules found to be necessary can be created under the Convention on Biological Diversity.

Stricter Measures: Avoid stricter measures unless required for biodiversity protection and commensurate with scientifically identified risks.

I. INTRODUCTION

The Cartagena Protocol on Biosafety (“Protocol”), a subsidiary agreement to the Convention on Biological Diversity (“CBD”), was adopted in January 2000 and entered into force on September 11, 2003. The objective of the Protocol is to contribute to ensuring an adequate level of protection with respect to the transfer, handling and use of living modified organisms resulting from the application of modern biotechnology (“LMOs”), specifically focusing on transboundary movements. The Protocol’s concentration on transboundary movements, i.e., imports and exports, means that it deals directly with international trade.

As of this writing, 129 countries are Parties to the Protocol. Many of these countries, however, have joined the instrument without the necessary infrastructure and therefore still are considering what is required by way of implementing legislation, technical guidelines, administrative structures, capacity building, and other components of a national biosafety framework to meet the obligations to which they are already legally committed.

Furthermore, a large majority of countries that are party to the Biosafety Protocol also are members of the World Trade Organization (“WTO”) (see Annex I for list of WTO members). Since several WTO agreements contain disciplines that are relevant to trade in products of agricultural biotechnology, those countries will need to take both sets of obligations into account as they develop implementation legislation.

Protocol negotiators dealt with a potential conflict between the Protocol and the WTO agreements by including the following language in the Protocol:

The Parties to this Protocol, . . .

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, . . .

This language provides a valid basis for WTO panels and the Appellate Body to conclude that the Protocol negotiators did not intend for the Protocol to supercede WTO rules. It is for this reason that biosafety regulators must take great care to ensure that national biosafety legislation is consistent with all potentially applicable WTO disciplines. In

other words, **being a Party to the Protocol does not excuse WTO members from their WTO obligations.**¹

Fortunately for countries that are Party to the Protocol as well as WTO members, it is possible to avoid conflict between WTO rules and the trade-related provisions of the Protocol by implementing the Protocol in a manner that is fully consistent with WTO obligations. The purpose of this paper is to examine the trade-related provisions of the Protocol, together with relevant WTO obligations, and to suggest WTO-compliant approaches to establishing a biosafety regulatory framework.

II. OVERVIEW OF THE RELEVANT WTO AGREEMENTS

A. General Agreement on Tariffs and Trade

The General Agreement on Tariffs and Trade (“GATT”)² is the basic body of law governing trade in goods under the WTO. The GATT requires Members, *inter alia*, to:

- Accord to other Members treatment “no less favorable than that provided for” in that Member’s WTO Schedule of Concessions. The Schedule of Concessions lists the maximum tariff a Member is permitted to apply on each tariff line, plus any other “terms, conditions or qualifications” that pertain to that tariff line (Article II).
- Treat imported products no less favorably than like products of national origin in respect of all laws, regulations and requirements (Article III.4).
- Impose no prohibitions or restrictions on imports other than duties, taxes or other charges governed by Article II (Article XI:1).

Under Article XX Members may claim an exception to other GATT disciplines for certain types of measures, including regulatory measures necessary to protect human, animal or plant life or health, provided that such measures are not applied in a manner that would constitute arbitrary or unjustifiable discrimination between countries or a disguised restriction on trade (Article XX). For standards affecting imported LMOs, this exception is subject to a number of safeguards and limitations, however, which are set forth in the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade (see sections B and C below). Relevant excerpts from the GATT can be found in Annex 2.

Many of the measures taken by WTO Members to implement the Protocol will be subject to the disciplines of the GATT. For example, any measure that imposes on an imported product new “terms, conditions or qualifications” that are not contained in a Member’s

¹ Trade relations between Parties to the Protocol that are WTO members and non-Parties that are WTO members are governed exclusively by the WTO agreements or other applicable bilateral or plurilateral trade agreements. See Vienna Convention on the Law of Treaties, Art. 30.4(b).

² The text of the GATT can be found on the web at http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf

Schedule of Concessions must be consistent with Article XX and with the related agreements discussed below. Therefore, **biosafety regulators must familiarize themselves with the WTO disciplines and undertake interagency consultations to ensure that proposed biosafety legislation fully complies with these disciplines and obligations.**

B. Agreement on the Application of Sanitary and Phytosanitary Measures

The Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement")³ explains the boundaries of the exception contained in GATT Article XX(b) for certain regulatory measures necessary to protect human, animal or plant life or health (see SPS Agreement, Article 2.4). It applies to all sanitary and phytosanitary measures that may affect international trade. SPS measures are defined in Annex A of the Agreement as any measure applied to protect human, animal or plant life or health from certain specified risks. Since the Protocol is concerned with many of the types of risks listed in Annex A, regulatory measures designed to implement the Protocol are likely to be covered by the SPS Agreement.

The SPS Agreement explicitly recognizes the right of WTO Members to implement legitimate SPS measures. However, it obliges Members to ensure that any regulatory measure is:

- a) Applied only to the extent necessary to protect human, animal or plant life or health;
- b) Based on scientific principles; and
- c) Not maintained without sufficient scientific evidence (Article 2.2).

All regulatory measures must be based on a scientific risk assessment (Article 5.1). Members also are required to ensure that SPS measures are not arbitrary or discriminatory and do not constitute a disguised restriction on trade. Where scientific evidence is incomplete, the Agreement allows Members, subject to certain well-defined conditions, to adopt provisional measures (Article 5.7). The Agreement also sets out requirements for notification and transparency (Article 7 and Annex B). Relevant excerpts from the SPS Agreement can be found in Annex 3.

C. Agreement on Technical Barriers to Trade

The Agreement on Technical Barriers to Trade ("TBT Agreement")⁴ elaborates various GATT rules, in particular the Article III provisions regarding non-discrimination. It applies to all technical regulations and standards that are not covered by the SPS Agreement (Article 1.5), including certain measures related to human, animal or plant life

³ The text of the SPS Agreement can be found on the web at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf

⁴ The text of the TBT Agreement can be found on the web at http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf

or health that are not covered by the SPS Agreement. The TBT Agreement requires Members that adopt technical regulations or standards such as would be required to implement the Protocol to ensure that they do not create unnecessary barriers to trade and that they are no more trade restrictive than necessary to fulfill a legitimate objective (Article 2.2). Measures must be non-discriminatory (Article 2.1) and must be based on relevant scientific and technical information, when appropriate (Article 2.2). Like the SPS Agreement, the TBT Agreement sets out certain requirements for notification and transparency (Article 10). Relevant excerpts from the TBT Agreement can be found in Annex 4.

III. IMPLEMENTATION ISSUES

As indicated above, Article II of the GATT requires that WTO Members provide tariff treatment for imported products no less favorable than that provided for in that Member's WTO Schedule of Concessions, and that Members spell out explicitly any terms, conditions or qualifications in that Schedule. Article III of the GATT requires that Members accord national treatment to imported products, and Article XI requires that they not impose other restrictions or prohibitions on imported products. Exceptions to these rules are permitted only under the conditions spelled out under GATT Article XX and, as appropriate, the SPS or TBT Agreements. Any country that imposes a biosafety regulation, or any other non-tariff barrier, that is inconsistent with those provisions violates its WTO commitments.

With respect to such regulations, there is a fundamental difference in orientation between the Protocol and WTO rules that policy makers must consider in developing a WTO-consistent biosafety regime. The Protocol is essentially a process-based agreement – *i.e.*, it regulates a category of products simply because they have been produced using a particular production method. WTO rules are, for the most part, product-based – *i.e.*, they focus on the end product rather than the production process. **The WTO does not expressly prohibit the regulation of particular production methods; rather, it requires that decisions taken under regulatory regimes established for biotechnology be justified on the basis of the characteristics of the end product.**

In the sections below, each of the provisions of the Protocol that could affect trade is identified along with relevant WTO rules. Suggestions and tips are provided for regulators to draft biosafety provisions that will be WTO-compliant.

A. AIA Procedure for Intentional Introduction into the Environment

Article 7.1 of the Protocol provides that an “advanced informed agreement procedure . . . shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.” The advanced informed agreement (“AIA”) procedure, involving notification, acknowledgement, risk assessment and decision-making in a concrete timeframe prior to the proposed import, is set out in Protocol Articles 8, 9 and 10. The AIA requirement

applies, for example, to seeds for planting, LMOs used for environmental remediation or industrial applications, transgenic animals and certain veterinary medicines. There is no AIA requirement for LMOs imported for direct use as food or feed, or for processing (“LMO-FFPs), which are not intended for release into the environment and therefore are subject to a different, less onerous procedure discussed below.

The SPS Agreement and the TBT Agreement implicitly permit pre-market approval requirements, such as the Protocol’s AIA procedure, however, it must be undertaken in a manner consistent with the provisions of these Agreements (see e.g., SPS Agreement, Annex C and TBT Agreement, Article 5). **To avoid conflict and potential contravention of WTO obligations, biosafety regulators must implement each element of the AIA in conformity with SPS and TBT requirements** as discussed below.

1. Roles of the Parties and Operators

Protocol Article 8 requires exporting Parties either to provide the required AIA notification themselves or to ensure that their exporters (e.g. operators) notify the importing Party prior to the first shipment of LMOs for intentional introduction into the environment. Nothing in the WTO agreements would prevent a WTO Member country from voluntarily taking on the notification obligation. On the other hand, a requirement by an importing country that the government of an exporting country, as opposed to a private exporter, take on the responsibility for issuing the notification and ensuring the accuracy of the information provided could in itself become a barrier to trade, since it could force governments of exporting countries to establish official controls especially for that purpose.

Fortunately, Protocol Article 8 does not place any obligation on the importer with regard to the notifier. An importing country could fulfill its obligations under the Protocol and avoid potential WTO problems by following normal practices for product approvals and allowing private parties to submit notifications.

<p><i>Recommendation: Ensure that regulations allow governments or operators to submit the required AIA notifications.</i></p>

2. Information Requirements

Detailed information requirements for notifications under the Protocol are set forth in Annex I of the Protocol. WTO members should be aware that there are some limits on the amount and type of data they can demand from notifiers. Annex C(1)(c) of the SPS Agreement requires Members to ensure, *inter alia*, that “information requirements are limited to what is necessary for appropriate control, inspection and approval procedures.” Article 5.2.3 of the TBT Agreement restricts information requirements “to what is necessary to assess conformity” with technical regulations or standards.

Asking for more information than has been agreed as necessary under the Protocol could create problems in complying with these SPS and TBT requirements. Further, national treatment and non-discrimination disciplines under the WTO suggest that the information requirements should be the same for similar LMOs and activities whether imported or produced domestically since requiring more information for imported LMOs would create a trade barrier and operate to protect domestic production.

It is also important to note that the wording of the information requirements found in Annex I creates a great deal of flexibility. Annex I requires, for example, supply of intended dates of transboundary movements and information on centers of origin only “if known” and domestic classifications “if any” (see Protocol Annex I (c), (d) and (f)). Similarly, the notifier must provide a risk assessment consistent with Annex III only where one was previously in existence and suggested methods for safe handling, storage, transport and use, “where appropriate” (see Protocol Annex I (k) and (l)).

The flexibility found in Annex I is particularly critical because this annex applies to all situations requiring AIA which range, for example, from early field research to placing an LMO on the market. Some information items referenced in Annex I will not be known in each of these very different situations.

One can ensure WTO compliance by using Annex I, with its built-in flexibility, as the information requirements for national biosafety legislation and applying it equally to imported and domestically produced LMOs.

Recommendation: Incorporate Protocol Annex I into national biosafety legislation, requiring domestic and foreign notifiers/applicants to submit the information contained in Protocol Annex I as appropriate for the specific application.

3. Risk Assessment and Risk Management

The risk assessment and risk management provisions of the Protocol are closely related and involve interplay between the notifier and the importing government. Thus while Protocol Article 15.2 makes the Party of import responsible for ensuring that risk assessments are carried out for AIA decision-making, the same provision allows the Party of import to require the exporter to carry out the risk assessment. Typically this means that the exporter supplies its own risk assessment report and/or any previous and existing risk assessment reports that may have been generated by other governments. The importing government “audits” the risk assessment(s), perhaps carrying out additional tests or analysis where necessary.

Risk assessment is the cornerstone of the Protocol. According to Protocol Article 15.1, it must be undertaken in a scientifically sound manner, in accordance with the principles set forth in Protocol Annex III, taking into account recognized risk assessment techniques. Annex III, in turn clarifies that risk assessment should be carried out in a scientifically sound and transparent manner and risks associated with LMOs should be considered in the context of risk posed by non-modified organism in the likely potential receiving

environment. This allows regulators to compare the advantages and disadvantages of using the biotech product versus continuing with the existing approaches (e.g., conventional or organic).

The risk assessment provisions in Article 15.1 and Annex III of the Protocol are broadly consistent with the rules of the SPS Agreement (see SPS Article 5.1). In an approach similar to that of Annex III of the Protocol, SPS Article 5.2 allows regulators to take into account relevant ecological and environmental conditions, which would include assessing the consequences both of authorizing the LMO/activity and not doing so (i.e., continuing with the existing situation). A risk assessment carried out in accordance with the science-based Protocol requirements and the Annex III guidelines would in all likelihood meet the SPS Agreement standards.

Secondly, requiring the exporter or the notifier to carry out the risk assessment, as provided for in Article 15.2, is permissible under WTO rules so long as the requirement is non-discriminatory – i.e., all notifiers, foreign and domestic, are subject to the same requirement – and consistent with a country’s approach to regulating similar risks.

Turning to risk management, Article 16.1 obliges Protocol Parties to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment and associated with the use, handling and transboundary movement of LMOs. According to Article 16.2, these measures are to be imposed to the extent necessary to prevent adverse effects of the LMO on the conservation and sustainable use of biodiversity, taking also into account risks to human health. In practice, risk management measures (e.g. specific isolation distances for field trials) often are proposed by the applicant and agreed by the governmental authority in order to address any risks to the conservation and sustainable use of biodiversity, taking also into account risks to human health, which may be identified in the risk assessment process.

As indicated above, WTO rules do not permit a member to impose measures simply because a product has been produced by a particular process. Therefore any risk management obligation must be based on an identifiable risk related to the particular product (SPS Article 5.1), and must conform to the other disciplines laid down in the SPS Agreement and the GATT. Accordingly, once they are identified, risks must be managed without unnecessary trade distortions. SPS Article 2.2 requires that measures be “applied only to the extent necessary to protect human, animal or plant life or health” (see also SPS 5.3 through 5.6). **Science-based risk management requirements for specific risks identified in the risk assessment process and which are necessary to protect human, animal or plant life or health should have no trouble conforming to both Protocol and WTO rules.**

Recommendation: Ensure that decisions under biosafety legislation are taken on the basis of a scientific risk assessment which conforms to the requirements of Article 15.1 and Annex III of the Protocol and that any risk management measures are based on specific risks identified in the risk assessment process and imposed only to the extent

necessary to protect human, animal or plant life or health.

4. Criteria for Decision-making

The Protocol explicitly requires that decisions are made in accordance with Article 15 (requiring scientifically sound risk assessment). **Basing regulatory decisions solely on the scientific conclusions of the risk assessment process, which includes identifying risk management measures that can adequately address any identified risks, will be compatible with WTO disciplines.** The Protocol also permits – but does not require – Parties, in reaching a decision on import under the Protocol or domestic measures implementing the Protocol, to take into account certain socio-economic considerations. This is permitted, however, only to the extent that doing so would be consistent with a country’s other international obligations, including those under the WTO. This topic is addressed in detail below.

As noted above, the Protocol permits the importing country to require the notifier to carry out the risk assessment. Also as indicated above, it is normal for products being produced commercially and traded internationally to undergo a safety evaluation in at least one country. An importing government may wish to base its decision either on the notifier’s risk assessment or on a previous and existing risk assessment from another country instead of carrying out its own risk assessment. This is permissible under the WTO. The WTO Appellate Body has concluded that “Article 5.1 [of the SPS Agreement] does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment. It only requires that the SPS measures be ‘based on an assessment, as appropriate for the circumstances ...’”⁵ Whether a country bases its decision on a risk assessment prepared by someone else or conducts its own, the critical point to remember is that the importing government is responsible under the Protocol to ensure that that risk assessment meets Protocol requirements and standards and that it is wholly responsible for the decision it makes.

Recommendation: Clarify in national biosafety legislation that decisions, including any risk management measures imposed in connection with an approval, must be based on scientifically sound risk assessment in conformity with Article 15.1 and Annex III of the Protocol.

5. Socio-Economic Considerations

As noted above, Article 26 of the Protocol allows – but does not require – Parties to take into account certain socio-economic considerations in their decision-making “consistent with their international obligations.” Under the Protocol, permissible socio-economic considerations are limited to those “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.”

⁵ Appellate Body Report on *EC – Hormones*, para. 190.

There is no provision under the WTO agreements that would allow a Member to justify regulatory restrictions affecting imports on the basis of general socio-economic considerations. As indicated above, the exceptions to GATT rules, as articulated further in the SPS and TBT Agreements, that allow countries to impose new restrictions are limited to specific circumstances, such as those “necessary to protect human, animal or plant life or health” (see GATT Article XX(b)). General socio-economic concerns are not included.

The SPS Agreement permits Members to take economic factors into account when assessing risks, but only in a very narrow sense. SPS measures must be based on scientific evidence (SPS Article 2.2) and an assessment of “risks to human, animal or plant life or health” (SPS Article 5.1). In assessing risks and identifying the appropriate level of protection against such risks (i.e., imposing risk management measures) WTO members must also take into account “as relevant economic factors: the potential damage in terms of loss or production or sales in the event of the entry, establishment or spread of a pest or disease; the cost of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks” (see SPS Article 5.3).

The context and the negotiating history make clear that these economic considerations are meant as constraints on regulators. When dealing with a pest or disease that poses an economic risk, as opposed to a food safety or environmental risk, Members are not to impose SPS trade barriers in cases where the risk of economic damage to the importing country is slight, or the cost of control or eradication is small. Moreover, Members are required to consider other, more cost-effective methods of risk management when they are available. This point is reinforced by SPS Article 5.4, which encourages Members to bear in mind “the objective of minimizing negative trade effects.” Since SPS measures must be related to risks to human, animal or plant life or health (remember: the SPS Agreement is an explication of GATT Article XX(b)), socio-economic considerations alone could not be used to justify the imposition of a measure.

Recommendation: Base measures and decisions on scientific evidence rather than socio-economic considerations. If socio-economic issues arising from impacts on biodiversity exist, address these through policies or programs that do not inhibit trade.

6. The Role of Precaution

The Biosafety Protocol explicitly references the precautionary approach as defined in Principle 15 of the Rio Declaration on Environment and Development. Some commentators, however, describe Protocol Article 10.6 as “operationalizing” the “precautionary principle.”⁶ The precautionary principle, contrary to the precautionary approach, is sometimes described as permitting a decision to disallow an activity in the face of scientific uncertainty about its possible environmental impacts.

⁶ Article 10.6 is applicable to AIA decision-making, however, the same language may be found in Article 11.8 which is applicable to LMO-FFPs.

While the “precautionary principle” has been a frequent topic of discussion in the WTO,⁷ it has not been defined by the international community and does not enjoy consensus. Accordingly, to date, the majority of WTO members have opposed amending or interpreting WTO rules to incorporate such a broad, open-ended principle.⁸ Moreover, when one WTO member used the precautionary principle to justify its rejection of a particular product, the WTO Appellate Body did not recognize it as a general principle of international law and stated that the precautionary principle did not “override” SPS Agreement obligations.⁹

The SPS Agreement, however, does incorporate important elements of precaution. Article 5.7 of the SPS Agreement provides:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

SPS Article 5.7 permits members to adopt – on a provisional basis only - measures in cases where information is incomplete. This right is accompanied by clear obligations, as described by the WTO Appellate Body below:

Article 5.7 of the SPS Agreement sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure. Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure if this measure is:

- (1) imposed in respect of a situation where ‘relevant scientific information is insufficient’; and
- (2) adopted ‘on the basis of available pertinent information’.

Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure:

- (1) ‘seek[s] to obtain the additional information necessary for a more objective assessment of risk’; and

⁷ The precautionary principle has been raised both in the Committee on Sanitary and Phytosanitary Measures and in the context of the Doha Development Agenda negotiations on agriculture. See, e.g., WTO document G/SPS/GEN/168, *Communication from the Commission on the Precautionary Principle*, 14 March 2000.

⁸ See WTO document G/SPS/R/18, *Summary of the Meeting Held on 15-16 March 2000*, Committee on Sanitary and Phytosanitary Measures, 18 April 2000, page 1.

⁹ Appellate Body Report on *EC – Hormones*, para. 123.

- (2) ‘review[s] the ... measure accordingly within a reasonable period of time’.

These four requirements are clearly cumulative in nature and are equally important for the purpose of determining consistency with this provision. Whenever one of these four requirements is not met, the measure at issue is inconsistent with Article 5.7.¹⁰

The right to act under Protocol Article 10.6 is less qualified. **To ensure full compliance with WTO limits on the use of precautionary measures, countries party to both agreements should ensure that any measures or decisions taken in the face of scientific uncertainty are provisional and subject to obligations to seek additional information and review the measures or decisions in a reasonable period of time.**

Recommendation: Ensure that national biosafety legislation allows for provisional decisions in the face of scientific uncertainty by incorporating Protocol precaution language accompanied by an obligation on the governmental authority to seek to obtain additional information necessary for a more objective assessment of risk and to review the decision within a reasonable period of time.

7. Timeframe for Decision-making

Protocol Article 9.1 requires acknowledgement of a notification within 90 days from its receipt and Article 10.3 requires a final decision within 270 days of receipt of the notification. Article 9.4 and 10.5, however, provide that failure of the importing Party to acknowledge the receipt of the notification or decide upon it within the stated timeframes “shall not imply its consent to an intentional transboundary movement.” Articles 9.4 and 10.5 of the Protocol thus imply that a party to the Protocol could ban the import of a product indefinitely simply by failing to reply to a notification or to make a final decision.

While neither the SPS Agreement nor the TBT Agreement puts an absolute time limit on pre-market approval procedures, both agreements require prompt action. The SPS Agreement stipulates that approval procedures must be “completed without undue delay” (SPS Annex C.1.a). Standard processing periods must be published or applicants informed, upon request, of the anticipated processing periods. Similarly, the TBT Agreement says that procedures must be “completed as expeditiously as possible” (TBT Article 5.2.1).

Concerning acknowledgement of receipt of notification, Annex C(1)(b) of the SPS Agreement provides that WTO Members must “promptly examine the completeness of the document and inform the applicant in a precise and complete manner of all deficiencies.” Even where the document has deficiencies, the competent authority must proceed as far as practicable with the procedure if the applicant so requests. Upon

¹⁰ Appellate Body Report on *Japan – Agricultural Products II*, para. 89.

request, an applicant must be informed of the stage of the procedure and any delay must be explained.

In short, notwithstanding the language in Protocol Article 9.4 and 10.5 stating that failure to act does not result in authorization, **WTO Members cannot engage in delay and avoidance tactics.** Furthermore, the timeframes established in the Protocol are highly likely to be viewed as important evidence of what should be considered a reasonable timeframe for acknowledgement and decision-making for purposes of determining WTO compliance.

Recommendation: Incorporate in national biosafety legislation acknowledgement and decision-making timeframes within the maximum limits established by the Protocol, accompanied by SPS Annex C(1)(b) rights and obligations.

8. Assigning Costs

As noted above, Protocol Article 15.2 allows an importing government either to require notifiers to carry out risk assessments or to do so itself. Where the government carries out the risk assessment, or incurs costs in auditing submitted risk assessments, Protocol Article 15.3 allows Protocol parties to require notifiers to pay the cost. Under WTO rules, any such fees may not exceed the cost of services rendered and must be equitable in relation to fees charged for similar services for like products of domestic origin (see SPS Annex C.1.f; TBT Article 5.2.5; GATT III.1 and II.2.c and VIII).

Recommendation: If fees are to be charged, establish and publish a uniform fee schedule for regulatory processes in line with actual costs and made applicable to all applicants equally.

B. Procedure for Imports for Food, Feed or Processing

Under Protocol Article 7(2), LMOs shipped for direct use as food, feed or processing (LMO-FFPs) are not considered as an intentional introduction into the environment. Therefore, the Protocol's AIA mechanism does not apply. Instead, LMO-FFPs are subject to a different procedure under Article 11 which applies prior to the first transboundary movement of an LMO-FFP. This procedure applies to the large majority of trade in LMOs, which is in the form of bulk commodity shipments.

Under Article 11(1), governments that make a final decision on LMOs for domestic use that may be subject to transboundary movement for direct use as food, feed or for processing must notify other Parties of that decision through the Protocol's Biosafety Clearing House ("BCH"). They must also provide summary risk assessment information about the LMO. This must be done within 15 days of the decision and requires submission of the information set forth in Annex II to the Protocol. This gives countries notice of what might be in the commodity stream coming from particular countries and also provides a contact point for additional information.

It is also possible, however, for Parties to subject the first import of an LMO-FFP into their country to advanced decision-making under Article 11(4) or 11(6) as a stricter domestic measure. If a Party decides to take this step, it can make decisions under its domestic legislation (as long as it is consistent with the objectives of the Protocol) or, if there is no such legislation, take a decision within 270 days based on a risk assessment conducted in conformity with Annex III of the Protocol under Article 11.6.

If a country decides to subject imported LMO-FFPs to advanced decision making as a stricter domestic measure, under the WTO, it must have a scientific basis for doing so (see section G below). The SPS Agreement requires that a measure be “based on” a risk assessment (SPS 5.1) – that is, there must be a “rational relationship between the measure and the risk assessment.”¹¹ In addition, a measure must comply with the other requirements laid down in the Agreement – e.g., sufficiency of scientific evidence (SPS 2.2); necessity (SPS 5.6, TBT 2.2, Article XX of the *General Agreement on Tariffs and Trade* (“GATT”)), and non-discrimination (SPS 2.3, TBT 2.1, GATT III.4). WTO consistent approaches to risk assessment, decision-making, use of precaution, and time limits for decision-making on LMO-FFPs where countries have chosen to subject them to advanced decision, are the same as outlined in section A above concerning the AIA mechanism.

Finally, under Article 11(5) of the Protocol, any “national laws, regulations and guidelines” applicable to the import of LMO-FFPs must be provided to the BCH. Such measures also must be notified to the WTO (see SPS 7 and Annex B, TBT 10) to ensure conformity with WTO obligations. The same is true of all other measures adopted to implement the Protocol.

Recommendation: Establish a mechanism to monitor BCH postings concerning approvals of LMO that may be subject to transboundary movement and limit advanced regulatory requirements to cases where scientifically justified based on the potential receiving environment.

C. Confidential Information

Article 21 of the Protocol sets forth specific mandatory requirements for the protection of confidential information as defined by applicants, as well as procedures to resolve disputes about the nature of claimed confidential information and items that may not be claimed as confidential. Any national implementing legislation must incorporate these basic protections to be consistent with the Protocol.

The WTO lays down rules regarding the protection of undisclosed information that are somewhat more protective of the rights of applicants than those contained in the Protocol. The SPS and TBT Agreements require that information provided in the course of an approval process be “respected in a way no less favourable than for domestic products

¹¹ Appellate Body Report on *EC – Hormones*, para. 193.

and in such a manner that legitimate commercial interests are protected” (SPS Annex C.1.d and TBT 5.2.4).

In addition, Article 39 of the WTO *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPs) contains more detailed obligations as follows:

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[*] so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

*For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

Recommendation: Incorporate all Protocol obligations, enhanced by TRIPs agreement protections, into national biosafety legislation.

D. Handling, Transport, Packaging and Identification

Article 18 of the Protocol sets forth requirements for handling, transport, packaging and identification for LMO shipments. Specific identification requirements for LMOs shipped for contained use, intentional introduction into the environment and for LMO-FFPs are found in Article 18(2) and are the subject of ongoing implementation talks. In these discussions, some participants in the talks are advocating more detailed identification requirements for LMO-FFPs and additional requirements, such as the use

of new documentation formats (as opposed to existing commercial invoices) for other shipments.

As indicated above, method of production is not a sufficient justification under the SPS Agreement for imposing restrictions on handling, packaging and transport of a product. Measures maintained for SPS-related purposes must be, *inter alia*, based on a proper risk assessment and supported by sufficient scientific evidence. Moreover, WTO rules do not permit members to discriminate between like products (GATT III.4, TBT 2.1). If the LMOs in question have been examined and approved for use, and there is no scientific reason to restrict their use, special handling, packaging and transport requirements would be inconsistent with WTO rules.

Article 18.2(a) requires exporters to clearly identify that shipments of LMO-FFPs “may contain” LMOs and are not intended for intentional introduction into the environment. They must also provide a contact point for further information. Parties also have agreed to be flexible with respect to the type of documentation provided – e.g., commercial invoice, annex to commercial invoice, etc. -- pending a decision on detailed requirements for this purpose, which could include development of a new stand-alone document. These requirements are not likely to have a significant effect on trade and would therefore probably be considered WTO-consistent. However, certain Parties continue to advocate moving beyond the “may contain” requirement. They favor requiring exporters to list precisely all LMOs contained in each shipment. Such a requirement would be significantly more burdensome to traders. Unless the Party imposing the restriction could demonstrate a scientific rationale for it, based on the characteristics of the individual LMOs covered, it would almost certainly be judged WTO-inconsistent.

While the Protocol does not address labeling in any way, it is important to understand the WTO treatment of this issue. Labeling for consumer information purposes, as opposed to labeling for a health or environmental risk, is permissible under WTO rules. However, the TBT Agreement requires, *inter alia*, that such labeling be non-discriminatory and “no more restrictive than necessary to fulfill a legitimate objective” (TBT 2.2). Mandatory labeling of LMOs for food, feed and processing for consumer information purposes can be burdensome and costly. On the other hand, a system that allows voluntary labeling of non-LMO products can provide the same information to consumers in a much less trade-restrictive manner.

Recommendation: Allow commodity imports to be accompanied by a “may contain” statement, and show flexibility regarding the type of document provided. Avoid mandatory requirements for food labeling for LMO products.

E. Bilateral, Regional and Multilateral Agreements

Article 14(1) permits Parties to enter into bilateral and multilateral agreements with other Parties or non-Parties as long as those agreements do not result “in a lower level of protection than that provided for by the Protocol.” WTO rules do not prohibit special

arrangements between or among members on regulatory matters, however, the SPS Agreement requires members to “ensure that their [SPS] measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members” (SPS 2.3). This provision is an elaboration of the “most-favored-nation” principle, the cornerstone of WTO law. The GATT requires that, with respect to all laws, regulations and requirements affecting trade:

any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties (Article I.1).

GATT Article XXIV provides an exception from Article I and other GATT rules for customs unions and free trade areas, but there is no such exception in the SPS Agreement. If a Protocol Party that is a WTO member reaches an agreement under Article 14.1 to grant special treatment to another country, that Party is obliged under WTO rules to grant the same treatment to any other WTO member that can meet the same standard as the country to which special treatment has been granted. The countries party to the Canada-U.S.-Mexico Trilateral Agreement on documentation for commodity shipments would be required, for example, to cooperate with other countries on the same basis.

Recommendation: Ensure that the content of any arrangement under Article 14(1) can be duplicated with any other country that is a member of the WTO.

F. Liability and Redress

Article 27 tasks Protocol Parties with elaborating “international rules and procedures in the field of liability and redress for damage resulting from transboundary movements” of LMOs. The Conference of Parties has established a process aimed at fulfilling this mandate. While some participants in this process urge use of existing laws and consideration of nonbinding instruments to build capacity to better protect biodiversity, others advocate the establishment of a legally binding international regime to hold technology providers strictly liable for a vast array of “harms” ranging from traditional damages (personal injury, property damage) to undefined and subjective socio-economic impacts such as loss of income, displacement of crops, damage to spiritual values, etc. These participants reject well-known defenses to liability such as the state-of-the-art and permit defenses as well as time limitations, caps on awards and other features that help to ensure that liability systems are both effective and fair. Some also propose establishing mandatory insurance requirements and funds created through compulsory payments by technology providers.

As indicated above, WTO Members are permitted to impose regulatory measures on imports of LMOs only if those measures meet the requirements of GATT rules and

exemptions and the SPS or TBT Agreements. Most of the types of regimes related to liability described above would be considered “measures” that fall under the SPS Agreement. That Agreement requires that measures be based on scientific evidence and an assessment of the risks to human, plant or animal life or health (SPS Article 2.2 and 5.1). A liability regime imposed on LMOs solely because they are products of biotechnology, rather than because of the identification of risks posed by an individual product, would almost certainly violate these rules. Similarly, an across-the-board requirement for liability insurance for LMOs, one that is not related to the risks associated with a particular product, would almost certainly violate those SPS rules.

The SPS Agreement also requires Members to avoid “arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade” (SPS Article 5.5). That means Members that adopt a liability regime for biotech products must be able to demonstrate that they impose similar requirements on other technologies or activities that pose a similar risk. GATT Articles III and XX and TBT Article 2 contain similar anti-discrimination requirements.

Recommendation: Enact a general environmental liability law at the national level that will provide redress in the case of harm to biodiversity whether caused by LMOs or activities far more likely to result in damage. Any international rules found to be necessary can be created under the Convention on Biological Diversity.

G. Stricter Measures

Article 2(4) of the Protocol reiterates the well-known legal right of countries to adopt stricter measures at the domestic level than set forth in the international agreements to which they are party. This right is qualified in the Protocol, however, and is permitted only where the action is “more protective of the conservation and sustainable use of biodiversity” and then only if consistent with the “objective and provisions” of the Protocol and if it is “in accordance with that Party’s other obligations under international law.” Under the Protocol itself, therefore, stricter measures cannot be imposed for purposes other than protection of the conservation and sustainable use of biodiversity (e.g., stricter measures to protect markets or competing products would not be allowed).

While some advocate stricter measures in almost every case ostensibly to increase biodiversity protection, stricter measures do not always have that effect. Instead, stricter measures may operate to render the regulatory system unworkable, rather than more effective, and may even discourage the subject activity altogether (thus explaining why anti-technology activists often urge the adoption of “stricter measures”). Another consequence can be the undermining of international harmonization created by the agreed standards. Moreover, for WTO members, there is an additional requirement that must be met. Article 3.3 of the SPS Agreement requires members to provide a scientific justification for any measure that is stricter than the internationally agreed standard. If this justification is lacking, the measure may be found to be in violation of WTO obligations and, therefore, Article 2(4) of the Protocol as well.

Recommendation: Avoid stricter measures unless required for biodiversity protection and commensurate with scientifically identified risks.

IV. CONCLUSION

As the foregoing analysis demonstrates, it is possible for countries party to both the Biosafety Protocol and the WTO to carry out their legal obligations in a way that is consistent with both instruments. It is clear, however, that neither persons responsible for biosafety nor those responsible for trade can do the job alone: the key to success will be the involvement of a multi-sectoral team of experts that can ensure that national biosafety measures are effective and workable as well as compliant with the WTO disciplines.

ANNEX 1

WTO Member Countries

Albania	Egypt
Angola	El Salvador
Antigua and Barbuda	Estonia
Argentina	European Communities
Armenia	Fiji
Australia	Finland
Austria	Former Yugoslav Republic of Macedonia (FYROM)
Bahrain, Kingdom of	France
Bangladesh	Gabon
Barbados	The Gambia
Belgium	Georgia
Belize	Germany
Benin	Ghana
Bolivia	Greece
Botswana	Grenada
Brazil	Guatemala
Brunei Darussalam	Guinea
Bulgaria	Guinea Bissau
Burkina Faso	Guyana
Burundi	Haiti
Cameroon	Honduras
Canada	Hong Kong, China
Central African Republic	Hungary
Chad	Iceland
Chile	India
China	Indonesia
Colombia	Ireland
Congo	Israel
Costa Rica	Italy
Côte d'Ivoire	Jamaica
Croatia	Japan
Cuba	Jordan
Cyprus	Kenya
Czech Republic	Korea, Republic of
Democratic Republic of the Congo	Kuwait
Denmark	Kyrgyz Republic
Djibouti	Latvia
Dominica	Lesotho
Dominican Republic	Liechtenstein
Ecuador	Lithuania

Luxembourg
Macao, China
Madagascar
Malawi
Malaysia
Maldives
Mali
Malta
Mauritania
Mauritius
Mexico
Moldova
Mongolia
Morocco
Mozambique
Myanmar
Namibia
Nepal
Netherlands — For the Kingdom
 in Europe and for the
 Netherlands Antilles)
New Zealand
Nicaragua
Niger
Nigeria
Norway
Oman
Pakistan
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Poland
Portugal
Qatar
Romania
Rwanda
Saint Kitts and Nevis
Saint Lucia
Saint Vincent & the Grenadines
Senegal
Sierra Leone
Singapore
Slovak Republic
Slovenia
Solomon Islands
South Africa
Spain
Sri Lanka
Suriname
Swaziland
Sweden
Switzerland
Chinese Taipei
Tanzania
Thailand
Togo
Trinidad and Tobago
Tunisia
Turkey
Uganda
United Arab Emirates
United Kingdom
United States of America
Uruguay
Venezuela
Zambia
Zimbabwe

ANNEX 2

Relevant Excerpts of the General Agreement on Tariffs and Trade(GATT)

Article I – General Most-Favoured-Nation Treatment

1. With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation, and with respect to all matters referred to in paragraphs 2 and 4 of Article III,* any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

.....

Article II – Schedules of Concessions

1. (a) Each contracting party shall accord to the commerce of the other contracting parties treatment no less favourable than that provided for in the appropriate Schedule annexed to this Agreement.

(b) The products described in Part I of the Schedule . . . shall, on their importation into the territory to which the Schedule relates, and subject to the terms, conditions or qualifications set forth in that Schedule, be exempt from ordinary customs duties in excess of those set forth and provided therein. Such products shall also be exempt from all other duties or charges of any kind imposed on or in connection with the importation in excess of those imposed on the date of this Agreement or those directly and mandatorily required to be imposed thereafter by legislation in force in the importing territory on that date.

.....

2. Nothing in this Article shall prevent any contracting party from imposing at any time on the importation of any product:

(a) a charge equivalent to an internal tax imposed consistently with the provisions of paragraph 2 of Article III* in respect of the like domestic product or in respect of an article from which the imported product has been manufactured or produced in whole or in part;

(b) any anti-dumping or countervailing duty applied consistently with the provisions of Article VI;*

- (c) fees or other charges commensurate with the cost of services rendered.

.....

Article III* - National Treatment on Internal Taxation and Regulation

1. The contracting parties recognize that internal taxes and other internal charges, and laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products, and internal quantitative regulations requiring the mixture, processing or use of products in specified amounts or proportions, should not be applied to imported or domestic products so as to afford protection to domestic production.*

.....

4. The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product.

.....

Article VIII – Fees and Formalities connected with Importation and Exportation*

1. (a) All fees and charges of whatever character (other than import and export duties and other than taxes within the purview of Article III) imposed by contracting parties on or in connection with importation or exportation shall be limited in amount to the approximate cost of services rendered and shall not represent an indirect protection to domestic products or a taxation of imports or exports for fiscal purposes.

.....

Article XI* - General Elimination of Quantitative Restrictions

1. No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licenses or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party.

.....

Article XX – General Exceptions

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

.....

- (b) necessary to protect human, animal or plant life or health;

.....

ANNEX 3

Agreement of the Application of Sanitary and Phytosanitary Measures

Article 2 – Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

.....

Article 5 – Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry,

establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.¹²

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

.....

Article 7 – Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

¹² For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

Article 8 – Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

.....

ANNEX A – DEFINITIONS¹³

1. *Sanitary or phytosanitary measure* - Any measure applied:
 - (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
 - (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
 - (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
 - (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

.....

ANNEX B – TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS

¹³ For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations¹⁴ which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.
2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:
 - (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;
 - (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
 - (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
 - (d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.
4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals¹⁵ of the Member concerned.

Notification procedures

¹⁴ Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

¹⁵ When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

- (a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;
- (b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;
- (c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;
- (d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

- (a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);
- (b) provides, upon request, copies of the regulation to other Members;
- (c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

7. Notifications to the Secretariat shall be in English, French or Spanish.

8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.

9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:

- (a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or
- (b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

ANNEX C – CONTROL, INSPECTION AND APPROVAL PROCEDURES¹⁶

1. Members shall ensure, with respect to any procedure to check and ensure the fulfillment of sanitary or phytosanitary measures, that:

- (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;
- (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

¹⁶ Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.

- (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;
- (d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;
- (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;
- (f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;
- (g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;
- (h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and
- (i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

ANNEX 4

Agreement on Technical Barriers to Trade

Article 1 – General Provisions

.....

1.5 The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.

.....

Article 2 – Preparation, Adoption and Application of Technical Regulations by Central Government Bodies

With respect to their central government bodies:

2.1 Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products.

2.3 Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.

.....

Article 5 – Procedures for Assessment of Conformity by Central Government Bodies

5.1 Members shall ensure that, in cases where a positive assurance of conformity with technical regulations or standards is required, their central government bodies apply the following provisions to products originating in the territories of other Members:

- 5.1.1 conformity assessment procedures are prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favourable than those accorded to suppliers of like products of national origin or originating in any other country, in a comparable situation; access entails suppliers' right to an assessment of conformity under the rules of the procedure, including, when foreseen by this procedure, the possibility to have conformity assessment activities undertaken at the site of facilities and to receive the mark of the system;
- 5.1.2 conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means, *inter alia*, that conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.
- 5.2 When implementing the provisions of paragraph 1, Members shall ensure that:
- 5.2.1 conformity assessment procedures are undertaken and completed as expeditiously as possible and in a no less favourable order for products originating in the territories of other Members than for like domestic products;
- 5.2.2 the standard processing period of each conformity assessment procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the assessment in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the conformity assessment if the applicant so requests; and that, upon request, the applicant is informed of the stage of the procedure, with any delay being explained;
- 5.2.3 information requirements are limited to what is necessary to assess conformity and determine fees;

- 5.2.4 the confidentiality of information about products originating in the territories of other Members arising from or supplied in connection with such conformity assessment procedures is respected in the same way as for domestic products and in such a manner that legitimate commercial interests are protected;
- 5.2.5 any fees imposed for assessing the conformity of products originating in the territories of other Members are equitable in relation to any fees chargeable for assessing the conformity of like products of national origin or originating in any other country, taking into account communication, transportation and other costs arising from differences between location of facilities of the applicant and the conformity assessment body;
- 5.2.6 the siting of facilities used in conformity assessment procedures and the selection of samples are not such as to cause unnecessary inconvenience to applicants or their agents;
- 5.2.7 whenever specifications of a product are changed subsequent to the determination of its conformity to the applicable technical regulations or standards, the conformity assessment procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the technical regulations or standards concerned;
- 5.2.8 a procedure exists to review complaints concerning the operation of a conformity assessment procedure and to take corrective action when a complaint is justified.

5.3 Nothing in paragraphs 1 and 2 shall prevent Members from carrying out reasonable spot checks within their territories.

5.4 In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by international standardizing bodies exist or their completion is imminent, Members shall ensure that central government bodies use them, or the relevant parts of them, as a basis for their conformity assessment procedures, except where, as duly explained upon request, such guides or recommendations or relevant parts are inappropriate for the Members concerned, for, *inter alia*, such reasons as: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems.

5.5 With a view to harmonizing conformity assessment procedures on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the

preparation by appropriate international standardizing bodies of guides and recommendations for conformity assessment procedures.

5.6 Whenever a relevant guide or recommendation issued by an international standardizing body does not exist or the technical content of a proposed conformity assessment procedure is not in accordance with relevant guides and recommendations issued by international standardizing bodies, and if the conformity assessment procedure may have a significant effect on trade of other Members, Members shall:

- 5.6.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular conformity assessment procedure;
- 5.6.2 notify other Members through the Secretariat of the products to be covered by the proposed conformity assessment procedure, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;
- 5.6.3 upon request, provide to other Members particulars or copies of the proposed procedure and, whenever possible, identify the parts which in substance deviate from relevant guides or recommendations issued by international standardizing bodies;
- 5.6.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

5.7 Subject to the provisions in the lead-in to paragraph 6, where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 6 as it finds necessary, provided that the Member, upon adoption of the procedure, shall:

- 5.7.1 notify immediately other Members through the Secretariat of the particular procedure and the products covered, with a brief indication of the objective and the rationale of the procedure, including the nature of the urgent problems;
- 5.7.2 upon request, provide other Members with copies of the rules of the procedure;
- 5.7.3 without discrimination, allow other Members to present their comments in writing, discuss these comments upon request, and

take these written comments and the results of these discussions into account.

5.8 Members shall ensure that all conformity assessment procedures which have been adopted are published promptly or otherwise made available in such a manner as to enable interested parties in other Members to become acquainted with them.

5.9 Except in those urgent circumstances referred to in paragraph 7, Members shall allow a reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member.

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Article 10 – Information About Technical Regulations, Standards and Conformity Assessment Procedures

10.1 Each Member shall ensure that an enquiry point exists which is able to answer all reasonable enquiries from other Members and interested parties in other Members as well as to provide the relevant documents regarding:

- 10.1.1 any technical regulations adopted or proposed within its territory by central or local government bodies, by non-governmental bodies which have legal power to enforce a technical regulation, or by regional standardizing bodies of which such bodies are members or participants;
- 10.1.2 any standards adopted or proposed within its territory by central or local government bodies, or by regional standardizing bodies of which such bodies are members or participants;
- 10.1.3 any conformity assessment procedures, or proposed conformity assessment procedures, which are operated within its territory by central or local government bodies, or by non-governmental bodies which have legal power to enforce a technical regulation, or by regional bodies of which such bodies are members or participants;
- 10.1.4 the membership and participation of the Member, or of relevant central or local government bodies within its territory, in international and regional standardizing bodies and conformity assessment systems, as well as in bilateral and multilateral arrangements within the scope of this Agreement; it shall also be able to provide reasonable information on the provisions of such systems and arrangements;

10.1.5 the location of notices published pursuant to this Agreement, or the provision of information as to where such information can be obtained; and

10.1.6 the location of the enquiry points mentioned in paragraph 3.

10.2 If, however, for legal or administrative reasons more than one enquiry point is established by a Member, that Member shall provide to the other Members complete and unambiguous information on the scope of responsibility of each of these enquiry points. In addition, that Member shall ensure that any enquiries addressed to an incorrect enquiry point shall promptly be conveyed to the correct enquiry point.

10.3 Each Member shall take such reasonable measures as may be available to it to ensure that one or more enquiry points exist which are able to answer all reasonable enquiries from other Members and interested parties in other Members as well as to provide the relevant documents or information as to where they can be obtained regarding:

10.3.1 any standards adopted or proposed within its territory by non-governmental standardizing bodies, or by regional standardizing bodies of which such bodies are members or participants; and

10.3.2 any conformity assessment procedures, or proposed conformity assessment procedures, which are operated within its territory by non-governmental bodies, or by regional bodies of which such bodies are members or participants;

10.3.3 the membership and participation of relevant non-governmental bodies within its territory in international and regional standardizing bodies and conformity assessment systems, as well as in bilateral and multilateral arrangements within the scope of this Agreement; they shall also be able to provide reasonable information on the provisions of such systems and arrangements.

10.4 Members shall take such reasonable measures as may be available to them to ensure that where copies of documents are requested by other Members or by interested parties in other Members, in accordance with the provisions of this Agreement, they are supplied at an equitable price (if any) which shall, apart from the real cost of delivery, be the same for the nationals¹⁷ of the Member concerned or of any other Member.

¹⁷ "Nationals" here shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

10.5 Developed country Members shall, if requested by other Members, provide, in English, French or Spanish, translations of the documents covered by a specific notification or, in case of voluminous documents, of summaries of such documents.

10.6 The Secretariat shall, when it receives notifications in accordance with the provisions of this Agreement, circulate copies of the notifications to all Members and interested international standardizing and conformity assessment bodies, and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

10.7 Whenever a Member has reached an agreement with any other country or countries on issues related to technical regulations, standards or conformity assessment procedures which may have a significant effect on trade, at least one Member party to the agreement shall notify other Members through the Secretariat of the products to be covered by the agreement and include a brief description of the agreement. Members concerned are encouraged to enter, upon request, into consultations with other Members for the purposes of concluding similar agreements or of arranging for their participation in such agreements.

10.8 Nothing in this Agreement shall be construed as requiring:

- 10.8.1 the publication of texts other than in the language of the Member;
- 10.8.2 the provision of particulars or copies of drafts other than in the language of the Member except as stated in paragraph 5; or
- 10.8.3 Members to furnish any information, the disclosure of which they consider contrary to their essential security interests.

10.9 Notifications to the Secretariat shall be in English, French or Spanish.

10.10 Members shall designate a single central government authority that is responsible for the implementation on the national level of the provisions concerning notification procedures under this Agreement except those included in Annex 3.

10.11 If, however, for legal or administrative reasons the responsibility for notification procedures is divided among two or more central government authorities, the Member concerned shall provide to the other Members complete and unambiguous information on the scope of responsibility of each of these authorities.

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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

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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;

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(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.

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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

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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

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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

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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,

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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

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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;

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(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.