

MODEL ACT

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

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**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

Authors' Introduction

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 (Biosafety Protocol or Protocol)* was adopted in January 2000, pursuant to a mandate contained in the Convention on Biological Diversity (CBD), an international convention that has now been adopted by 186 countries. 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. It is widely expected that the Protocol will take legal effect in 2003 following its ratification by fifty countries.

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 Biosafety Protocol and other related materials are available from The Secretariat of the Convention on Biological Diversity (<http://www.biodiv.org>).

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

To contribute to this process, the authors have developed and made freely available a Model Act that contains proposed provisions for a transparent, effective and workable national biosafety regulatory framework. Most importantly, the Model Act provides for systems that are compliant with the Cartagena Protocol on Biosafety 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 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.

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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

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.

To test the appropriateness of the proposed provisions, two eminent legal scholars with long standing involvement in the field of biosafety were asked to provide an independent peer review of an initial draft of the model. The reviewers were asked to respond to the following questions:

Does the Proposed Act comply with the Biosafety Protocol?

Does the Proposed Act include all necessary provisions to implement the Biosafety Protocol's requirements?

Does the Proposed Act comply with other relevant international obligations under the Convention on Biological Diversity and World Trade Organisation Agreements?

Does the Proposed Act constitute a viable, balanced approach to the development of a workable and effective biosafety regulatory framework by individual nations?

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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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. 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 (E-mail address: ModelBiosafetyAct@arentfox.com).

The authors gratefully acknowledge the assistance of the peer reviewers and the many contributions made by friends and colleagues who offered valuable suggestions and insights throughout the drafting process.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

TABLE OF CONTENTS

PREAMBLE

PART ONE: GENERAL PROVISIONS

- Article 1. Objective
- Article 2. Definitions
- Article 3. Scope

PART TWO: INSTITUTIONAL ARRANGEMENTS

- Article 4. Establishment of Competent Authority
- Article 5. Establishment of Scientific Advisory Committee

PART THREE: NOTIFICATION AND AUTHORIZATION REQUIREMENTS

- Article 6. Notification Requirements and Procedures for Contained Use Activities
- Article 7. Authorization Requirements for Intentional Introduction into the Environment
- Article 8. Application Procedures for Intentional Introduction into the Environment
- Article 9. Confidential Information
- Article 10. Acknowledgment and Preliminary Response
- Article 11. Risk Assessment and Risk Management
- Article 12. Decision-making and Communication of Decision
- Article 13. Simplified Authorization Procedures

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

Article 14. Petition for Exemption or Simplified Procedures

PART FOUR: REVIEW MECHANISMS

Article 15. Review of Decisions

Article 16. Right of Appeal

PART FIVE: SAFEGUARDS

Article 17. Monitoring and Submission of New Information

Article 18. Unintentional Introduction into the Environment

Article 19. Cessation Orders

PART SIX: PUBLIC INFORMATION, AWARENESS AND PARTICIPATION

Article 20. Public Awareness and Participation

Article 21. International Information Sharing

PART SEVEN: IDENTIFICATION AND DOCUMENTATION

Article 22. Documentation for Imports of LMOs Intended for Contained Use

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

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

PART EIGHT: ENFORCEMENT

Article 25. Enforcement

Article 26. Offences and Penalties

Article 27. Liability and Redress

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

PART NINE: IMPLEMENTATION MEASURES

- Article 28. Regulations
- Article 29. Effective Date
- Article 30. Transitional Provisions
- Article 31. Review of Act

ANNEXES

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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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;ⁱ
- (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.
- (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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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.ⁱⁱ
- (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 making an LMO or LMOs available to third parties on a commercial basis.
- (p) "Registry" means the compilation of LMOs or activities that are authorized, exempted or subject to simplified procedures in

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.ⁱⁱⁱ
- (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;^{iv}
 - (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 et seq. in consultation with the Scientific Advisory Committee and in conformity with the requirements of this Act;

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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.^v
- (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;
 - (iv) Recommending containment measures, limitations on the duration of authorizations, reporting mechanisms, remedial measures, monitoring procedures and other appropriate and

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- 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.
- (d) The SAC also may appoint temporary non-voting expert advisors from scientific disciplines not otherwise adequately represented on the SAC and its subcommittees.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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 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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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 nature 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
 - (vii) A description of remedial measures to be undertaken in the event of any unintentional introduction into the environment

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.^{vi}

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
 - (ii) Placing on the market of an LMO.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (b) No person shall import an LMO for activities subject to paragraph (a) without authorization under this Act.^{vii}
- (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.^{viii}

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, 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; and
 - (iii) Any additional information applicants deem relevant to an assessment of the potential risks and/or benefits of the requested activity.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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 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:

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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.

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) Within thirty (30) days of receipt of the application, based on information provided by SAC, 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, what additional information within the scope of Annex I is required.
- (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.

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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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.
- (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 and any additional risk management measures that may be necessary to minimize any identified risks. Where additional risk assessment is required, it may be undertaken by the Applicant, SAC or other experts at the discretion of the Competent Authority.^{ix}
- (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 indicates any measures or actions that need be taken to ensure the safe use of the LMO. 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 and control risks identified during the risk assessment process and shall impose such mechanisms, measures or strategies to the extent necessary to prevent adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
- (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).

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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;
 - (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.
- (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.^x
- (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.^{xi}
- (e) 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.^{xii}
- (f) The final decision of the Competent Authority shall be recorded in a decision document that:

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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.
- (g) Any specific conditions, limitations or requirements related to the authorization must be clear on the face of the decision document.
- (h) 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.
- (i) 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 and sustainable use of biological diversity, taking also into account risks to human health.^{xiii}

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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) LMOs or activities exempted or subject to simplified procedures under paragraphs (b), (c) or (h) 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.^{xiv}
- (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;
 - (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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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.
- (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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.^{xv}
- (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.
- (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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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

- (d) 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.
- (e) 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
 - (v) A point of contact for further information.
- (f) 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.
- (g) Where it knows of an occurrence within its jurisdiction resulting in an introduction that leads or may lead to an unintentional

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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 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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.^{xvi}
- (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 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:

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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) or (h) of the Act.^{xvii}
- (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.*;
 - (iv) Reports concerning national implementation of the Cartagena Protocol in accordance with Article 33 of the Protocol;

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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.

PART SEVEN: IDENTIFICATION AND DOCUMENTATION^{xviii}

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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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;
 - (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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- 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.
- (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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.^{xix}

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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

ANNEXES

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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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:

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

- (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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

Explanatory Notes

ⁱ **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.

ⁱⁱ **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 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. Article 21 of the Act contains the documentation requirements included in the Protocol for LMOs intended for direct use as food or feed or for processing.

ⁱⁱⁱ See note i.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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

^v **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.

^{vi} **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).

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

^{vii} **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.

^{viii} **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.

^{ix} **Responsibility for 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.

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.

^x **Consideration of Socio-economic Aspects:** The language in Article 12(c) of the Act is taken from Article 26 of the Biosafety Protocol. 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. Assuming both of these requirements can be met and a country wishes to consider socio-economic aspects in its decision-making, that consideration should include both the benefits and the risks of the LMO on the conservation and sustainable use of biological diversity.

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

^{xi} **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).

^{xii} **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.

^{xiii} **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.

^{xiv} **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.

^{xv} **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.

^{xvi} **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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.

^{xvii} **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.

^{xviii} **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 regulation 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 consumer labelling.

^{xix} **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 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

**MODEL ACT:
PROPOSED PROVISIONS FOR A
TRANSPARENT, EFFECTIVE AND WORKABLE
BIOSAFETY REGULATORY FRAMEWORK**

December 2002

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.