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A Reference Guide

Biosafety Frameworks Addressing the Release of Plant LMOs

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A Reference Guide For Biosafety Frameworks Addressing the Release of Plant LMOs

INTRODUCTION

This Reference Guide is designed to assist governments in developing effective, science-based national legal regimes to oversee agricultural uses of modern biotechnology. Specifically, it offers a recommended framework for establishing national science-based risk assessment and risk management measures governing the intentional introduction of plants that have been improved through modern biotechnology. Plants, animals, and micro-organisms all can be, and are, genetically modified for a variety of purposes, including pharmaceutical, industrial and agricultural applications. In addressing living modified organisms ("LMOs"), governments must consider how to allow the benefits of biotechnology to be realized while ensuring the conservation and sustainable use of biological diversity and protection of public health. This Reference Guide is designed to assist governments with the development of science-based national regimes to oversee agricultural uses of Plant LMOs, and to do so in a transparent and predictable manner.

Biotechnology offers many benefits for agriculture, including a means to increase crop yield, enhance the flexibility of crops to thrive in varied growing environments, improve nutritional content, and optimise the use of agricultural inputs. While the potential risks associated with biotechnology are not different in kind from other techniques, governments must ensure the safe introduction into the environment of agricultural crops derived from modern biotechnology to avoid any potential adverse impacts on the conservation and sustainable use of biodiversity.

The primary aim of this document is to promote the international harmonization of objective, science-based national biosafety frameworks. This document focuses, in particular, on approaches to identifying potential risks, and, where necessary, assessing and managing potential impacts on the conservation and sustainable use of biological diversity that may be associated with the intentional introduction of new Plant LMOs.
The Reference Guide offers a recommended framework for establishing a science-based oversight regime for Plant LMOs that draws from existing national approaches, international guidance and certain provisions of key international agreements. Following each provision or set of provisions is a discussion of the proposal's rationale and, where appropriate, of related features in existing national measures, international accords or guidance. References are provided to national measures, international guidance documents, such as the International Guidelines for Safety in Biotechnology developed by the United Nations Environment Program ("UNEP") and reports developed by the Organization for Economic Cooperation and Development ("OECD"). References are also provided to international agreements, such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, that are consistent with the recommended approaches.

This document is intended as an aid to those governmental authorities responsible for overseeing the intentional introduction of Plant LMOs into the environment. Developed in light of international guidance and existing national regimes, the Reference Guide is intended to serve as a practical tool for governments as they develop national regimes tailored to fit their unique national priorities, legal systems and traditions. It is designed with the understanding that governments may take a variety of approaches to the development of regimes to oversee the intentional introduction of Plant LMOs. Options range from developing new oversight and review mechanisms, to amending or augmenting existing law on related issues such as phytosanitary review and management, to the development of appropriate guidance documents.

The Reference Guide does not comprehensively address all issues related to the expanding field of biotechnology. This document is limited to oversight of the intentional introduction of Plant LMOs into the environment. Accordingly, issues regarding the oversight of contained and food/feed uses are not addressed in the Reference Guide.

The Reference Guide includes provisions aimed at ensuring transparency and public participation in the development and implementation of national biosafety oversight measures for the release or import of Plant LMOs. This approach is also consistent with many national biosafety regimes.

This document makes reference to but does not track all of the provisions in the Cartagena Protocol on Biosafety. Various provisions of the Protocol will require interpretation and further elaboration at the national and international level, which will affect the implementation of those provisions. It is expected that this document will be of assistance to governments developing national biosafety regimes regardless of whether such governments ultimately become Parties to the Protocol.

Additional information on the topics covered in this Reference Guide can be obtained from CropLife International, Avenue Louise 143, B-1050 Brussels, Phone: +(322) 542-0410, Fax: +(322) 542-0419. Additional information on CropLife International is available at www.croplife.org.

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NOTE ON CITATIONS

Where appropriate, citations are provided to national measures, international guidance, and relevant international agreements. An abbreviations list is provided at the end of this document. While in some instances provisions of a national measure, guidance or international agreement may be used verbatim, references to existing measures are more often intended to reflect examples of existing authorities supportive of various approaches taken in this Reference Guide.

MODEL PROVISIONS & COMMENTARY

Following are model biosafety provisions, accompanied by commentary. The model provisions draw from existing national measures, international guidance and relevant international agreements. The commentary briefly describes the rationale for the proposed approaches and discusses national measures, provisions of relevant international accords and other international guidance that are consistent with and supportive of the model provisions.

PART ONE - GENERAL PROVISIONS

Article 1
Objective

The objective of this measure is to ensure an adequate level of oversight with respect to the intentional introduction into the environment of plant living modified organisms ("Plant LMOs") resulting from modern biotechnology to prevent or mitigate adverse effects on the conservation and sustainable use of biological diversity.

Article 1 Commentary
An objective can be helpful in articulating the overall purpose of a national measure. This can facilitate interpretation of individual provisions of the measure and promote transparent and predictable implementation. Many national regimes include a statement of their objectives for such reasons.

Article 2
Scope

This measure applies to the intentional introduction into the environment of Plant LMOs resulting from modern biotechnology, including the import and export of such Plant LMOs for that purpose.

Article 2 Commentary
A scope provision is often included as an efficient means of defining the reach of a measure. Such a provision can facilitate interpretation and implementation of other provisions, and promote transparent and predictable application of the regime overall. This Reference Guide addresses the oversight of Plant LMOs that are intentionally introduced into the environment for agricultural purposes, and the transboundary movements (i.e., import and export) of such Plant LMOs.

As noted in the introduction, though beyond the scope of the approaches outlined in this document, governments may also wish to establish appropriate standards for the use of Plant LMOs in contained facilities and subject Plant LMOs used for food and feed to appropriate health safety reviews.

Article 3
Definitions

For purposes of this measure, the following definitions shall apply:

See Singapore Guidelines, ¶ 3 (defining "proponent"); Inst. Norm No. 10 (Brazil) (defining "proponent").

"Applicant" means a legal or natural person applying for authorization for the intentional introduction into the environment of a Plant LMO or the import of a Plant LMO for such use in *[name of country or territory].*

CBD, art. 2.

"Biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

"Competent Authority" means the governmental authority designated to carry out the functions specified in this measure.

See CP, art. 3(c).

"Export" means intentional transboundary movement from the territorial jurisdiction of *[name of country or territory]* to another country.

See CP, art. 3(d).

"Exporter" means any legal or natural person, under the jurisdiction of the country of export, who arranges for a Plant LMO to be exported.

See CP, art. 3(e).

"Import" means intentional transboundary movement into the territorial jurisdiction of *[name of country or territory]* from another country.

See CP, art. 3(f).

"Importer" means any legal or natural person, under the jurisdiction of *[name of country or territory]*, who arranges for a Plant LMO to be imported.

See generally 7 C.F.R. § 340.1 (United States); Singapore Guidelines, ¶ 3 (defining "release"); CP, art. 7.

"Intentionally introduce" or "intentional introduction" means the deliberate release of a Plant LMO resulting from modern biotechnology into the environment for the purpose of field testing or commercialization, or the import of a Plant LMO resulting from modern biotechnology for the purpose of field testing or commercialization; this term does not refer to Plant LMOs intended for contained uses that are subject to other measures, or for direct use as food or feed, or for processing.

CP, art. 3(g). "Living modified organism" or "LMO" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

See CP, art. 3(i). "Modern biotechnology" means the application of:
a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection; or
b. Fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

See CP, art. 19. "National Focal Point" means the government authority designated to provide coordinated communication on behalf of all relevant ministries, agencies, and departments of *[name of country or territory]* on matters concerning the transboundary movement of Plant LMOs with entities that produce, sell, import, export, transport or otherwise are engaged in the transboundary movement of Plant LMOs, governments, and international organizations, including the secretariat to the Biosafety Protocol *[include if the country is a Party to the Cartagena Protocol]*.

EC 2001/18, art. 2(1) (European Community). "Organism" means any biological entity capable of replication or transferring genetic material.

PBG, Def. of Terms (Philippines). "Person" means any individual, partnership, corporation, company, society, association or other organized group.

7 C.F.R. § 340.1 (United States). "Plant" means any living stage or form of any member of the plant kingdom including, but not limited to, eukaryotic algae, mosses, club mosses, ferns, angiosperms, gymnosperms, and lichens (which contain algae), including any parts (e.g. pollen, seeds, cells, tubers, stems) thereof, and any cellular components (e.g. plasmids, ribosomes, etc.) thereof.

7 C.F.R. § 340.1 (United States). "Release" means the use of a Plant LMO outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.

See CP, art. 3(k). "Transboundary movement" means the movement of a Plant LMO from the territorial jurisdiction of one country to the territorial jurisdiction of another country.

Article 3 Commentary
These definitions generally track those found in various national measures and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The terms and definitions are intended to ensure that this measure is workable and transparent. Field trials are included within the scope of the definition of "release" provided above.

Article 4
Institutional Arrangements

See generally GTA, § 27 (Australia); CP, art. 19. The *[name of the government authority designated to be the Competent Authority]* shall be the Competent Authority for the intentional introduction of Plant LMOs and, as such, shall take actions necessary to implement this measure including:
a. Performing administrative functions related to Plant LMO authorizations, including the exercise of final administrative authority over all authorizations under this measure;
b. Issuing technical and procedural guidance to facilitate the implementation of this measure consistent with its Objective;
c. Ensuring compliance with this measure;
d. Providing information and advice to other governmental authorities on the intentional introduction of Plant LMOs;
e. Overseeing the development and implementation of risk assessment procedures;
f. Overseeing the development and implementation of risk management activities;
g. Providing information to the public and the regulated community on the regulation of Plant LMOs under this measure; and
h. Serving as the designated Competent Authority for *[name of country or territory]* for the receipt of notifications of proposed first-time imports of Plant LMOs intended for release.

Article 4 Commentary
This article provides for the designation of a national Competent Authority for Plant LMOs and specifies the functions of the Competent Authority for implementing the regime. Having one body responsible for implementing an agricultural biosafety regime can enhance the effectiveness and efficiency of the regime, and facilitate its transparency and predictability. If additional regulatory regimes are created to cover other aspects of biosafety (e.g., contained use), a competent authority should also be established for those purposes.

PART TWO - AUTHORIZATION PROCEDURES FOR INTENTIONAL INTRODUCTION OF PLANT LMOS

Article 5
Authorization Requirements

See 7 C.F.R. § 340.0 (United States).

a. No person may intentionally introduce a Plant LMO into the environment or import a Plant LMO for such use, except in accordance with an authorization obtained from the Competent Authority.
b. Applicants shall prepare, and the Competent Authority shall review, respond to, and decide upon all applications for authorizations to intentionally introduce a Plant LMO in accordance with this Part Two.
c. The review and decision-making procedures established under this Part Two shall apply to all applications to intentionally introduce a Plant LMO, unless the Plant LMO is exempt from these procedures under Article 10 or the intentional introduction is subject to simplified procedures established by the Competent Authority in accordance with Article 11.

Article 5 Commentary

Existing national regimes typically establish authorization, permitting or equivalent approval requirements, similar to those proposed in this article. This is only one possible approach. Alternative approaches may be appropriate to consider. A system for authorizations should incorporate notice and review requirements for first-time imports of Plant LMOs in a manner that provides for consistent application, review and notification requirements for imported and domestic Plant LMOs alike. This would provide administrative efficiencies for governments and also reduce the potential for discriminatory practices that might conflict with international obligations including rules applicable to members of the World Trade Organization.

As a practical matter, the Competent Authority should have final administrative authority to make all authorizations. Governments should avoid having an oversight system that allows other national or sub-national regulatory bodies to approve, overrule, qualify or otherwise modify a final authorization.

Imports of Plant LMOs not intended for release should be subject to a limited review tailored to address any adverse effects on the conservation and sustainable use of biological diversity that might arise from an incidental unintentional release.

Article 6
Application Requirements

See generally 7 C.F.R. § 340.4 (United States); CP, arts. 7, 8.

a. Except for Plant LMOs that are exempt under Article 10 or subject to simplified procedures under Article 11, any person, prior to intentionally introducing a Plant LMO shall apply to the Competent Authority for authorization. In the case of imports, the Exporter or the competent authority in the country of export may submit an application on behalf of an Applicant, and may designate in the application with whom the Competent Authority shall communicate regarding the application.
b. Applicants shall provide the information specified in Annex I, excluding any information the Competent Authority identifies as unnecessary to its review.

See GTA, § 45 (Australia); EC 2001/18, arts. 6, 13 (European Community).

c. Applicants may reference confidential information provided by another Applicant(s), upon submitting proof of authorization from such prior Applicant(s).
d. In the case of an application to field test a Plant LMO, the Applicant shall document to the Competent Authority that participating personnel will have appropriate training and that the field test will be overseen by an individual possessing appropriate technical expertise.

See generally GTA, § 44 (Australia).

e. The Competent Authority shall, upon request, be available to consult with each Applicant, on matters concerning the proposed application, including:
    i. Whether the Plant LMO is subject to this measure, and, if so, whether the activity to be undertaken qualifies as an intentional introduction;
    ii. Whether the application qualifies for review under simplified procedures established by the Competent Authority in accordance with Article 11;
    iii. Whether the Plant LMO is exempt from review under Article 10; and
    iv. Data the Applicant must submit in support of its application that is within the scope of Annex I and necessary and appropriate to evaluate the application, taking into account factors such as the intended use, type of Plant LMO, the scale of the proposed intentional introduction, the proposed receiving environment(s), and experience with the Plant LMO, including previously authorized field trials in *[name of country or territory]* or in other countries.

See GTA, § 41 (Australia).

f. An Applicant may withdraw its application at any time.

Article 6 Commentary

This article proposes application procedures and requirements consistent with existing policies and practices of many national governments. To maximize the efficient use of both government and private sector resources, the article calls for the Competent Authority to consult with Applicants to ensure that applications include only such data as the Competent Authority needs for a risk assessment. In undertaking a review of a Plant LMO, the Competent Authority should also consider the risk assessments that may have been conducted by other competent authorities.

Under the definition of "intentional introduction," this Reference Guide in effect establishes one set of application provisions that apply to persons seeking to release a Plant LMO, as well as persons seeking to import a Plant LMO intended for release. In the provisions and definitions suggested here, authorization to import would be included in an authorization to release (i.e., cultivate) a Plant LMO. Governments also have the option of separating provisions addressing imports for release from those addressing releases of Plant LMOs.

Some governments oversee the import of Plant LMOs not intended for release into the environment (e.g., those destined for contained use or intended for food or feed uses). In such cases, any data submission, application or review requirements related to possible impacts on the conservation and sustainable use of biological diversity should be limited and tailored to the intended use of the Plant LMO.

Article 7
Acknowledgement by the Competent Authority

See 7 C.F.R. § 340.4 (United States); Reg. No. 1420 § 5 ¶ 7 (South Africa); CP, arts. 9, 10.

a. Within a reasonable period of time, not to exceed ninety (90) days of receiving an application, the Competent Authority shall, in writing, acknowledge receipt and respond to the Applicant in accordance with Article 7(b).

b. The acknowledgment and response to the application shall include:
   i. The date of receipt of the application;
   ii. Whether the application contains the information specified by the Competent Authority under Article 6(b);
   iii. A statement of whether the application is prima facie complete;
   iv. A brief description of the applicable review procedure;
   v. A statement whether the application will be processed in accordance with the procedures set forth under Articles 5 through 9 or under simplified procedures adopted by the Competent Authority under Article 11; and
   vi. A statement whether:
      (A) The proposed intentional introduction may proceed after no less than 90 days without a subsequent written consent; or
      (B) The proposed intentional introduction may proceed only in accordance with an authorization issued under this measure.

c. If the Competent Authority determines that the application is not prima facie complete, the acknowledgement shall include an explanation of any required information that was not included in the application.

Article 7 Commentary
This article provides for prompt acknowledgement and review of applications. The article also provides for streamlined data requirements for Plant LMOs in light of knowledge gained in prior reviews of similar products and/or applications made by that same Applicant.

Article 8
Application Review and Risk Assessment

See generally CP, arts. 15, 16; UNEP Technical Guidelines, Part III.

a. The Competent Authority shall review prima facie complete applications on the basis of the results of a risk assessment, which shall be performed:
   i. In accordance with Annex II and taking into account recognized risk assessment techniques;
   ii. Based on available scientific and technical data, including the information provided in the application;
   iii. Taking into account the risk management measures proposed by the Applicant and other relevant risk management measures; and
   iv. On a case-by-case basis, recognizing that the information necessary to evaluate the application may vary depending on the type of Plant LMOs, the release, and the likely receiving environment.

See CP, Annex III(6).

b. The Competent Authority may request from the Applicant additional information necessary to conduct a risk assessment in accordance with Annex II, provided that any such request for additional information is in writing to the Applicant and is within the scope of Annexes I and II.

See EU-US BCF Final Report, § 2.3.1.

c. All individuals responsible for conducting risk assessments performed by or on behalf of the Competent Authority shall be well qualified to make determinations in the area(s) under review, and shall be required to disclose publicly any and all actual conflicts of interest relating to any risk assessment in which they may participate or be requested to participate. Where practicable, the Competent Authority shall ensure an individual having an actual or potential conflict of interest with regard to an application does not participate in the risk assessment for that application.

See generally CP, art. 16.

d. To avoid adverse effects of a Plant LMO on the conservation and sustainable use of biological diversity, the Competent Authority may, as necessary, and consistent with a risk assessment conducted in accordance with Annex II:
   i. Require Applicants to undertake specific risk management measures or submit additional risk management plans in accordance with adverse effects identified in the risk assessment;

See Act 153/2000, § 3(7) (Czech Rep.) Res. 289/1997, Part D(4) (Argentina).

See Res. 289/1997, Part D(7) (Argentina); Inst. Norm No. 10 (Brazil); RD 94-08, § B8.0 (Canada); Act 153/2000, art. 3(7) (Czech Rep.); EC 2001/18, art. 10 (European Community).

   ii. Require Applicants to report to the Competent Authority after completion of the intentional introduction of the Plant LMO, on the results of the release with respect to adverse effects of the Plant LMO on the conservation and sustainable use of biological diversity; and

See RD 2000-07, ¶ 3.4 (Canada); Act 153/2000, § 3(7) (Czech Rep.); GAR, Ch. 3, § 2.5 (Japan).

iii. Require Applicants to maintain records relating to the intentional introduction of the Plant LMO and to make such records available to the Competent Authority upon request.

e. Consistent with the requirements of Article 24 of this measure, the Competent Authority shall protect confidential information submitted by the Applicant.

Article 8 Commentary
These review and risk assessment procedures reflect the current approaches and requirements of many existing national measures. The review procedures proposed in this article also generally follow the obligations established under Articles 15 and 16 of the Cartagena Protocol. As under existing national measures, and consistent with other international guidance, the central feature of these proposed procedures is the performance and consideration of a risk assessment. Sources of guidance on risk assessment that might be taken into account include: the 1995 UNEP International Technical Guidelines for Safety in Biotechnology; Safety Considerations for Biotechnology: Scale-up of Crop Plants (OECD 1993); Report of the Working Group on Harmonization of Regulatory Oversight in Biotechnology (OECD 2000); and the recent report of the U.S. National Research Council, Environmental Effects of Transgenic Plants (2002). Other helpful references on particular Plant LMOs include various OECD Consensus documents available on the OECD website at http://www.oecd.org.

Article 8 provides that risk assessments should be consistent with the principles and methodology contained in Annex II of this document. Annex II of this document generally tracks Annex III of the Cartagena Protocol.

A requirement that Applicants authorized to release a Plant LMO report to the Competent Authority at specified intervals on any adverse effects of the Plant LMO on the conservation and sustainable use of biological diversity is consistent with many national regimes. Applicants should also be obligated to promptly notify the Competent Authority of unauthorized releases of a Plant LMO that may have a significant adverse effect on the conservation and sustainable use of biological diversity. (See Article 17).

Article 9
Timeframe for Decisions and Communication of Decisions to Applicant

See CP, art. 10(3).

a. The Competent Authority shall, on the basis of a scientifically sound risk assessment conducted in accordance with Annex II, make a final decision:
   i. Approving the intentional introduction of the Plant LMO with or without conditions;
   ii. Denying the application to intentionally introduce the Plant LMO; or
   iii. In extraordinary circumstances, informing the Applicant that the review period is extended by a defined period of time, and explaining the reason for the delay.

b. Final decisions shall be communicated to the Applicant

and appropriate international bodies in writing within a reasonable period of time, not to exceed two hundred and seventy (270) days of the date of receipt of a prima facie complete application.

See EC 2001/18, art. 6.6(a) (European Community).

c. In calculating the time periods in Article 9(b) above, any time during which the Competent Authority must wait for additional relevant information requested from the Applicant shall not be counted toward the number of days accrued.

d. The communication shall set out the basis for the decision.

e. In the event that the Competent Authority issues a decision in accordance with Article 9(a)(iii), it shall make a final decision within the time-period specified in the initial decision extending the review period.

See 7 C.F.R. § 340.6(f) (United States); Reg. No. 1420 § 9 (South Africa).

f. Any person whose application has been denied or who determines that an authorization granted is unacceptable due to the restrictions imposed by the Competent Authority may appeal the decision in writing to the Competent Authority within 30 days from receipt of the written notification of denial or authorization. The appeal shall state the facts and reasons, including any new information, that form the basis for an assertion that the application was wrongfully denied or that the authorization was unduly restricted.

g. The Competent Authority shall review information provided by an Applicant who has appealed a decision and shall issue a final decision on the appeal within 30 days of the date the appeal is filed.

h. Any person whose application has been denied shall be permitted to re-apply for an authorization to intentionally introduce the Plant LMO.

Article 9 Commentary
The notification procedures and timelines proposed in this article are consistent with the requirements of various national measures. However, it is likely that with experience governments will be able to act more expeditiously, and will seek to do so in order to promote administrative efficiency and minimize any unnecessary interference with economic activity and development. While the Cartagena Protocol stipulates maximum time periods during which governments must take various actions, governments remain free to stipulate shorter time periods for such actions, where they believe required oversight actions can and should be accomplished more quickly.

It is also likely that international mechanisms for sharing national approvals or other decisions on proposed releases of Plant LMOs will develop. These mechanisms may include, among others, the Biosafety Clearing-House proposed under the Cartagena Protocol.

Article 10
Exemptions

See Inst. Norm No. 10 (Brazil); CP, art. 7(4).

a. A Plant LMO that has already been authorized for intentional introduction by the Competent Authority shall be exempt for that use from the authorization procedures of this measure.
b. The Competent Authority may exempt from the authorization procedures of this measure those Plant LMOs that the Competent Authority has determined are not likely to have adverse effects on the conservation and sustainable use of biological diversity.
c. The Competent Authority shall maintain a list of Plant LMOs authorized for intentional introduction or which are otherwise exempt from authorization requirements. Such list shall be made available to the public.

Article 10 Commentary
The exemption provisions proposed in this article are consistent with certain national laws, as well as the Advanced Informed Agreement ("AIA") provisions of the Cartagena Protocol. They exempt from the authorization requirements subsequent releases or imports of a Plant LMO previously approved for that use. These provisions also allow the Competent Authority to designate certain LMOs as exempt from the approval requirements outlined above where such approvals would be redundant or otherwise unnecessary. Imports of Plant LMOs destined for contained use would not require an authorization from the Competent Authority as such imports are not destined for release into the environment, provided such import and use are conducted pursuant to oversight measures governing contained use.

Article 11
Simplified Approval Procedures

See EC 2001/18, art. 7, Annex V (European Community); Inst. Norm No. 10 (Brazil).

a. The Competent Authority shall apply simplified information requirements and/or review procedures to those applications, or categories of applications, where the Competent Authority determines that sufficient scientific knowledge is available or experience has been obtained relevant to the intentional introduction of Plant LMOs in appropriate ecosystems.

See Inst. Norm No. 10 (Brazil); CP arts. 13,14; 7 C.F.R. § 340.3 (United States).

b. Measures providing for simplified procedures may be adopted by the Competent Authority and may address reduced information requirements, more limited review processes, shortened review periods, and exemptions from information and review requirements.
c. The Competent Authority shall, at a minimum, consider the need for simplified procedures or exemptions in the following circumstances:
    i. A Competent Authority of another country or established at a regional level by multiple countries

has previously approved intentional introduction into the environment of the Plant LMO in comparable ecosystems;
    ii. Sufficient scientific knowledge otherwise exists about the risks, if any, to the conservation and sustainable use of biological diversity associated with the parental, where appropriate, and recipient organism(s) in the likely receiving environment;

See CP, art. 13.

    iii. The Competent Authority has identified categories of Plant LMOs for which the information contained in the notification of movement to the Competent Authority is sufficient to allow import at the same time;
    iv. With respect to an application for field-testing, scientific information is available on any interaction of particular relevance for the risk assessment, involving the parental, where appropriate, and recipient organism and other organisms in the receiving environment;
    v. Sufficient scientific information is available that the Plant LMO does not present additional or increased risks to the conservation and sustainable use of biological diversity under the conditions of the release that are not presented by releases of the corresponding parental, where appropriate, and recipient organisms;
    vi. Sufficient scientific information is available that any capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms will not result in adverse effects; or

See CP, art. 7(4).

    vii. Parties to the Cartagena Protocol acting through a decision of the Parties have exempted the Plant LMO from the Advanced Informed Agreement procedures.

Article 11 Commentary
Consistent with many existing national regimes, this article provides for the development and application of simplified procedures for review of applications, in light of experience gained over time. Use of such streamlined procedures can reduce the time and other administrative costs associated with review of applications, enhance administrative efficiency, and thereby enable governments to allocate limited staff and other resources more productively. Simplified procedures also allow economically productive activity to proceed as expeditiously as possible consistent with the conservation and sustainable use of biological diversity.

Simplified procedures or other provisions that exempt previously approved Plant LMOs from approval requirements and AIA procedures would be consistent with the requirements of the Cartagena Protocol, which apply AIA requirements to the first intentional transboundary movement of an LMO intended for introduction into the environment. Similarly, in undertaking a review of an application to release or import a Plant LMO, a Competent Authority should take account of available risk assessments and approvals from other competent authorities for the same Plant LMO.

Article 12
Review of Decisions

See CP, art. 12.

a. The Competent Authority may review its decisions regarding the authorization of an intentional introduction of a Plant LMO at any time:
   i. In light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity;
   ii. In the event of any purposeful modification of, or unintended change to, the Plant LMO that causes adverse effects on the conservation and sustainable use of biological diversity where such modification or change was not addressed as part of the initial authorization; or
   iii. Upon request of an Applicant or a country of export where such Applicant or country considers that:
      (A) The risk assessment upon which the decision was based was not scientifically sound;
      (B) A change in circumstances has occurred that can influence the outcome of the risk assessment upon which the decision was based; or
      (C) Additional relevant scientific or technical information has become available that can change the outcome of the risk assessment upon which the decision was based.

See GTA § 68 (Australia); SPS Agmt., art. 5.7 (WTO).

b. The Competent Authority shall have the authority to restrict or prohibit, on a provisional basis, the intentional introduction of a Plant LMO in accordance with these measures, where:
   i. The Competent Authority has detailed scientifically justified grounds for concluding that the Plant LMO is likely to have significant adverse effects on and the conservation and sustainable use of biological diversity as a result of:
      (A) New or additional information made available since the date the Applicant received authorization for the intentional introduction of the Plant LMO into the environment affecting the risk assessment required under Article 8; or
      (B) Reassessment of existing information on the basis of new or additional scientific knowledge; and
   ii. The Competent Authority determines that adequate measures cannot be identified and implemented to manage or mitigate the significant adverse effects.

c. In considering any action under Article 12(b), the Competent Authority shall, consistent with Annex II, consider all information relevant to a re-evaluation of the potential adverse effects of the Plant LMO on the conservation and sustainable use of biological diversity. Such information may include additional information provided by the Applicant.
d. The Competent Authority shall provide immediate notice to the Applicant of any decision taken under Article 12(b) to restrict or prohibit the intentional introduction of a Plant LMO, setting out the reasons for the decision.

See SPS Agmt., art. 5.7.

e. Where the Competent Authority acts to restrict or prohibit the intentional introduction of a Plant LMO pursuant to Article 12(b), and such action is taken in part on the basis of insufficient relevant scientific evidence, the Competent Authority shall seek to obtain the additional information necessary for a more objective and complete assessment of risk, and shall review the decision accordingly within a reasonable period of time.

Article 12 Commentary

Consistent with Article 12 of the Cartagena Protocol and common governmental practice, this article provides for reconsideration of authorization decisions in light of relevant new science-based information.

Authority to apply safeguard measures, such as the provisional measures authorized under paragraph (b) of this Article 12, is a special case of a general authority to review prior decisions on intentional introduction of Plant LMOs into the environment. Provisional safeguard measures enable regulators to take steps to restrict or prohibit the intentional introduction of a Plant LMO into the environment on the basis of new science-based information or knowledge, while they seek and evaluate additional information needed to make a final determination. Use of this important authority only in cases where new relevant scientific information indicates that the Plant LMO is likely to have significant adverse effects on the conservation and sustainable use of biological diversity allows governments to provide the necessary level of safety while avoiding unjustified restrictions on the use of Plant LMOs.

Article 13
Notice of Changes to Decisions and of Denials of Requests to Change Decisions

See CP, art. 12.

Except for actions taken pursuant to Article 12(b), the Competent Authority shall:
a. Provide written notice within thirty (30) days of making a change to a final decision pursuant to Article 12, to any Applicant to which the Competent Authority has granted an authorization that will be affected by the change, setting forth the reasons for the change;

b. Ensure that any such decision provides a reasonable period of time for the Applicant to implement the prescribed changes, taking into account the risks posed to the conservation and sustainable use of biological diversity and the need to minimize impacts on international trade; and
c. In the case of a denial of a request made by an Applicant or country of export in accordance with Article 12 to change a decision, provide a written response within a reasonable period of time, not to exceed ninety (90) days of receipt of the request, stating the decision to deny the request, and setting forth the reasons for the denial.

Article 13 Commentary
A reasonable transition period is necessary for those conducting activities pursuant to a previously granted authorization to alter their activities in light of a change in the scope of the authorization. These measures provide the Competent Authority with the authority needed to require changes to previous decisions while ensuring fair notice to Applicants.

PART THREE - HANDLING, TRANSPORT, PACKAGING AND EXPORT REQUIREMENTS

Article 14
Exports of Plant LMOs Intended for Deliberate Release into the Environment

See CP, art. 8.

The exporter of a Plant LMO intended for release into the environment in the country of import shall:
a. Prior to the first intentional transboundary movement of a Plant LMO intended for release into the environment in the importing country, ensure that written notice containing the information specified in Annex I is provided to the Competent Authority of the importing country;
b. Not export a Plant LMO intended for release into the environment to any potential country of import, except in accordance with the importing country's approval, where required; and
c. Keep a record of the notification and any acknowledgement received from the Competent Authority of the importing country.

Article 14 Commentary
Article 8 of the Cartagena Protocol requires notification of the potential country of import prior to the first import of certain LMOs intended for intentional introduction into the environment. Governments may wish to require exporters of Plant LMOs to provide notifications to importing countries, consistent with the AIA procedures established in the Cartagena Protocol.
This approach places the responsibility on the potential exporter to ensure that information on planned imports of Plant LMOs is provided to the Competent Authority in the importing country while ensuring that the Competent Authority in the exporting country has access to information on such shipments. This Article also requires the planned import to be approved by the country of import.
Similarly, this approach requires the exporter to keep records that are accessible to the Competent Authority of all notifications made and acknowledgements received from the potential country of import. In addition, these provisions stipulate that the exporter may only export the Plant LMO in accordance with the laws of the applicable country of import.

Article 15
Handling, Transport, Packaging and Identification

See generally CP, art. 18.

The Competent Authority shall require that Plant LMOs intended for intentional introduction into the environment are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and customary commercial practices.

Article 15 Commentary
Governments may wish to establish documentation requirements to ensure the proper handling, storage, transport and use of Plant LMOs. In many instances, the documentation that would typically accompany a commercial transaction (e.g., pro forma invoice, commercial invoice, shippers declaration) should be sufficient.

PART FOUR - RELEASE MODIFICATIONS AND UNAUTHORIZED RELEASES

Article 16
Release Modifications and New Scientific Information

See EC 2001/18, art. 8 (European Community).

In the event of any purposeful modification of, or unintended change to an authorized intentional introduction of a Plant LMO that could have adverse effects on the conservation and sustainable use of biological diversity, or if new scientific information has become available on the risks of such adverse effects, the Applicant shall immediately:

a. Take actions necessary to minimize such adverse effects;
b. Inform the Competent Authority in advance of any modification or as soon as the unintended change is known or the new information is available; and
c. Take actions to minimize the risk of significant adverse effects as directed by the Competent Authority.

Article 16 Commentary
This article addresses Applicant obligations in instances where the intentional introduction into the environment of a Plant LMO is modified or new scientific information on adverse effects on the conservation and sustainable use of biological diversity becomes available.

Article 17
Unauthorized Releases of Plant LMOs - Reporting and Response

In the event of an unauthorized release into the environment of a Plant LMO, the following requirements shall apply.

See generally Inst. Norm No. 10 (Brazil); GESMM, art. 25 (China).

a. Any Applicant with knowledge of an unauthorized release of a Plant LMO into the environment that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity shall, within 24 hours:
    i. Notify the Competent Authority, providing:
        (A) Available information on the estimated quantities and relevant characteristics and/or traits of the Plant LMO;
        (B) Information on the circumstances and estimated date of the release, and on the intended use of the Plant LMO;
        (C) Any available scientific information about the possible adverse effects on the conservation and sustainable use of biological diversity, as well as available information about possible risk management measures;

        (D) Any other available relevant scientific information; and
        (E) A point of contact for further information.
    ii. Initiate appropriate responses and necessary actions, including emergency measures.

See CP, art. 17.

b. Working with the National Focal Point, the Competent Authority shall notify affected or potentially affected countries, the Biosafety Clearing-House *[to be included if the country is a Party to the Cartagena Protocol]* and, where appropriate, relevant international organizations, as soon as the Competent Authority knows of any intentional introduction of a Plant LMO that has led, or may lead, to an unintentional transboundary movement of a Plant LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity. Such notifications shall include, to the extent possible:
    i. Available information on the estimated quantities and relevant characteristics and/or traits of the Plant LMO;
    ii. Information on the circumstances and estimated date of the release, and the intended use of the Plant LMO;
    iii. Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, as well as available information about possible risk management measures;
    iv. Any other available relevant scientific information; and
    v. A point of contact for further information.
c. The Competent Authority where the release occurs shall hold immediate consultations with the competent authorities of any affected or potentially affected countries to enable them to determine appropriate responses and initiate necessary action, including emergency measures.
d. Any Applicant required to make an initial notification under Article 17(a) shall, within 30 days of the initial notice, provide the Competent Authority with a written follow-up notification updating the information provided in the initial notification and summarizing:
    i. Any possible adverse effects on the conservation and sustainable use of biological diversity; and
    ii. Actions taken or planned to be taken to minimize any risks to the conservation and sustainable use of biological diversity.

Article 17 Commentary
This article provides for prompt reporting of and response to unauthorized releases that are likely to have significant adverse effects on the conservation and sustainable use of biological diversity. The measure includes notice to other potentially affected countries and consultation with them, to ensure effective responses to such releases. These provisions generally track the requirements of Article 17 of the Cartagena Protocol and other national measures.

PART FIVE - PUBLIC AWARENESS AND PARTICIPATION

Article 18
Public Information and Awareness

The Competent Authority shall:

See CP, art. 23; Act 153/2000, § 12 (Czech Republic); Act No. XXVII, arts. 13(3), 30 (Hungary).

a. Subject to the provisions for the protection of confidential business information under Article 24, publish or otherwise make available to the public information on all authorizations for the intentional introduction of a Plant LMO;
b. Promote and facilitate public awareness and education concerning the safe transfer, handling and use of Plant LMOs by preparing and distributing accurate, factual educational materials to the regulated community and the public on biotechnology, including the actions taken by the Competent Authority under this measure to oversee the intentional introduction into the environment of Plant LMOs and promote the conservation and sustainable use of biological diversity; these materials shall include educational materials that describe the legal regime of *[name of country or territory]* governing the intentional introduction into the environment of Plant LMOs;
c. Assist the regulated community and the public in understanding the requirements of this measure; and
d. *[To be included if the country is a Party to the Cartagena Protocol]*. Provide the public with access to information on the functions of the Biosafety Clearing-House, including the means for the public to access the information contained in the Biosafety Clearing-House relating to Plant LMOs intended for intentional introduction into the environment in *[name of country].*

Article 18 Commentary
This part provides model text for implementing the public awareness and educational mandates of Article 23 of the Biosafety Protocol, relating to the intentional introduction of Plant LMOs into the environment. Numerous national regimes call for such efforts. Government participation in the preparation and dissemination of complete and accurate information is of particular importance, given the current availability of information of wide-ranging accuracy, quality and completeness, and the importance of ensuring public understanding of the uses, potential risks and benefits of Plant LMOs. The proposed text also encourages public awareness by calling for publication of information on granted authorizations. Public awareness and participation might also be enhanced in additional ways. For example, consistent with existing legal requirements, administrative capacity and other considerations, governments might also publish draft authorizations and decisions to deny applications. Many national regimes currently provide for public notice and comment on authorization decisions.

Article 19
Implementation, Transparency and Public Participation

In furtherance of this measure, the Competent Authority shall:

See SPS Agmt., Annex B; APA, 5 U.S.C. § 553(b) (United States).

a. Cooperate, as appropriate, with other agencies, departments, ministries, subnational authorities and international bodies, including the secretariat to the Cartagena Protocol *[to be included if the country is a Party to the Cartagena Protocol]*, in the furtherance of this measure's objective;
b. Upon written request, provide non-confidential business information to any person on any Plant LMOs authorized for intentional introduction in *[name of country or territory]*; and
c. Make available to the public any proposal by the Competent Authority to implement this measure, ncluding any proposals for simplified procedures under Article 11. The public shall have sixty (60) days from the date of release of such proposals to submit comments and the Competent Authority shall take such comments into consideration in finalizing such proposals.

See SPS Agmt., Annex B.

d. Ensure that mechanisms are in place to respond to all reasonable questions and provide relevant documents related to the authorization requirements of this measure.

Article 19 Commentary
This article promotes international cooperation and domestic coordination among relevant authorities. This provision also promotes transparency and public participation in the development of national oversight measures, consistent with WTO obligations. Governments should consider the need to coordinate application review and approval procedures with other subnational authorities (e.g. state or provincial governmental departments). As a general matter, governments may also wish to consider the need for a specific law governing the development and adoption of rules and other administrative measures comparable to the Federal Administrative Procedure Act, 5 U.S.C. § 551 et seq. ("APA") in the United States.

PART SIX - INSPECTION AND ENFORCEMENT
Article 20
Inspection and Enforcement Authorities

See PPA, 7 U.S.C. § 7731 (United States).

a. Subject to the limitations in Article 20(b), where the Competent Authority has reason to believe a violation of this measure has occurred, the Competent Authority shall have the authority to inspect any area, facility, vessel or equipment for the purpose of determining compliance with the requirements of this measure in accordance with the terms of this Article and other applicable guidelines, measures and requirements.
b. An inspector is not authorized to enter a facility, vessel or privately held property under this Article unless: (1) the owner or operator of the facility or property has consented to the entry; or (2) the entry is made pursuant to an order issued by a court with competent jurisdiction; or (3) the owner or operator of the facility or property has received authorization for the intentional introduction of a Plant LMO and the entry is made at a reasonable time and in a reasonable manner.
c. An inspector with the Competent Authority may seize, quarantine or otherwise stop the sale of Plant LMOs that were released or imported in violation of this measure.
d. The Competent Authority shall have the authority to inspect Plant LMOs imported into *[name of country or territory]* from an area outside the territorial jurisdiction of *[name of country or territory]* to ensure compliance with the requirements of this measure.

See GTA, § 163 (Australia).

e. The owner of any Plant LMOs, products, goods, equipment, facility or other property damaged as a result of an inspection or seizure by the agents or authorities of *[name of country or territory]* shall be entitled to compensation from the *[name of country or territory]*, if the damage was caused as a result of insufficient care being exercised in the course of the inspection or seizure.

Article 20 Commentary
The compliance monitoring, inspection and enforcement authorities and traditions of countries vary widely. Governments should consider the importance of establishing a fair, transparent and consistently applied compliance and enforcement regime to ensure effective implementation of their domestic biosafety regimes and, where appropriate, the Biosafety Protocol. Such approaches will facilitate trade and investment in biotechnology, agriculture and related sectors. This article provides one set of options.

PART SEVEN - INTERNATIONAL OBLIGATIONS
Article 21
International Reporting Obligations

The Competent Authority shall establish procedures to ensure compliance with all international reporting obligations that *[name of country or territory]* has agreed to satisfy relating to the intentional introduction into the environment of Plant LMOs, including, in cooperation with the National Focal Point, obligations set forth under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and/or the Marrakesh Agreement Establishing the World Trade Organization *[to be included, respectively, if country is a Party to the Protocol or a Member of the WTO].*

Article 21 Commentary
This article provides for the establishment of procedures to ensure that a government complies with any international reporting obligations to which it has agreed with respect to oversight activities related to the international introduction of Plant LMOs into the environment.

Article 22
Notice to the Biosafety Clearing-House

[To be included if country is a Party to the Biosafety Protocol]

See CP, arts. 10, 11, 12, 13 and 20.

The Competent Authority shall establish procedures to ensure that prompt notification of the following is provided by the National Focal Point to the Biosafety Clearing-House established under the Cartagena Protocol on Biosafety:
a. Laws, regulations and guidelines applicable to the import of Plant LMOs intended for intentional introduction into the environment;
b. National contact points for notification of unintentional transboundary movements of Plant LMOs;
c. Any bilateral, regional and multilateral agreement and arrangements regarding intentional transboundary movements of Plant LMOs;
d. Final decisions taken under Article 9 regarding the use, release or import of a Plant LMO;
e. Any summary of risk assessments or reviews of Plant LMOs authorized for intentional release into the environment performed by or for the Competent Authority;
f. Any review of decisions taken under Article 12, within thirty (30) days of taking such decisions; and
g. Any cases of transboundary movements of Plant LMOs in violation of this measure or the law of another country.

Article 22 Commentary
This article provides for notification of key measures, decisions and risk assessments to the Biosafety Clearing-House. It is anticipated that both Parties and non-Parties to the Biosafety Protocol will be able to make use of this important mechanism for sharing and disseminating information. Although this measure does not apply to Plant LMOs destined for food, feed or processing, the National Focal Point should also consider the benefits of promptly notifying the Biosafety Clearing-House of final decisions regarding domestic use, including placing on the market, of a Plant LMO that may be subject to transboundary movement for direct use as food or feed, or for processing.

Article 23
Reporting Requirements under the WTO Agreements

See generally SPS Agmt., Annex B (WTO); TBT Agmt., art. 5 (WTO).

[To be included if country is a WTO Member]
The Competent Authority shall ensure that prompt notification of the following is provided by the representative to the World Trade Organization ("WTO") for *[name of country]* to the WTO Secretariat:

a. Proposed regulations to address the intentional introduction of Plant LMOs, at an early stage when amendments can still be introduced and comments taken into account;
b. In emergency situations, adopted regulations, immediately upon adoption; and
c. Regulations which may have a significant effect on trade that:
    i. Qualify as phytosanitary measures under the WTO Agreement on Sanitary and Phytosanitary Measures, and include content not substantially the same as that of international standards, guidelines or recommendations; or
    ii. Qualify as technical regulations under the WTO Agreement on Technical Barriers to Trade and are not in accord with the technical content of relevant international standards.

Article 23 Commentary
Countries that are Members of the WTO are obliged to comply with the additional reporting requirements reflected in this article. Such disclosure is important to promoting transparency, facilitating compliance with national biosafety measures, and minimizing barriers to international trade.

PART EIGHT – OTHER IMPLEMENTING PROVISIONS
Article 24
Protection of Confidential Information

See CP, art. 21; Res. 289/1997, part D.13 (Argentina); RD 2000-07, ¶ 2.7 (Canada); Act 153/2000, § 11 (Czech Republic); CPA, §§ 15, 16 (Singapore).

The Competent Authority shall protect confidential information submitted by the Applicant.

a. Specifically, the Competent Authority shall:
    i. Permit the Applicant to identify information submitted that is to be treated as confidential, with justification for claims of confidentiality to be given upon request;
    ii. Consult the Applicant if it decides that information identified by the Applicant as confidential does not qualify for such treatment;
    iii. Prior to any disclosure, inform the Applicant of its decision, providing reasons upon request, as well as an opportunity for consultation and for an internal review and appeal of the decision prior to disclosure;
    iv. Not disclose confidential information except with the written consent of the Applicant; and
    v. In the event that an Applicant withdraws or has withdrawn an application, respect the confidentiality of commercial and industrial information, including research and development information, as well as information on which the Competent Authority and the Applicant disagree as to its confidentiality.
b. Without prejudice to Article 24(a), the following information shall not be considered confidential:
    i. The name and address of the Applicant;
    ii. A summary description of the Plant LMO and its purpose that excludes information protected as confidential under Article 24(a);
    iii. A summary of any risk assessments; and
    iv. Any methods and plans for emergency response.

Article 24 Commentary
As is the case in any research-dependent business sector, protection of confidential business information is essential to ensuring an equitable return on the Applicant's investment in research and development. Protection of such investments is important both to ensure access to the benefits of biotechnology and to promote domestic capacity to develop such technologies. Existing national measures, as well as the Cartagena Protocol, recognize the importance of ensuring this protection, and establish requirements for doing so. Governments should adopt and enforce sanctions against individuals who unlawfully release confidential business information. The unauthorized release of confidential business information by a competent authority in another country should not be a basis for limiting the protections available to Applicants for such information under this measure.

Article 25
Authority to Promulgate Necessary Implementing Regulations and Guidance

This measure is self-executing. The Competent Authority may promulgate measures (e.g. regulations) and/or guidance, as it deems appropriate, to facilitate implementation of this measure, consistent with the provisions and Objective of this measure.

See APA, 5 U.S.C. § 553 (United States); CP, art. 23.

a. The Competent Authority shall ensure that the public has an opportunity to review and comment on any proposed regulations that are adopted in furtherance of this measure, as required under Article 19(c).
b. The Competent Authority shall ensure that all legal requirements adopted in furtherance of this measure are made available to the public, including the regulated community.

Article 25 Commentary
This part provides for public participation in the development of implementing measures, consistent with the goals of the UNEP/GEF project for the Development of National Biosafety Frameworks, Article 23 of the Biosafety Protocol, and with the objectives of various other international efforts and instruments aimed at promoting public participation and transparency. These include the International Covenant on Civil and Political Rights, other United Nations instruments and programs, and the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters.

Article 26
Review and Re-Authorization of this Measure

See GTA, § 194 (Australia); CP, art. 35.

The government of *[name of country or territory]* shall review this measure and related measures regularly in light of technical and scientific advances, in a transparent manner, providing for notice to the public of proposed changes to the measure and an opportunity for public comment on proposed changes. The first review of this measure shall occur no later than three years after its effective date. Thereafter, the measure shall be reviewed at least every five years with the goal of evaluating the effectiveness of this measure, including an assessment of its procedures and annexes.

Article 26 Commentary
Regular review of biosafety measures in light of technical and scientific advances, as provided for in existing national regimes, is essential to the maintenance of an effective and efficient system of oversight. Combining ad hoc review in light of specific developments with scheduled periodic review will help ensure that measures receive timely review. Public participation in this process can help ensure public confidence in the measures applied. This approach is consistent with current practice in many countries, Article 23 of the Cartagena Protocol, and the goals of the UNEP/GEF project for the Development of National Biosafety Frameworks.

Article 27
Effective Date

This measure shall become effective. . . .

Article 27 Commentary
The procedures and timing for making national measures effective vary widely among jurisdictions.

ANNEX I
INFORMATION REQUIRED IN APPLICATIONS UNDER ARTICLE 6

See CP, Annex I.

The following information shall be included in any application submitted pursuant to Article 6:

a. Name, address and contact details of the Applicant;

b. As applicable, name, address and contact details of whichever of the importer and/or exporter is not the Applicant;

c. Name and identity of the Plant LMO, as well as the domestic classification, if any, of the biosafety level of the Plant LMO in the country of export;

d. Intended date or dates of any transboundary movement, if known;

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

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

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

h. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the Plant LMO;

i. Intended use of the Plant LMO or products thereof, namely, processed materials that are of Plant LMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

j. Quantity or volume of the Plant LMO to be transferred;

k. Report(s) for any previous and existing risk assessment(s) consistent with Annex II;

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

m. As applicable, regulatory status of the Plant LMO within the country of export (for example, whether it is prohibited in the country of export, whether there are other restrictions, or whether it has been approved for general release) and, if the Plant LMO is banned in the country of export, the reason or reasons for the ban;

n. As applicable, result and purpose of any notification by the Applicant to other countries regarding the Plant LMO to be transferred; and

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

Annex I Commentary
This Annex I generally tracks the information requirements of Annex I of the Cartagena Protocol.

ANNEX II
RISK ASSESSMENT

See CP, Annex III.

Objective

a. The objective of risk assessment is to identify and evaluate the potential adverse effects of Plant LMOs 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

b. Risk assessment is, inter alia, used by Competent Authorities to make informed decisions regarding Plant LMOs.

General principles

c. 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.

d. 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.

e. Risks associated with Plant LMOs or products thereof, namely, processed materials that are of Plant LMO 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.

f. 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 Plant LMO concerned, its intended use and the likely potential receiving environment.

Methodology

g. 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.

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

   i. An identification of any novel genotypic and phenotypic characteristics associated with the Plant LMO that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

   ii. 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 Plant LMO;

   iii. An evaluation of the consequences should these adverse effects be realized;

   iv. An estimation of the overall risk posed by the Plant LMO based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

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

   vi. 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 Plant LMO in the receiving environment.

Points to consider

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

   i. 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;

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

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

   iv. 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;

   v. Plant LMO. Identity of the Plant LMO, and the differences between the biological characteristics

of the Plant LMO and those of the recipient organism or parental organisms;

vi. Detection and identification of the Plant LMO. Suggested detection and identification methods and their specificity, sensitivity and reliability;

vii. Information relating to the intended use. Information relating to the intended use of the Plant LMO, including new or changed use compared to the recipient organism or parental organisms; and

viii. 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.

Annex II Commentary
This Annex II tracks the provisions of Annex III of the Cartagena Protocol. References to "taking also into account risks to human health" in Annex III of the Biosafety Protocol are recognized to concern indirect or secondary human health effects that might arise from adverse effects of an LMO on biological diversity. Use of this language in this Annex II is made with this same understanding.

NOTES

ABBREVIATIONS LIST

Acronym	Complete Name
Act 153/2000	Act No. 153/2000, Use of Genetically Modified Organisms and Products and Amendments of Some Related Acts (2000) (Czech Republic).
Act No. XXVII	Act No. XXVII of 1998 on Biotechnology Activities (1998) (Hungary).
APA	Federal Administrative Procedure Act, 5 U.S.C. § 551 et. seq., as amended, (1966) (United States).
CBD	Convention on Biological Diversity (1992).
7 CFR Part 340	Code of Federal Regulations Establishing Rules for the Introduction of Organisms Altered Through Genetic Engineering, Animal and Plant Health Inspection Service, Department of Agriculture (2002) (United States).
CP	Cartagena Protocol on Biosafety to the Convention on Biological Diversity (1999).
CPA	Control of Plants Act (2000) (Singapore).
EC 2001/18	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (2001) (European Community).
EU-US BCF Final Report	The European Union - United States Biotechnology Consultative Forum Final Report (2000) (E.U.-U.S.).
GAR	Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries, as amended (2000) (Japan).
GESMM	Genetic Engineering Safety Management Measures, Order No. 17 of the State Science and Technology Commission (1993) (China).
Inst. Norm No. 10	Instructional Norm No. 10 (concerning Planned Release into the Environment of Genetically Modified Plants) (1998) (Brazil).
PBG	Philippine Biosafety Guidelines (1991) (Philippines).
PPA	Plant Protection Act, 7 U.S.C. §§ 7701-7773 (2000) (United States).
RD 94-08	Regulatory Directive 94-08, Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits (1994) (Canada).
RD 2000-07	Regulatory Directive 2000-07, Guidelines for the Environmental Release of Plants with Novel Traits within Confined Field Trials in Canada (2000) (Canada).
Reg. No. 1420	Regulation No. 1420 under the Genetically Modified Organisms Act of 1997 (1999) (South Africa).
Res. 289/1997	Resolution No. 289/1997, Application for a Permit for Experimentation and/or Release into the Environment of Genetically Modified Plants (1997) (Argentina).
Singapore Guidelines	Singapore Guidelines on the Release of Agriculture-Related Genetically Modified Organisms (GMOs) (1999) (Singapore).
SPS Agmt	Agreement on the Application of Sanitary and Phytosanitary Measures (1994) (WTO).
TBT Agmt	Agreement on Technical Barriers to Trade (1994) (WTO).
UNEP Technical Guidelines	United Nations Environment Programme International Guidelines for Safety in Biotechnology (1995) (UNEP).

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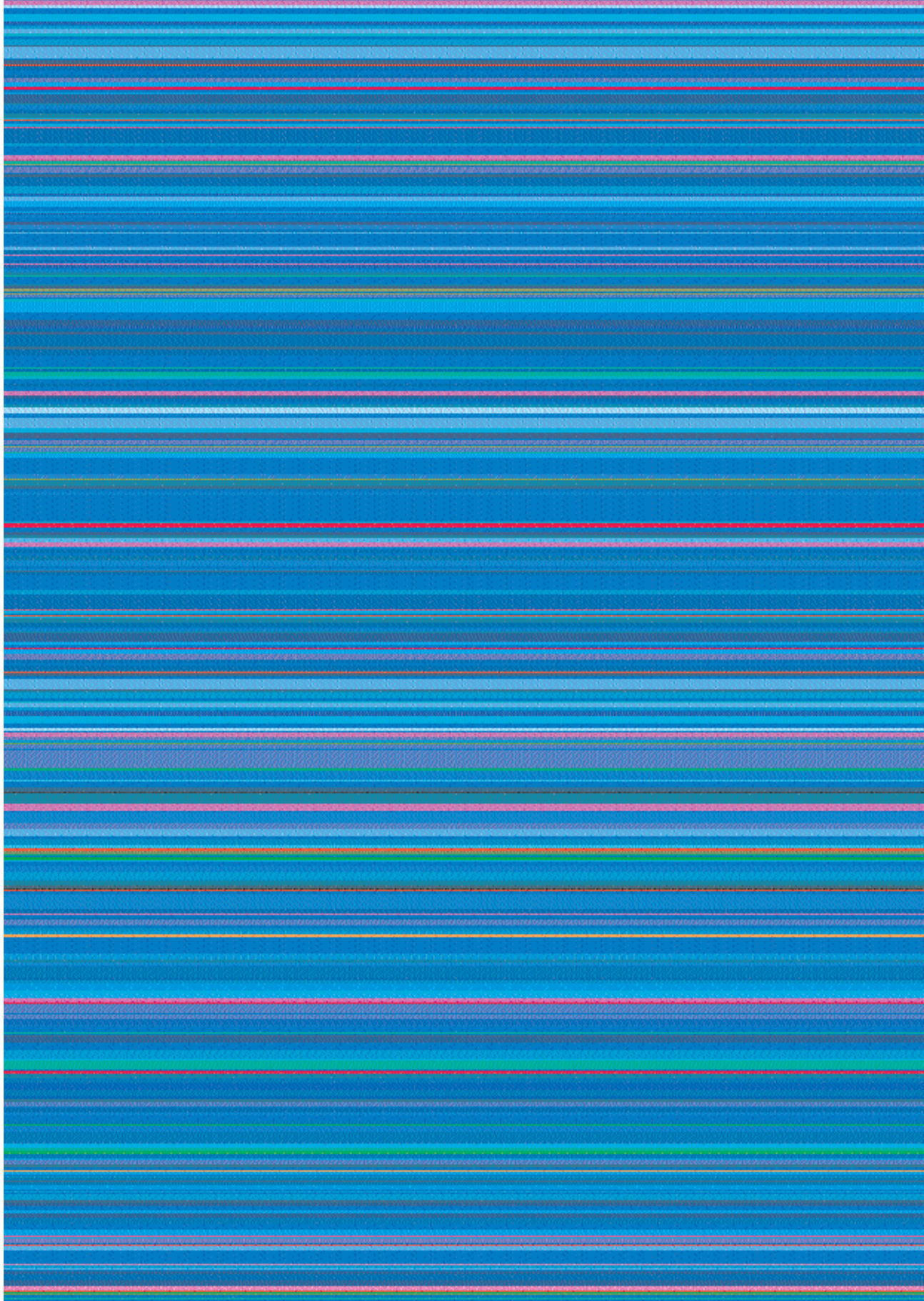

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