LEGAL AND POLICY FRAMEWORK FOR THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Introduction

This document is intended to assist the Government of Jamaica to create a framework that will implement the provisions of the Cartagena Protocol on Biosafety and other developments in the regulation of biodiversity. It will inform policy decisions as the Government seeks to balance the advantages to be gained by advances in modern biotechnology against the risks that may attend those advances.

A Draft Biosafety Concept Paper prepared by the National Biosafety Committee expresses the aims and objectives which influenced the decision of Jamaica to become a Party to the Cartagena Protocol on Biosafety. The Committee identified the advantages of the application of modern biotechnology and acknowledged local initiatives.

The Committee considered that while substantial benefits are to be gained from the application of biotechnology in several sectors, there are ecological, health and socio-economic implications that have not been adequately addressed and there is evidence that genetically modified organisms can have negative ecological and health impacts.

The Cartagena Protocol therefore, treating with the transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effects on the conservation and the sustainable use of biological diversity, and recognizing also the concern over risks to health, was a useful international instrument to begin the process of addressing health and environmental concerns about the application of modern biotechnology.

Arrangement of the Document.

The arrangement of the Document was determined by the Scope of Services of the Contract that was agreed between the National Environment and Planning Agency and the Consultant. Accordingly, the substantive part of the Document is in four Sections in the following order:

- Review and Analysis of the Cartagena Protocol identifying the Legal Implications for Jamaica.
- Review of Legislation that may impact on the use of Modern Biotechnology identifying Gaps and Weaknesses.
• Drafting Instructions for national legislation necessary for implementation of the National Biosafety Framework Policy and the requirements of the Cartagena Protocol on Biosafety.

Methodology

In the preparation of the Document, the Consultant held consultations with several persons who were either experts or resource persons familiar with the subject of biosafety. A list of persons interviewed is appended as Appendix III.

The Sections of the document that treat with legal issues did not receive any substantive comments.

The Policy by contrast was subject to extensive scrutiny. Several drafts of the document were prepared and circulated to experts and resource persons for comments. Those drafts were also considered in the meetings of the National Coordinating Committee. The Policy therefore reflects all the comments that were received from the experts both in their individual capacities and as members of the National Coordinating Committee. Additionally, the Policy was informed by submissions made by Government Ministries, the National Biosafety Committee and the Consumers Affairs Commission.

One significant factor which impacted on the preparation of the document was the relative lack of responses to requests for comments. Several persons expressed the view that while they were committed to the process of developing a biosafety Framework for Jamaica, they were unable to devote the required time to the Project because of other commitments. Accordingly, the Consultant experienced considerable difficulties in obtaining comments, and those which were received were often submitted after several requests, thereby causing long delays.

It should also be pointed out that the Final Report was prepared according to the Contract Schedule, but was unable to incorporate any of the discussions of the national workshops as none was held during the period of the contract as was originally agreed.

Finally, the form that the Policy document takes was adopted principally for two reasons. Firstly, the National Environment and Planning Agency (NEPA) was of the view that there was no set form for writing a Policy. Therefore, no guidelines as to form were given to the Consultant. Secondly, the particular form of presentation was adopted because it was thought that the members of the Committee would be assisted in their consideration of policy options, if the relevant Protocol provisions that would influence the Policy were set out and analyzed in the document.
Section 1

REVIEW AND ANALYSIS OF THE LEGAL IMPLICATIONS OF THE CARTAGENA PROTOCOL ON BIOSAFETY FOR JAMAICA

Background to the Protocol

The biotechnology revolution over the last thirty years posed serious challenges about the safety to health and the environment. For the most part there was broad consensus that modern biotechnology must be developed with adequate safety measures. However there was distinct difference in the way safety measures were treated in law especially evident in the cases of technologically advanced countries on the one hand, and developing countries on the other. There was concern that because many of these products were traded internationally, the lacuna in the law regarding rules for LMOs subject to international trade ought to be addressed.

In 1995, pursuant to Article 19, paragraph 3 of the Convention on Biodiversity, the Conference of Parties sought to address the issue by establishing an Open-ended Ad Hoc Working Group on Biosafety to develop a Draft Protocol On Biosafety. The Working Group was to focus specifically on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity. The negotiations resulted in the adoption of the Cartagena Protocol on January 29, 2000.

Status of the Protocol in relation to Jamaica

Jamaica, a Contracting Party to the Convention on Biological Diversity, may in accordance with Article 32 of the Protocol on Biosafety, ("the Protocol") become a party to the Protocol. Jamaica signed the Protocol on June 4th, 2001, but may not ratify it until it has enacted legislation necessary to implement the provisions and enable the fulfillment of its obligations. This is a necessary exercise in the legal system.

Constitutional requirements

The present exercise of examining the Protocol to determine its implications for Jamaica is necessary because of our Constitutional requirements. Under the Jamaica Constitution, the legal capacity to enter into treaties and undertake treaty obligations belongs to the Executive. However if those treaties involve a change in the law or require the Courts to enforce any provisions of those

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1 For a discussion of this point and other issues relating to the formalities of the Protocol as they affect Jamaica, see Opinion of the Attorney General dated 12th February 2001.
treaties, the provisions of the treaties must be enacted as law by the Parliament. It must be noted that it is not all the provisions of a treaty which may require Parliamentary intervention—only those which may require a change in the law or those which the Courts may be called upon to enforce, for example sanctions for breach of a regulation. So, while the Executive may go ahead and bind Jamaica in international law, Jamaica as a party to an international agreement may find itself in breach of its international obligations if it does not have in place the legislation required for it to carry out its international obligations. And it is a well-settled rule of international law that a State may not invoke deficiencies in its internal law as justification for breach of its international obligations.

This basic obligation to enact legislation as far as the Protocol is concerned, is contained in Article 2 paragraph 1. This provides that “Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.”

This paper will focus on the legal measures which Jamaica will need to adopt to implement the Protocol. A subsequent paper will address the administrative and other necessary measures.

It is generally considered that although many countries have existing legislation that cover aspects of the movement and use of flora and fauna in the country, these pieces of legislation were usually sectoral, and do not adequately address the issue of biosafety.

Legislation which will be enacted will need to address, at a minimum, the following issues:

- The import and export of living organisms;
- Food safety and human health related issues;
- Plant and animal quarantine;
- Pesticide and herbicide use;
- Invasive Species;
- Biodiversity.

The examination which follows will indicate the nature of the action which will be needed to implement a particular obligation. Specific attention will be focused on those provisions where legislation is required.
EXAMINATION OF THE PROTOCOL

Preamble

The Preamble does not create any binding obligations. It is however not devoid of legal significance. The Preamble may be used as an aid to interpretation in so far as it sets out the philosophical underpinnings of the treaty. In this regard, paragraphs 4, 5, 6, 9 and 10 are significant. Paragraph 4 reaffirms the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development. Paragraphs 5 and 6 highlight the concerns with regard to safety measures as they relate to human health and the environment, while paragraphs 9 and 10 focus on the relationship between international trade and biosafety, recognizing that trade and environment agreements are mutually supportive in achieving sustainable development.

Objective

The objective of the Protocol is set out in Article 1. The objective is stated as being “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.

The legal effect of the objective is that all actions purporting to implement the Protocol will be measured against this objective. The primary rule in treaty interpretation is that a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

General Provisions

The Protocol describes as general provisions certain provisions which are contained in Article 2. The title of the Article may however be misleading as the substance of the provisions are more than general, including substantive issues as to jurisdiction and minimum standards.

The Article reiterates the objective contained in Article 1 but in this Article there is a positive obligation placed on Parties. Paragraph 2 mandates the Parties to ensure that the development, handling, transfer, transport, use and release of any living modified organisms are undertaken in a manner that prevents or
reduces the risks to biological diversity, taking into account risks to human health.

The jurisdiction provisions in paragraph 3 are important as they state the limits for the exercise of national jurisdiction of a Party. For Jamaica the extent of Jurisdiction will be governed primarily by the Maritime Areas Act and the Exclusive Economic Zone Act.

Scope

Articles 4, 5 address the Scope of the Protocol.

Thus Article 4 provides that the Protocol applies to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

By Article 5, the Protocol does not apply to living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations. It is important to note that the limitation applies only where the relevant pharmaceuticals are addressed by other relevant international agreements or organizations.

Advance Informed Agreement Procedure

Central to the regime set up by the Protocol is the Advance Informed Agreement Procedure. This is the procedure that allows Parties to regulate the importation of living modified organisms which they consider to have adverse effects on the environment or human health.

The relevant provisions for the consideration of this subject are Articles 7, 8, 9, 10, 11 and 12.

Article 7 sets out the basic provision. Subject to specified provisions, the advance informed agreement set out in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms or intentional introduction into the environment of the Country of import.

Excluded from the scope of the provision are

- pharmaceuticals referred to in Article 5 above;
- decisions by a Party regarding the transit of living modified organisms transiting its territory;
- the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import;
- the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing; and
• the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to the Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

The elements of the advance informed procedure are set out in Articles 8, 9, 10 and 12. Article 11 does not impose the advance informed procedure, but treats specifically with the procedure relating to living modified organisms intended for direct use as food or feed or for processing.

Article 8 provisions will require legislation where Jamaica is the Party of export. The Article imposes an obligation on the country of export or the exporter to inform the country of import of its intention to export modified living organisms covered by the Protocol. The notification shall contain minimum information contained in Annex 1.

There is no existing legislation which contains the specifics included in Annex 1. Therefore the provisions will have to be incorporated into the new legislation.

The legislation will also need to provide that the exporter shall be liable for the accuracy of any information which he provides. This requirement is not novel and may be found in other pieces of legislation, the most familiar being customs legislation. See also the Natural Resources (Hazardous Waste) (Control of Transboundary Movement) Regulations, 2003. The obligation is usually enforced through criminal sanctions relating to fraud.

The procedures which are applicable to the country of import are set out in Articles 9 and 10. While there is an obligation on the Party of import to acknowledge receipt of the notification within ninety days of receipt, the Protocol contains a very important provision to the effect that a failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an international transboundary movement. This provision is consistent with other instruments of its kind and is meant to reinforce the concept that every State exercises sovereignty over its territory and sovereign rights and exclusive jurisdiction in accordance with international law over its continental shelf and exclusive economic zone. Any activity in those areas must therefore be conducted only with its express consent.

The provisions relating to notification and acknowledgement will be legislated.

**Risk Assessment**

The decision of a Party of import must be based on a risk assessment undertaken in accordance with the provisions of Article 15. The risk assessment must be carried out in a scientifically sound manner, in accordance with the
provisions of Annex III. The risk assessment must be based at a minimum on the information provided in the original notification. In arriving at its decision, the Party of import may also take into consideration certain additional factors. For example, the decision may not be prevented because of lack of certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the Party of import. (Article 10 para.6).

Secondly, Article 26 permits the Parties in reaching a decision on import under the Protocol or under its domestic measures implementing the Protocol, to take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

Implementing legislation will be needed to provide for the basis of risk assessments, especially with respect to Annex III. In this regard, reference may be made to the Draft Biosafety Policy prepared by NEPA. In discussing the applicability of the Natural Resources Conservation Authority Act to regulate aspects of biosafety, the scope of section 10 of the Act which addresses Environmental Impact Assessments “EAI” was considered. The document opines that a risk assessment may be required as a component of the EAI. It however makes the point that the section of the Act would not however cover all LMOs or govern any products thereof. “In fact the applicability of this provision to the regulation of GMO’s is questionable as any regulatory framework addressing GMO’s requires substantive provisions and a multidisciplinary and inter-agency approach for successful implementation”. ²

The legislation should also provide that the additional socio-economic considerations may be taken into account in arriving at a decision whether to allow an import of living modified organisms.

**Risk Management**

Article 16 paragraph 1 provides that the Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions associated with the use, handling and transboundary movement of living modified organism. This fundamental obligation is elaborated upon in other paragraphs of the Article. The obligation is germane to the implementation of the Protocol and the development of Jamaica’s Biosafety Framework Policy.

² NEPA Draft Biosafety Policy, unpaginated.
The several elements which will be identified in the Policy may not need to be legislated immediately. However the legislation must provide for the essential elements that are contained in the Protocol.

**Decision Making and Issues of Transparency**

Article 10 provides the procedure to be followed by a Party of import in arriving at its decision. These provisions will need to be legislated. They are particularly important as they seek to introduce elements of transparency and certainty into the procedure. Paragraph 4, for example, provides that except in a case in which consent is unconditional, a decision shall set out the reasons on which it is based.

Further issues of transparency are addressed in Article 12. Under that Article, provision is made for review of decisions by a Party of Import. Thus, that Party may at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, review and change a decision and shall notify, inter alia, any notifier that had previously notified movements of the living modified organisms referred to in the decision. In addition, a Party of export or a notifier may also request the Party of import to review its decisions on two narrow grounds. Firstly, where it is considered that there is a change of circumstances that may influence the outcome of the risk assessment upon which the decision was based, and secondly, additional relevant scientific or technical information has become available. Reasons for a decision shall be set out in writing.

These provisions for review affect the rights of persons, either natural or legal and must therefore be provided for in the legislation.

**Procedure for Direct Use as Food or Feed or For Processing**

The procedure for living modified organisms intended for direct use as food or feed, or for processing raise legal issues similar to those identified above. However, it should be pointed out however that the application of the Protocol to exports of genetically modified agricultural commodities remains one of the most controversial issues regarding the extent to which a State may exclude imports of commodities traded in the world trading system. This was a contentious issue during the negotiations and the resolution of the issue in the Protocol is still not without difficulties. Firstly, the Protocol provides that where a Party makes a decision on domestic use of a living modified organism that may be exported as food or feed for processing, it must inform the other parties and provided information that is specified in Annex II to the Protocol. This obligation will require legislation since it is specific to the Protocol.
A Party to the Protocol may take a decision on the import of modified living organism based on its domestic legal procedures that are consistent with the Protocol. Alternatively, a developing country or a Party with an economy in transition may in the absence of the domestic regulatory framework, an in exercise of its domestic jurisdiction declare that its first import will be taken according to the following:

- a risk assessment undertaken in accordance with Annex III; and
- a decision made within a predictable timeframe, not exceeding two hundred and seventy days.

Although the two procedures provided for will be attractive to some countries, they are not available to Jamaica without the enactment of specific legislation for reasons which by now we are familiar with.

Simplified Procedure

Article 13 provides for a simplified procedure the elements of which are as follows:

A Party of import may specify in advance to the Biosafety Clearing House:

- Cases in which intentional transboundary movement may take place at the same time as the movement is notified to the Party of import;
- Imports of living modified organisms which would be exempted from the advance informed agreement procedure.

It is important to note however that this procedure may be utilized only where adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of the Protocol.

The simplified procedure represents an alternative procedure. If Jamaica wishes to provide for this alternative, it will have to be included in the legislation.

Handling, Transport, Packaging and Identification

The importance of the advance informed procedure in the scheme of the Protocol is paralleled by those provisions which treat with handling, transport, packaging and identification.

Article 18 provides that in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety taking into consideration relevant international rules and standards. It will
be observed that considerations of safety apply to all living modified organisms in their handling, transportation and packaging. Additional rules are applied to documentation accompanying the different categories of living modified organisms.

Living modified organisms that are intended for direct use as food or feed or for processing must clearly identify that they may contain living modified organisms and are not intended for intentional introduction into the environment.

Living modified organisms that are destined for contained use should be clearly identified as living modified organisms and the documentation should specify the requirements for safe handling, storage, transport and use, and the contact point for further information.

Living modified organisms that are intended for intentional introduction into the Party of import and any other living modified organism within the scope of the Protocol should clearly identify them as living modified organisms, specify the identity and relevant traits and/or characteristics any requirement for safe handling, storage, transport and use information as to the exporter and very importantly, a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

All these measures will need to be legislated for. Specifically, the Bureau of Standards will need to be very active in the promulgation on the standards relating to packaging and identification.

**Protection of Confidential Information**

The basic obligation with respect to confidentiality of information is found in paragraph 3 of Article 21. Each Party is obligated to protect confidential information received under the Protocol. It shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms. While there are procedures in place that may be used to protect confidential information that relates to trade secrets and revenue information, it is doubtful whether those general procedures may satisfy the requirement here. This provision may also pose some problems for the Access to Information Act and therefore further examination of the issue is called for.
Non-Parties

Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objectives of the Protocol, Article 24. For Jamaica therefore, were it to become a Party to the Protocol and the question of importing living modified organisms arose, Jamaica would be obliged to apply the standards of the Protocol.

Illegal Transboundary Movements

Penal provisions are provided for in Article 25. The Article mandates each Party to adopt appropriate measures aimed at preventing and if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures. Such movements shall be deemed to be illegal transboundary movements.

The elements which need to be addressed here are that the appropriate legislation may be criminal or civil. The regime adopted however must be such that it will not only prevent the illegal shipments, but will also penalize anyone who undertakes those shipments.

There are also financial implications for Jamaica if it fails to be vigilant with respect to activities under its jurisdiction. Paragraph 2 provides that in the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction.

Administrative and other Measures

It will be recalled that Article 2 of the Protocol imposes an obligation on all Parties to take necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol.

Several key Articles fall to be considered under this heading.

- **Competent National Authorities and National Focal Points**
  Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. A Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required under the Protocol. The Secretariat shall be informed no later than the date of the entry into force of the Protocol for the Party, the name and addresses of both the focal point and the competent national authority. One entity may perform both functions.

- **Biosafety Clearing House.**
Article 20 of the Protocol establishes a Biosafety Clearing House (BCH). The aims of the BCH are to:

- Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and
- Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centers of origin and centers of genetic diversity.

The obligations of the Parties are contained in paragraph 3 of the Article and they are central to the effective implementation of the Protocol. The paragraph provides that without prejudice to the protection of confidential information, each Party shall make available to the BCH any information required to be made available to the BCH under the Protocol and:

- Laws, regulations and guidelines for implementation of the Protocol as well as information required by the Parties for the advance informed agreement procedure;
- Bilateral, regional and multilateral arrangements under Article 14;
- Final decisions on import or release of LMO;
- Summaries of risks assessments or environmental reviews of LMOs generated by regulatory processes of Parties and carried out in accordance with Article 15 of the Protocol;
- Reports submitted by it regarding measures it has taken to implement the Protocol.

These obligations will not require legislation to fulfill Jamaica’s obligations under the Protocol.

Public awareness and Participation

Article 23 imposes an obligation on the Parties to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so the Parties shall cooperate as appropriate, with other States and international bodies.

The general nature of the obligation does not require any new and specific piece of legislation. This obligation may be implemented either through the existing government entities charged with education generally and public awareness programs, or by establishing agencies charged specifically to undertake the functions outlined in the paragraph.
One aspect of the obligation which may however be legislated for is the participation of the public in the decision making on certain applications through providing for, for example, notice of intention to grant certain permits and inviting comments. In this regard, reference may be made to section 22 of the Food and Drugs Act which provides that a draft of all proposed regulations made under the Act shall be published in the Gazette so as to permit representations to be made to Minister by any person concerning any provision of the regulations to which that person objects.

- Capacity Building
  Article 22 imposes an obligation to cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety. Of particular importance to Jamaica is paragraph 2 which provides that in the implementation of the cooperation provision, the needs of developing country Parties, in particular the least developed and small island developing States among them for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity building in biosafety.

Relationship between the Protocol and International Instruments in International Trade.

The Principal Instruments in this respect are the World Trade Organisation Agreements (“the WTO Agreements”), the Vienna Convention and the Montreal Protocol on Ozone, the Basel Convention on the Control of transboundary Movements of Hazardous Wastes and the Convention on international trade in Endangered Species of wild Fauna and Flora.

The WTO Agreements

The relationship between the Protocol and the WTO Agreements is a vexed one which is certain to lead to trade disputes in the future. Three of the WTO agreements are particularly relevant to the regulation of LMOs under the Cartagena Protocol, namely, the Agreement on the application of Sanitary and Phytosanitary Measures (SPS), the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Trade related Aspects of Intellectual Property (TRIPS).

The Agreement on the application of Sanitary and Phytosanitary measures regulates the imposition by Members of measures in protecting public safety and the environment. The Agreement establishes a system for harmonizing the sanitary and phytosanitary procedures. It is in the specifics however that the
Cartagena Protocol and the measures under the SPS Agreement may conflict. The Agreement provides that Sanitary and Phytosanitary measures which conform to international standards will be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of the Agreement and the GATT 1994 unless there is a scientific justification. Decisions will be made on risk assessments. However, unlike the Cartagena Protocol, which provides for decisions based on the precautionary principle/approach, the SPS Agreement provides that where there is insufficient scientific evidence, a Member may only adopt those measures provisionally.

The Agreement on Technical Barriers to Trade applies to all technical regulations and standards, including packaging, marking and labeling requirements. The Agreement recognizes that no country should be prevented from taking measures necessary to ensure the quality of exports or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disused restriction on international trade. The proviso that attaches to the right to take action will be the real test of the independence of Members independence to take action to achieve the objectives of protection of plants, human and the environment in their regimes relating to LMOs.

In fact we are aware of the beginning of such a dispute between the United States and the European Union, in which the United States is challenging a number of import and marketing bans in some European Union Member States. During the negotiations of the Protocol, a number of countries expressed concern that the rights and obligations of States Parties under the Protocol should not supercede the rights and obligations of Members of the WTO. This concern was motivated primarily because at the heart of the Protocol is the recognition that environmental, human health and socio-economic considerations are valid rounds for denying imports of living modified organisms. The compromise which was adopted was the insertion in the Preamble of three paragraphs which speak to the relationship between trade and environment agreements.

Firstly, preambular paragraph 9 expresses the recognition that trade and environment agreements should be mutually supportive with a view to achieving sustainable development. This paragraph however does not create an obligation. It establishes the objective to which Parties to the Protocol will work towards.

Secondly, preambular paragraph 10 emphasizes that the Protocol should not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements.
However, preambular paragraph 10 records the understanding of the Parties that the above recital is not intended to subordinate the Protocol to other international agreements.

The language of the preambular paragraphs has generated fierce debate among commentators as they seek to address the scope of the language and its effect on international trade. Specifically, there is concern about the use of the Protocol to limit imports of certain commodities.3

Interesting questions of treaty interpretation are raised by the language used in the Preamble. But when all is said and done, one cannot say with certainty how the legal interpretation arguments will be resolved, as international tribunals have not developed a body of predictable jurisprudence in this area.

More importantly however from a policy point of view, we should identify the policy issue which is in question. If one examines the present dispute between the USA, a non-Party to the Protocol, and the European Union, a Party to the Protocol, the critical issue at stake is revealed. Should the Parties to the Protocol have the right to set up their own regulatory regime to protect human health and the environment although they are members of the WTO, or should such standards be set by the WTO. In particular, the more relevant WTO Agreements, the SPS and The Technical Barriers to Trade would be the standard setting instruments.

But if we recall how these bodies operate, as a developing country, Jamaica may wish to affirm the position that each Party to the Protocol has the right to set up its own regulatory regime which is consistent with the GATT exception to take measures necessary for the protection of the environment and necessary to protect human health. In this connection, an example of the dangers of allowing the international bodies to set standards is found in a letter sent to the UN’S Codex Alimentarius with regard to certain mischaracterizations which were made in a document CX/FTB/00/3 dated February 2000.

The authors were concerned because the mischaracterizations related to issues such as commodities, the precautionary principle and the relationship between the Protocol and the WTO. The authors were particularly concerned “because CODEX is recognized by the World Trade Organization, in the text on Sanitary and Phytosanitary Measures, as the presumptive body on standards for food safety. As written, the Codex summary of the Cartagena Protocol could be viewed as preparatory to a WTO action intended to force nations to accept GMO imports or pay penalties for lost trade revenues, contrary to the provisions of the Protocol.”

3 See e.g. Waincymer, Jeffrey Cartagena Protocol on Biosafety, Deakin University, Australia; Convention on Biological Diversity An Information Package for Pacific Island Countries.
Similar concerns are possible in relation to plants and animal health as the WTO Agreement recognizes the International Plant Protection Convention and the World Organization for Animal Health as having competence to set standards in their respective areas.

Conclusion

The preceding examination and analysis of the Protocol have revealed that Jamaica will have no choice but to enact a comprehensive piece of legislation in order to implement the Protocol. The general elements of the legislation will be informed by the provisions of the Protocol. There are however at least two possible sources of influence on the final form the legislation will take. Firstly, the stakeholders will be very influential on how their interests are protected and reflected in the legislation. Secondly, certain disciplines will be developed by the Conference of States Parties which may become binding obligations before Jamaica becomes a Party to the Protocol and will therefore have to be considered for inclusion in the legislation.
Section 2

REVIEW OF LEGISLATION RELEVANT TO THE IMPLEMENTATION OF THE CARTEGENA PROTOCOL

The scope of the Protocol and the nature of modified living organisms (“LMOs”) indicate the extensiveness of the regulatory framework which has to be put in place in order to implement the Cartagena Protocol. Article 4 of the Protocol provides that it applies to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

The Cartagena Protocol defines several terms which are relevant in this context. The following are of immediate significance.

“Living modified organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

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

“Contained use “ is also an important definition. The term is defined to mean any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

It is important to ascertain what current legislation regulates in order to determine the areas that will need to be addressed in new legislation. The observation has been made that the concerns associated with the use of living modified organisms are of recent origin and Jamaica’s legislative and administrative framework did not conceive of the development of LMOs and the emerging concerns relating to human health and environmental protection all over the world.\(^4\)

An indication of the scope of the legislation which is required may be gleaned from an examination of the legislation which has been introduced in other countries. In this regard it may be important to bear in mind that some countries,

\(^4\) NEPA, Draft Biosafety Policy, p.1.
like the United States, have legislation regulating the use of LMOs, but are not parties to the Protocol. The importance of this point is that the standard of legislation which is required by the Protocol is a minimum standard only, and the standards adopted by non-parties is indicative of what may be regarded as an acceptable standard.

Two basic approaches have been adopted in existing biosafety rules. On the one hand, some States have opted to regulate genetically modified products using product-based regulations where, for example, crops used as pesticides are regulated as pesticides, while foods are assessed in relation to food safety rules. This is the system which obtains in the USA. Canada also uses a product base approach for evaluation, placing emphasis on the novel traits or attributes introduced into a plant.

The product-based approach may be contrasted with that which obtains in other States which have implemented technology-based regulations, i.e. regulations applicable to all LMOs. This was the approach adopted by the European Union. Central to the approach incorporated in European regulations is that Genetically Modified products are considered new and special for which pre-existing legislation is insufficient.

There are also the new regulations adopted on July 23, 2003 by the European Union. The European Union has adopted two proposals of the European Commission to complete its legislative framework governing Genetic Modified Organisms. One proposal establishes a system to trace and label these products of biotechnology, and the other regulates the marketing and labeling of food and feed products derived from Genetically Modified Organisms. These regulations therefore enhance its process-based approach.

Neither of the two basic approaches described in the preceding paragraphs is applied exclusively by China which chooses to implement a pragmatic approach. Regulations are basically product based and explicit attention is given to the economic interest of a given application.

Whatever approach is adopted however, it is possible to identify the activities which are addressed in national biosafety frameworks, albeit that many existing regulations do not address all the activities. The following activities may be regulated:

- the contained use of LMOs;
- field testing of LMOs;
- large scale or commercial releases into the environment;
- the import and export of LMOs; and
- the placing on the market of LMOs and/or products containing Genetically Modified Organisms (such as seeds, foods; and animal feed.)

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5 Convention on Biological Diversity- An Information Package for Pacific Countries, p.5.1.
Legislation Relating to LMOs in Jamaica.

It may be important to mention as a preliminary point, that the novelty of the subject of LMOs and their regulation in Jamaica, makes it highly unlikely that the legislation will be consistent with a process based approach. Instead we will more than likely see that the legislation is product based as the regulatory regime was not intended to address LMOs specifically.


The Plant (Quarantine) Act

The Plant (Quarantine) Act regulates the importation of plant species, and establishes controls on plant pests. Part III of the Act establishes quarantine requirements in specified instances. The Act empowers the Minister to prohibit absolutely the importation of such plant, article or thing from any country, where he is satisfied that plant pests may be introduced into the Island. The Act also requires the quarantine of plants as a result of the presence of plant pests. It is the definitions of “plant” and “plant pests” which will allow the Minister to take action to prohibit the importation of LMOs, if the Government is influenced by the debate about the release of genetically modified crops into the environment.

“Plants” is defined as, “all species and types of plants, either living or dead and includes stems, branches, tubers, corns, stocks, budwood, cuttings, slips, layers, suckers, roots, leaves, flowers, seeds and seedlings.”

“Plant pests” means “any form of plant or animal life or any pathogenic agent injurious to plant or plant products.”

The Plants (Importation Control) Regulations

This piece of legislation complements the Plants Quarantine Act. Made pursuant to section 38 (j) of the Act, the regulations define “plant” to mean a plant that has been genetically modified and imported into the Island for the purpose of experimentation under controlled conditions. Plants which fall in this definition are quarantined and may be released from quarantine if the Chief Quarantine Officer is satisfied with the results of a diagnostic examination and any tests for
the detection of disease to verify if they show symptoms of disease the spread of which would endanger the health of any person, animal or other living organism.

**The Animals (Disease and Importation) Act**

The principal provisions which are relevant to our study are sections 13, 14, and 17. Under section 13, no bird, reptile, or insect may be imported into the Island except under and in accordance with a licence granted by the Director of Veterinary Services.

Section 14 provides that the Minister may for the purpose of preventing the introduction or spread of any disease into the Island, make regulations prohibiting, restricting, controlling or regulating the importation of animals or poultry, or any specific kind thereof, or of carcasses, fodder, litter, dung or other similar things.

Section 17 provides that all animals, birds, reptiles and insects imported into the Island shall, subject to any regulations made under the Act or to any terms and conditions of any licence granted under the Act, be placed in a quarantine depot for such time and under such conditions as may be specified in such regulations or in any such licence.

**The Natural Resources Conservation Authority Act**

The Act establishes the Natural Resources Conservation Authority which has among its functions:

- to take such steps as are necessary for the effective management of the physical environment of Jamaica so as to ensure the conservation, protection and proper use of its natural resources;
- to promote public awareness of the ecological systems of Jamaica and their importance to the social and economic life of the Island; and
- to advise the Minister on matters of general policy relating to the management, development, conservation and care of the environment.

While the Act does not expressly address the issues of biosafety and risks to human health, the regulation making power of the Minister is liberal enough to facilitate the enactment of regulations in this area. For example, under section 38, the Minister may make regulations which contain provisions in relation to:

- the importation, collection, storage, recycling, recovery or disposal of substances which may be hazardous to the environment;
- the limitation or prohibition of any action or method which may bring about the extinction of or major adverse effects on, prescribed fauna or flora; and
- the protection of particular species of prescribed fauna and flora.
Acting on the authority of section, the Natural Resources Conservation (Permits and Licences) Regulations, 1996, were enacted. The Regulations require a permit for the introduction of any species of fauna and flora or genetic material into the Island. We have been informed that “introduction” has been interpreted broadly by the National Resources Conservation Authority “NRCA” to mean, “place in” therefore including both importation and deliberate release. A permit is granted where the NRCA is satisfied that the activity is not injurious to public health or to the environment. Permits are granted with terms and conditions, and their compliance and observation are usually monitored by the NRCA.6

The Food and Drugs Act

The Food and Drug Act is the principal piece of legislation treating with the importation, sale, labeling, packaging, advertising and standard of food and drugs.

Section 4 of the Act is very useful in the implementation of the Cartagena Protocol. The section provides that except as provided by regulations, a person shall not import into the Island any food, drug, cosmetic or device unless it wholly conforms to the law of the country in which it was manufactured or produced and is accompanied by a certificate in prescribed form and manner that it does not contravene any known requirement of the law of that country and that its sale therein for consumption or use by or for man or animal would not constitute a violation of the law thereof. The sale of any food, drug, cosmetic or device imported into the Island in contravention of the provision is an offence.

Food and drugs are to be correctly labeled and packaged and should not be done in a manner that is false, misleading, or deceptive that it would likely create an erroneous impression regarding character, value, quantity, composition, merit or safety of the product.

The Act includes important provisions on standards. Sections 6 (3) and 7(3) provide that where a standard has been prescribed for a food or a drug, respectively, a person shall not label, package, sell or advertise any substance in such a manner that is likely to be mistaken for such food or drug, as the case may be, unless the substance complies with the prescribed standard. There are additional provisions respecting drugs where standards have not been prescribed.

In the area of food safety, it is important to bear in mind that this area may see a conflict between the obligations of Jamaica under the World Trade Organization regime, and its obligations under the Protocol as the Agreement on Sanitary and Phytosanitary Measures treats the Codex Alimentarius Committee as the authority for prescribing standards for food safety.

6 Draft Biosafety Policy, unpaginated.
The areas in which the Minister may make regulations may be invoked to provide legislation to deal with LMOs. The Minister may make regulations:

- declaring that any food, drug or class of food or drugs is adulterated if any prescribed substance or class of substances is present therein or has been added thereto or extracted or omitted there from;
- respecting-
  1. the labeling and packaging, exposing and advertising for sale of food, drugs, cosmetics and devices;
  2. the size, dimensions, fill and other specifications of packages of food, drugs cosmetics and devices;
  3. the sale, the prohibition of sale or the conditions of sale of any food, drug, cosmetic or device; and
  4. the use, the prohibition of use or the conditions of use of any substance as an ingredient in any food, drug, cosmetic or devise;

...to prevent the consumer or purchaser thereof from being deceived or misled as to its quantity, character, value, composition, merit or safety or to prevent injury to the health of the consumer or purchaser.

- Providing for the registration of drugs or devices, the granting of licences for the manufacture or importation of any drug or device and the imposition of fees in respect of any such registration or licence.

The provision that a draft of all regulations shall be published before they are finalized to enable public to comment is also noteworthy. It will be recalled that one of the Protocol obligations is that the Parties shall in accordance with their respective laws and regulations consult the public in the decision-making process regarding LMOs.

**The Pharmacy Act**

The question which will have to be addressed by the experts, if LMOs are to be brought within the scope of the Pharmacy Act, is whether the definition of “drug” embraces LMOs. It should also be borne in mind that the Protocol does not apply to the transboundary movement of pharmaceuticals for humans that are addressed by other relevant international agreements or organizations. (Article 5).

The Pharmacy Act establishes a Pharmacy Council whose responsibilities include registering pharmacists, pharmaceutical students, pharmacies and owners of pharmacies. The Council also has the responsibility of ensuring compliance with the provisions of the Act. An important provision of the Act which may be useful in the regulation of LMOs is the power which the Council has in determining the specified lists of drugs and poisons and their condition for sale.
See section 17. Further the Council is authorized to make regulations respecting inter alia, the compounding, dispensing, labeling, storing for sale and retailing of drugs and poisons; and prescribing the places in which drugs included in a particular list may be stored for sale and retailed and the requirements which shall be satisfied in relation to the keeping and retailing of such drugs in those places.

The Pesticides Act

The Pesticides Act is perhaps the piece of legislation which treats most directly with many of the issues raised by the Cartagena Protocol. It regulates the importation, manufacture, sale and use of pesticides. The exportation of pesticides is however not included within its scope and will therefore have to be addressed elsewhere.

“Pesticides “ is defined by the Act to include “any product, organism, substance or thing that is manufactured, represented, sold or used as a means of directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pests.” It will be observed that the definition is non-exhaustive.

A "pest" is any insect, fungus bacterium, nematode, weed, rodent, predatory animal or any form of animal or plant life, including a virus, which may infest or be detrimental to vegetation, man, animals, or households, present in any environment where not desired, or which may be declared by the Minister to be a pest.

The Act provides for the registration of pesticides and the licensing of facilities for the manufacture or importation of pesticides. Anyone desiring to sell pesticides requires written permission.

The Act establishes a Pesticides Control Authority to carry out the objectives of the Act and any policy directives that are given by the Minister.

Responsibilities of the Authority include:

- the maintenance of a Register of pesticides;
- the review of applications for the disposal of pesticides; and
- the issue of regulations for the disposal of pesticides and packaging.

Issues of packaging and labeling are also addressed in the Act. Article 18 of the Protocol sets out stringent packaging and labeling requirements of LMOs subject to intentional transboundary movement to ensure safety. While the Pesticides Act prohibits any person from packaging labeling or advertising any pesticide in a manner that is false, misleading or deceptive, or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety,
this provision would not go far enough to satisfy the provisions of Article 18 which is very specific and detailed about the labeling and packaging requirements of LMOs subject to intentional transboundary movement. The requirements of the Article may however be satisfied through the exercise of the regulation making powers of the Minister.

The Minister is empowered to make regulations with respect to the following matters:
- the registration of pesticides;
- experimental samples of pesticides and matters related thereto;
- licensing of persons to import or manufacture registered pesticides;
- restricted pesticides and the authorization and eligibility of persons to sell restricted pesticides;
- the labeling, packaging, storage, transportation and use of pesticides; and
- providing for the keeping of books and records by authorized persons.

The Schedules to the Act list the pesticides which are either prohibited because of their hazardous nature, or the sale of which is restricted because they are not considered as being so hazardous that they should be prohibited. The mechanism provided in the Schedules could be employed in the short term to address the issue of the importation of LMOs.

The Standards Act

The Standards Act will be important in the regulation of LMOs particularly in the promulgation of standards relating to food and drugs.

In this context, the relevance of Jamaica’s other international obligations is also relevant. Specifically, one must have regard to any international standards adopted in the World Trade Organization. For example, in the Agreement on Sanitary and Phytosanitary Measures, the Codex Alementarius Commission is recognized as the presumptive body on standards on food safety. The standards adopted by that body will therefore become binding on Jamaica where such standards are mandatory.

The work of the Standards Council of the Caribbean Community would also be relevant in this context.

The Public Health Act

The impact of the Catagena Protocol on the Public Health Act is marginal only. The Act is primarily concerned with the maintenance of the environment to ensure that it is maintained in sanitary and healthy condition. The Act also treats with the prevention and containment of communicable diseases. Its relevance to
the issue of LMOs is considered to lie in the power of the Minister to make regulations in relation to, inter alia:

- the importation, preparation, and distribution of food or drink intended for human consumption, so far as it concerns public health; and
- the inspection and prevention from contamination of food and drink intended for human consumption, the analyzing and testing of samples of such food and drink by an official analyst, the issuing of certificates in relation thereto, and the condemnation, seizure and disposal of such articles as are unfit for human consumption.

Conclusion

The examination of the existing legislation relevant to the implementation of the Cartagena Protocol has shown that while there are some pieces of legislation to address some of the issues under the Protocol, there is no coherence to the legislative scheme. The Acts, for the most part lack specificity relating to biosafety concerns and are mainly facilitative only, since the possibility of bringing biosafety issues within their scope lies in the regulation-making powers of the Minister.

One significant area which is not addressed by any existing legislation, is the administrative measures which will have to be put in place to do risk assessments and risk management. It has been observed that despite differences in philosophy and implementation of regulations in various countries, the questions asked and the science underpinning the regulations are generally alike. A key component of applications for environmental release, for example, is a detailed environmental risk assessment, which considers potential harm to human health, other organisms and the environment. Possible ways that any risks can be minimized or avoided must also be identified. The process involves a panel of experts reviewing the proposal with the regulatory body making the final decision. Particular emphasis is placed on the risk assessment and any procedures for risk management. This observation is validated by Annex III of the Protocol which sets out the procedure for the conduct of risk assessments under the Protocol.

There are therefore several gaps in the legislation and accordingly, Jamaica could not use the existing legal framework to satisfy all of its obligations under the Protocol.

The challenge is therefore to choose the approach which satisfies not only its biosafety concerns, but will also be integrated in other development policy areas.

\[^7\] Blackwell Publishing Ltd. The Plant Journal, 2003 33,1-18, The release of genetically modified crops into the environment.
In this regard, it will be recalled that while the predominant approaches are either the product-based approach or the process-based approach, there is scope for applying a more pragmatic approach as is done in China which takes into account its commercial interests. However since Jamaica is more likely to be an importer rather than an exporter or grower of LMO’s, it is recommended that the focus should be on border measures to ensure that LMO’s which have not been generally accepted as safe are not imported into the Island.

It is therefore recommended that a single piece of legislation should be enacted to treat with biosafety issues. What is of immediate concern however is to bear in mind that the regulations with which this study are concerned are regulations to be adopted for regulating transboundary movement under the Protocol. These need to be consistent with Protocol provisions.

There may also be areas of concern that are identified in the policy which may need to be legislated for. However, it must be borne in mind that Article 2 provides that the Protocol shall not be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than is called for in the Protocol, provided that such action is consistent with its objective and provisions and is in accordance with that Party’s other obligations under international law.

Persons responsible for the administration of the Protocol will therefore be mindful of the standards which may apply under the World Trade Organization disciplines and within the Caribbean Community.
Section 3

NATIONAL BIOSAFETY FRAMEWORK POLICY

Introduction

The Biosafety Policy is predicated on acknowledging that products of modern technology may be useful, but may also have inherent risks associated with the use of technology. The Policy is intended to set the framework for the handling, development, use and trade in LMOs, to assure minimum risks to the population. At the same time it is recognized that the Policy is prepared against the background of relatively limited knowledge of risks to the environment and human health and the rapid rate of developments in the field of biotechnology. It is therefore in recognition of these parallel considerations that it is determined that the primary focus of the Policy will be the implementation of the Cartagena Protocol.

In determining the elements of the Policy of the National Biosafety Framework, one major issue which was identified for decision before the contents of that policy framework were finalized, was the form that the legislative framework would take. This decision was considered necessary as both the policy and the legislation are complementary stages in facilitating Jamaica’s ratification of the Cartagena Protocol and subsequently fulfilling the obligations of the Protocol.

Basically, Jamaica had the benefit of other regional approaches which can inform its decision.

There has been discernible in the region, the following basic trends:

1. The use of existing legal systems in force as they relate to the issues.

2. Initiation of the development of specific legislation with significant focus on legislation on agricultural biotechnology and the emergence of the first set of specific laws on the subject.

3. Incipient and unequal legislative development, observed in a group of countries that have a significant absence of legislation.

4. Development of new legislation specific to LMOs.

The adoption of any one practice is a matter of policy and therefore the decision on this issue was the first policy decision of the Framework. However in arriving at a decision, the present legislative regime was examined to determine to what extent, if any, the adopted approach would advance the Country’s objective.
It will be recalled that in the examination of the legislative framework of Jamaica, it was observed that there were several pieces of legislation which treated with some aspects of biosafety. However, the legislation was sectoral, and in totality did not treat comprehensively with the issues. A decision to use the existing legislative framework would therefore require amendments to several pieces of legislation. The amendments would need to address not only the substantive biosafety issues, but also issues of competence with respect to decision-making and the establishment of rules and regulations within each sector.

The Government has decided to adopt the fourth and better approach and enact new legislation. This legislation would be biosafety specific and would ensure that all the relevant provisions of the Protocol would be addressed.

The consultations which were held to inform the development of the National Biosafety Framework Policy recommended that the policy should address issues beyond the scope of the Cartagena Protocol, 'the Protocol'. This recommendation was considered to be sound since it is thought that effective implementation of the Protocol, and the benefits of protection it offers to countries will depend on an effective national regulatory system addressing not only imports and exports (international trade), but also the use, development, safe handling and release of LMOs at domestic level.

However, to the extent that this exercise is intended to facilitate Jamaica’s ratification of the Protocol by implementing its provisions into domestic legislation, attention was focused on the provisions of the Protocol. This was not however intended to obscure the fact that all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health, are subject to the provisions of the Protocol. The novelty of the Protocol is that it sets up a special regime, the Advanced Information Agreement Procedure to regulate certain specified LMOs.

An examination of existing national approaches to comprehensive biosafety regulation reveals two basic approaches.

1. Some states have opted to regulate LMOs using product-based regulations. For example, crops used as pesticides are regulated by pesticide regulations and food is addressed by food safety rules.

2. Other states have implemented technology-based regulations and have adopted regulations applicable to all LMOs.

There however seems to be a developing hybrid that applies both the general legislation together with sector based product specific rules.
The Government has decided that the hybrid approach to legislation which incorporated technology-based regulations applicable to all LMOs and included provisions that were sector specific was the most appropriate for the Jamaican situation.
The Elements Of The Policy Of The National Biosafety Framework

Objective

The primary objective of the Policy of the National Biosafety Framework is to implement the provisions of the Cartagena Protocol. Accordingly, this objective, taken from Article 1 of the Protocol, is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

It is important to note that the objective of the policy is quite distinct from the scope of the legislation. The scope relates to the activities which are regulated and therefore there is no need to mention all activities in the objectives. Further, not all policy objectives will be legislated immediately. The primary legislation will provide for subsidiary legislation to provide additional technical details. What is significant is that whatever regime is adopted, the protection of human health and the environment are identified as paramount objectives for the policy and the purpose of the regulatory framework.

The suggestion made by some commentators that the objective of the Policy and the Regulatory Framework should recite that the objective is in accordance with the precautionary principle contained in Article 15 of the Rio Declaration on Environment and Development.

The Government has decided that the policy and the legislation adopt the provision as it is contained in preambular paragraph 4 of the Protocol thereby reflecting the political importance developing countries attach to the principle.

Scope

In this section, the policy should specify the activities which are to be covered and governed by the framework. Where a range of activities is covered, the regulatory regime usually provides for authorizations for each activity. The following are examples of regulatory provisions.

1. The Cuban legislation in treating with facilities that use biological agents and their products, organisms and their fragments with their genetic information must meet the safety measures and requirements established for several separate activities including the handling, transfer and setting

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8 Compare Article 1 of the Cuban Decree Law No.190 of Biological Safety.
9 See Julian Kinderlerer and the Model Act prepared by Arent Fox, November 2003.
up of structures that support biological safety in facilities and the treatment and disposal of dangerous biological waste.\textsuperscript{10}

2. The legislation of Sweden, the Genetically Modified Organisms Act, in Section 1 provides that it applies to the contained use and sending of samples; the work with laboratory plants and animals; deliberate release of genetically modified organisms. It shall also apply when products containing or consisting of such organisms are placed on the market.

3. The Gene Technology Act of Norway applies to both contained use and deliberate release. Several activities are identified as being among those that are considered to be deliberate release under the \textit{Act}.\textsuperscript{11}

The Policy deals with products containing proteins and nucleic acids and any other product derived from modern biotechnology that may be found to present risks to human health and the environment.

The \textit{government considered that the policy should be comprehensive in scope and should address the full scope of modern biotechnology.}

\textbf{It has decided that initially the scope of the policy, and consequently the legislation, focus on, but not be limited to, the implementation of the provisions of the Cartagena Protocol and therefore cover the import, export, transit, contained use, deliberate release or placing on the market of any LMOs.}

\textsuperscript{10} See e.g. Article 13
\textsuperscript{11} Section 8
Institutional Arrangements

This section treats with the institutional framework in which the entities responsible for policy and those entities that are responsible for the implementation of the administrative arrangements of the framework and legislation are identified.

All Parties to the Protocol must designate one or more national competent authorities to be responsible for performing the administrative functions required by the Protocol and shall be authorized to act on its behalf with regard to those functions.\footnote{Article 19. The functions of the Competent authority are primarily set out in the provisions relating to the AIA, such as Articles 8, 9, 10 and 12, provisions regarding confidential information Article 21 and responsibility for monitoring implementation of the Protocol Article 33.}

A survey of the biosafety frameworks regulating policy and legislation reveal that there is really no uniformity in the approach adopted by states. There is however usually the designation of an entity or entities responsible for the regulation of biosafety and decision making with respect to authorizations.

It has been observed that some regulations provide for shared responsibilities depending on the activity which is being regulated. This consideration may be particularly relevant to the Jamaican situation as the decision has to be taken whether the competence of the several institutions which currently exercise jurisdiction with respect to certain product and process related activities would continue in the same form or whether there would be modifications to treat with the new issues.

A brief description of the \textbf{existing institutional arrangements demonstrates the point}. The following Ministries and Agencies perform legal responsibilities that impact on biosafety.

1. The Ministry of Agriculture administers the Plant Quarantine Act and the Animals (Disease and Importation) Act.

2. The National Environment and Planning Agency administers the Natural Resources and Conservation Authority Act.

3. The Ministry of Health administers the Food and Drugs Act; the Pharmacy Act; the Pesticides Act and the Public Health Act.

4. The Ministry of Commerce, Science and Technology is responsible for the Standards Act and the National Science and Technology Policy. The Scientific Research Council is also an agency of the Ministry.
5. The Ministry of Foreign Affairs and Foreign Trade which is responsible for the negotiation of international trade agreements and is responsible for the formulation of international trade policy.

While the identified Ministries are responsible for policy, the actual administration of the respective Acts is carried out in some instances by Departments in those Ministries. So, for example, there is a Pharmacy Council under the Pharmacy Act, and a Pesticides Authority under the Pesticides Act.

In addition to these bodies that exercise legislative functions, there exists bodies which are advisory to the Cabinet. There is also the National Biosafety Committee which has been mandated to develop procedural guidelines for the importation of plant LMOs for experimentation. This Committee also exercises legislative functions pursuant to its mandate, as under the Plants (Importation) Control Regulations, it is responsible for granting permission for the importation of plant, seed, cutting or slip for the purposes of the Regulation. “Plant” is defined to mean a plant that has been genetically modified and imported into Jamaica for the purpose of experimentation under controlled conditions.

Clearly therefore, there will be need for some kind of rationalization. In rationalizing the existing arrangements however, it is possible that the responsibilities of some institutions will be left intact, but they will all be responsible to an institutional body which will be paramount in decision-making regarding LMOs. The procedure for consultation will therefore be critical to the exercise of the decision-making power.

Under the Policy and Legislation, it will therefore be necessary to identify:

Which entity will be responsible for issuing policy directions on the one hand and on the other, the entity or entities that will be responsible for giving approvals.

There must be a designated Government Ministry which has portfolio responsibility for implementation and coordination of the functions and powers assumed by the Government of Jamaica under the Protocol.\(^\text{13}\)

This issue is quite separate and distinct from the issue of advisory functions, although the Protocol does not mandate an advisory body. The responsible Minister will be free to establish any technical or scientific advisory bodies considered necessary to advise him/her on matters relating to the implementation of the Protocol.

This issue of technical and advisory bodies needs to be addressed further. Under the Protocol, at least an advisory body with scientific representation would need

\(^\text{13}\) Article 10, decision on import; Article 11, final decision regarding LMOs intended for direct use as food, or feed or for processing; Article 18, measures relating to handling, transport, packaging and identification.
to be established to advise the Competent Authority on, inter alia, whether approval should be given to import living modified organisms taking into account risk to human health. Similarly, only a body with scientific representation could advise the Competent Authority on the policy which should be adopted on decisions to allow or refuse importation although there is lack of scientific certainty due to insufficient scientific relevant 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. And more importantly, only scientific experts can carry out the risk assessments which are required under Article 10,16, and Annex III.

Regarding the Ministerial responsibility, the Minister responsible for Agriculture would be the principal Minister responsible for giving policy directions. However, where the matter concerns a subject under the portfolio of another Minister, policy directions may only be given after that Minister has been consulted.

The composition and competence of the competent authority and the advisory body on biosafety were considered.

The Natural Resources Conservation Authority would be designated the Competent Authority.

The National Biosafety Committee would be designated the Advisory Body, with necessary amendments to its composition and mandate.

In this context, given the breadth of the subjects which will need to be decided on by both the Competent Authority and the Advisory Body, it was recognized that there does not presently exists a sufficiently capable pool of experts available in Jamaica to efficiently discharge the responsibilities.

Steps will be taken to develop local capacity as a matter of urgency. In the interim, efforts will be made to enter into international and regional arrangements to pool resources while local capacity is addressed.

Three further issues of importance in this context were considered.

Firstly, it was recognized that the Advisory Body should not be described in terms which will not permit it to coop experts in areas it considers necessary in the consideration of any particular matter.

Secondly, since the Protocol provides that Parties, in reaching a decision on import under the Protocol; or its domestic measures implementing the Protocol

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14 See National Strategy and Action Plan on Biological Diversity in Jamaica, Section 4.5.7.2, Technical Scientific Cooperation p.46.
may take into account, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, consideration was given to finding a procedure that would allow this obligation to be implemented by the kind of representation on the Advisory Body.

Thirdly, the participation of the public must be facilitated. Attention was directed to the National Strategy and Action Plan on Biological Diversity which identifies public awareness and education and community empowerment as a goal, and sets out strategic directions to reach it.\textsuperscript{16}

\begin{quote}
The approach for public participation set out in the National Strategy and Action Plan on Biological Diversity is endorsed and is incorporated as part of this Policy.
\end{quote}

Another area which was considered relates to the ‘Competent Authority- National Focal Point’ issue.

The issue is addressed in Article 19 of the Protocol. It will be observed that paragraph 1 speaks to one national focal point which is responsible for liaising with the Secretariat. The competent national authority, on the other hand, performs important functions on behalf of the Government. This implies that when the competent authority exercises its functions, it engages the international responsibility of the Government. The Protocol provides that the State may designate a single entity to exercise both functions.

\begin{quote}
It has been decided that the National Focal Point shall be the National Council on Science and Technology. The Functions of the National Focal Point shall include those functions as are agreed by the Conference of Parties from time to time.
\end{quote}

The Secretariat of the Protocol will be informed, not later than the date of the entry into force of the Protocol for Jamaica, of the names and addresses of the Competent Authority and the national focal point.

An important element of the institutional arrangements is the national clearing house mechanism. The need to have national information on LMOs readily available to the all interested persons and groups cannot be overemphasized. This information should be centrally located in one entity. Precedence for the kind of institutional arrangements exists in the Institute of Jamaica.

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{15} Article26
\item \textsuperscript{16} p. 45
\end{itemize}
\end{footnotesize}
The Government has decided therefore that the institution which currently performs the functions of the national clearing-house under the Convention on Biological Diversity will assume similar functions with respect to the Protocol.
The Regulatory Procedure

Activities to be regulated
It is worth recalling in this section that when the Scope of the Policy was discussed, it was pointed out that the activities that are to be regulated by the policy are to be clearly identified. The Protocol activities which are to be regulated by the legislation implemented in accordance with the provisions of the Protocol are obvious.

The issue of what other activities should be incorporated in this Policy was considered. The concept of Biological safety has paralleled the development of modern biotechnology. The field of biosafety is said to promote safe laboratory practices, procedures, and proper use of containment equipment and facilities. The provisions that currently regulate experiments/contained use in Jamaica were found to be unsatisfactory. They were not uniform, being based on a series of separate guidelines from which each institution was free to choose which to apply.

The Government has decided that the development of uniform procedures should be done by the Advisory Body for the approval of the Competent Authority. Pending the finalization of these procedures, guidelines would be developed to cover matters such as infrastructure, equipment, storage, and disposal of materials and apparel.

Release into the environment

The Protocol does not address the subject of the environmental release of LMO crops with confined field trials.

The Government decided that release into the environment should also be included in the Policy.

The Biosafety Committee is presently debating the regulations that are necessary to properly manage the release of GMOs so as to minimize harm to human health and the environment.

It recognized that the work being done by the Biosafety Committee is an important part of the Government’s Policy on biosafety. The regulations which are enacted as the product of those deliberations will become part of the primary legislation, with the necessary adaptations and modifications, when that piece of legislation is enacted.
The Advance Informed Agreement Procedure

It may be said that the most fundamental aspect of the Protocol is the Advance Informed Agreement, “AIA” procedure which in the Protocol is reserved for regulating the trade in LMOs that are to be intentionally introduced into the environment.

The essence of the AIA is that the first intentional transboundary movement of LMOs for intentional introduction into the environment may not be undertaken without notification in writing to the Competent Authority.

The following are the elements of the procedure that are provided for in the provisions of the Protocol. Although Article 7 speaks to the application of the AIA, there are other provisions that are relevant. The central Articles are Articles 8,9,10 and 12. Other Articles which are relevant are:

1. Article 15 and Annex III (Risk Assessment)
2. Article 19 (Competent Authority)
3. Article 21 (Confidential Information)
4. Article 26 (Socio-economic Considerations)
5. Annex I (Information required in Notifications)

There is some ambiguity about the meaning of the expression, “the first intentional transboundary movement”.
The ambiguity revolves around the issue of whether the AIA will be required each time a particular LMO is imported into a Party for the first time from a “new” Party of export, or whether it only applies the first time a particular LMO is imported into the Party from any Party- after which, assuming the first import is allowed, imports of the same LMO should be allowed under the same conditions from all Parties.

A decision by Jamaica that once it approves the Importation of an LMO from a Party then the AIA does not apply to subsequent imports from any other Party would expose it to the difficulty to determine that those subsequent imports are the same LMO for which approval was given. It would therefore need to put in place identification mechanism. The
possibility that approvals may however be subject to conditions, (although those conditions would relate to the particular application for approval to import) was considered; so too was the fact that in any case, nothing in the Protocol prejudices any right of a Party to subject all LMOs to risk assessment prior to decisions on import.

Having considered the issues, the Government decided that every import of an LMO would be subject to the AIA procedure.

Exceptions to the Advanced Informed Agreement Procedure are provided for under the Protocol. These are:

1. Pharmaceuticals
   The transboundary movement of LMOs which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations.\(^{17}\)

   **The Government has decided that it will apply the WHO’s Certification Scheme on Pharmaceutical Products Moving in International Commerce, an administrative instrument which governs, in general, the cross-border movement of pharmaceuticals for humans.**

2. LMOs in transit and contained use\(^{18}\)

   LMOs in transit are not included in the Protocol regime because the shipments are not destined for the territory of the transit State and are not intended to be released into the environment.

   **The Government has decided that LMOs in transit in and over areas over which it exercises jurisdiction would require prior notification.**

3. LMOs intended for direct use as food or feed or for processing

   This provision is applicable where a Party has made a final decision regarding domestic use, including placing the relevant LMO on the market, of a LMO that may be subject to transboundary movement.

4. Certain specified LMOs, when they satisfy certain conditions.\(^{19}\)

\(^{17}\) Article 5
\(^{18}\) Article 6
\(^{19}\) Article 13. This exemption is however not available to Jamaica since its application is conditional on there being in place adequate measures to ensure the safe intentional transboundary movement of LMOs in accordance with the Protocol. Jamaica would still need to enact legislation which is Protocol consistent.
5. The intentional transboundary movement of LMOs identified in a decision of the Conference of the Parties as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

The non-applicability of the Advanced Informed Agreement procedure to the exceptions under the Protocol does not imply that an importing country will not subject such LMOs to an import regime.

Regarding, the import of LMOs for contained use, the Protocol provides that a Party has the right to subject all LMOs to risk assessment prior to its decision to allow an import, and to set standards for contained use in its jurisdiction.\(^{20}\)

The only regulations which exist governing import of LMOs for experiments were reviewed and it was evident that they had significant limitations. They will therefore be improved upon to reflect prevailing scientific standards.

It was decided that the import of LMOs for contained use will be subject to a modified AIA Procedure.

Regarding, LMOs intended for direct use as food or feed, or for processing, the Protocol also provides that a Party may make a decision on the import of such LMOs under its domestic regulatory framework that is consistent with the objective of the Protocol. Additionally, there are four other provisions that are relevant.

Firstly, the Party making the final decision on their use has to inform the Biosafety Clearing –House of the decision. It is mandatory that the information contains at a minimum, information specified at Annex II to the Protocol.\(^{21}\) There is also the obligation in these cases that the exporting Party ensures that there is a legal requirement for the accuracy of information provided by an applicant to export.

This point is developed below as it relates to the export of Genetically Modified products from Jamaica.

Secondly, a developing country Party may, in the absence of a regulatory framework, declare through the Biosafety Clearing- House that its decision prior to its first import of a LMO intended for direct use as food or feed, or for

\(^{20}\) Article 6.

\(^{21}\) Article 11 (1)
processing will be undertaken on a risk assessment in accordance with Annex III.\(^{22}\)

Thirdly, each Party shall take measures to require that documentation accompanying LMOs that are intended for direct use as food or feed, or for processing clearly identifies that they “may contain” LMOs that are not intended for intentional introduction into the environment.\(^{23}\)

Fourthly, a Party may make a decision based on the precautionary principle/approach.

The provisions regarding the treatment of LMOs intended for direct use as food or feed, or for processing are important to Jamaica both as an importer and as a potential exporter of LMOs.

As a potential exporter, Jamaica is aware of the obligation that once it makes a final decision regarding domestic use, including placing on the market, of a LMO that may be subject to transboundary movement for direct use as food or feed, or for processing, to inform the Parties of the Protocol through the Biosafety Clearing House within fifteen days of its decision.

As an importer of food and feed, and a beneficiary of food aid, Jamaica is aware that lack of proper monitoring of these imports will seriously expose the population to risks to their health. Groups such as infants and aid recipients are particularly vulnerable.

*The Government has decided that the existing regulations, particularly those under the Food and Drugs Act, supplemented by the Protocol provisions, particularly those provisions that are contained in Annex II, sufficiently address immediate concerns.*

The regulations and arrangements under which LMOs which are used for food, or feed or processing are imported will be reviewed continuously to ensure that they adequately protect human health and the environment.

The reviews will consider among other matters, what further action can be taken to improve upon those procedures provided under the Protocol provisions.

These Protocol provisions will have to be incorporated into the legislation.

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\(^{22}\) Article 11(6)  
\(^{23}\) Article 18(2)(a)
Notification and Acknowledgement Procedures

Notification

The notification required to be provided by either the exporter or the Party of export must satisfy the following:

1. It must be in writing addressed to the national competent authority of the importing Party.

2. It must contain, at a minimum, the information contained in Annex I.

3. Any additional information considered necessary and relevant. The additional information referred to here is information the applicant considers relevant to the potential risks or benefits of the proposed activity.

4. Evidence from the Party of export certifying to the accuracy of the information provided by the exporter.

Since the information identified in the Article is the minimum information that must be submitted with the application, the scientific and technical experts on the Advisory Body will on a continuous basis examine that information and advise the Competent Authority what other information may be required.

In this context, although the intended use of the LMO is part of the information that is required in the original submission, the legislation will clarify that the approval of specific final uses of the LMO in the Island will be dealt with as part of the import approval procedure.

The legislation will not be too definitive in the type of information which may be required since there should be scope for providing for information that becomes available as technology develops and more information becomes available regarding safety of LMOs.

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24 Article 8
Acknowledgement

An acknowledgement\textsuperscript{25} of the receipt of the notification has to be made in writing within 90 days. It shall state
\begin{itemize}
\item the date of receipt of the notification;
\item whether the notification, prima facie, contains the information required; and
\item whether the notifier may proceed with the transboundary intentional movement of the LMO. Here the acknowledgement will indicate whether the importer will proceed according to the domestic framework or in accordance with the procedures specified in Article 10 of the Protocol.
\end{itemize}

The point relating to the alternative procedures may not be very relevant to Jamaica. Jamaica has to implement the provisions of Article 10 legislatively so there is therefore no alternative Protocol procedure available to the importer.

Confidential Information

The issue of confidentiality receives special treatment in the Protocol because of the business information that will be necessary to submit when requests for permission to import LMOs are made. Under Article 21, the notifier has a right to request that information he identifies in his submission as part of the AIA procedure be treated as confidential. He however must give justification for his request if the Party of imports asks for it.

Where the Party decides that the information identified by the notifier does not qualify for confidential treatment, the information may not be disclosed before the notifier has been notified of the decision, with reasons if so requested, and there is an opportunity for consultation and review of the decision.

The Competent Authority will set the standard that will be used to determine the confidentiality or lack thereof of the information which has been identified by the notifier.

Once there is agreement that the information is confidential the importing Party has the following obligations:

1. Protect the confidential information received in the context of the AIA in a manner no less favourable than its treatment of confidential information in connection with domestically produced LMOs.

\textsuperscript{25} Article 8
2 Ensure that the information is not used for a commercial purpose except with the written consent of the notifier.

3 Where a notifier withdraws or withdraws a notification, respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to confidentiality.

The following information shall not be considered confidential:

1. The name and address of the notifier;
2. A general description of the LMO;
3. A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking into account risks to human health; and
4. Any methods and plans for emergency response.

Administrative arrangements will be put in place to ensure that the information remains confidential. So, the members of the Competent Authority, the Advisory Body and any person co-opted to serve on that Body will have to give some form of undertaking. In areas of comparable legislation, every person who has an official relationship in the administration of the legislation has an obligation for secrecy and is expected to subscribe to a declaration to deal with as secret and confidential, information relating to applicants for licences etc.

The provisions on confidentiality will be legislated in their entirety and sanctions will be provided for any breach of the confidentiality provisions.
Decision-Making Procedure

The procedure to be followed by a Party of import in reaching its decision whether to permit the first transboundary movement of an LMO for intentional introduction into its territory is contained in Article 10. The Article addresses the basis on which the Party of import should base its decision; the time limit within which the decision should be taken; and the nature of the decision. Article 15 is also critical to the decision-making process as Article 10 provides that the decisions taken by a Party of import shall be in accordance with that Article. The Article treats with the issue of risk assessment.

Basis for the decision.

Risk Assessment
The principal basis for the decision is a risk assessment. Risk assessment is the use of scientific data to estimate the effects of exposure to potentially hazardous materials or conditions. In the regime under the Protocol, risk assessment is undertaken in accordance with Article 15 and Annex III. Article 15 provides that risk assessments under the Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques.

The criteria to be applied in the risk assessment are set out in the Article and are supplemented by an Annex. Accordingly, risk assessments shall be based, at a minimum, on information provided in accordance with Article 8, and other available scientific evidence in order to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking into account risks to human health.

In this regard, reference may be made to the Draft Guidelines for the Release of Genetically Modified Organisms (GMOs) into the Environment prepared by the National Biosafety Committee (“Guidelines”).

The questions of who carries out the risk assessment and who bears the cost of the assessment are left open in the Protocol. The Protocol provides that the Party of import may require the exporter to carry out the risk assessment and may require him to bear the cost. This question clearly has cost implications for Jamaica.

The Government has decided that the notifier should be required to pay for the risk assessment although the question of who conducts the risk assessment was left open. It was recognized that the importing Country

26 Elements of these provisions will need to be developed, as the language will have to be interpreted for purposes of the legislation.
27 NEPA, Draft Survey Report, National Biosafety Project on Activities, Projects and Biosafety Experts in Jamaica, p.30.
always has the option of doing its own risk assessment. While the Government of Jamaica reserves the right to decide who conducts the risk assessment, the notifier should pay the associated costs.

The legislation will incorporate the provisions of Article 15 and Annex III and the additional information contained in the Guidelines.

The decision with respect to whether the exporter will be required to carry out the risk assessment and that notwithstanding this obligation, Jamaica as an importing Country may conduct its own assessment will also be legislated for.

Likewise the obligation of the notifier to pay for the risk assessments.

**The Protocol also provides two additional bases on which a decision may be made.**

The first relates to the precautionary principle/approach. Paragraph 6 of Article 10 addresses a situation where, having carried out a risk assessment based on information provided in accordance with Annex I, and on the basis of Article 15 and Annex III, the Party of import concludes that there remains a lack of certainty about the extent of potential adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking into account risks to human health. The paragraph is also relevant to a situation where there is insufficient information to carry out a risk assessment. In these cases, a Party of import has the right to base its decision on the precautionary approach and may prohibit the import or attach conditions based on the precautionary approach.  

The second consideration which may influence a decision would be of the socio-economic type. Article 26 permits the Parties in reaching a decision on import to take into account, consistent with their international obligations, 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.

**Provision will be made for representation of experts who may advise on socio-economic implications.**

**Public participation in the decision-making process**

Article 23, paragraph 2, provides that the Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making

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process regarding LMOs and shall make the results of such decisions available to the public while respecting confidential information. This obligation does not impose a standard on public participation but provides each Party with the discretion on how it implements it according to its laws. In this regard the Food and Drugs Act offers a useful precedent by the provision that requires the publication of a rule before it is enacted.

**Jamaica will implement this obligation by requiring the Competent Authority to notify the public on receipt of an application and inviting submissions on the application by a specified date. The public may also be invited to submit views in cases of requests for reviews.**

**The Competent Authority should also inform the public of any decisions relating to release into the environment of LMOs, and provide access to information derived from Laboratory research and field tests.**

The additional bases for the decision and the participation of the public must be legislated for.

**Post-decision**

Article 10 provides that having considered the application, the Party of import, shall within ninety days of receipt of the notification, inform the notifier in writing whether the intentional transboundary may proceed either only after written consent has been given; or after no less than ninety days without a subsequent written consent.

**It has been decided that the import should take place only on express consent.**

The Party of import must however, subject to a limited exception\(^\text{29}\), within 270 days of receipt of the notification, communicate in writing to the notifier and the Biosafety Clearing –House, the decision whether or not to allow the import.

The decision may either:

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\(^{29}\) In calculating the period of time in which there must be a response, the number of days it has to wait for additional information shall not be taken into account. Article 10 para.3 ©.
• Approve the import with or without conditions, including how the decision will apply to subsequent imports of the same LMO.
• Prohibit the import;
• Request additional relevant information in accordance with Annex I.
• Inform the notifier that there is an extension of a specified time.

Two aspects of this provision merit further elaboration. One raises legal issues, while the second should be addressed by the experts on biosafety.

First the legal issues.

Paragraph 4 of the Article provides that except in the case in which consent is unconditional, a decision under paragraph 3 (discussed in the previous paragraph) shall set out the reasons on which it is based.

This provision will have to be included in the legislation.

The reasons given for a decision are important to the review process. Where the importer wishes to have the decision subject to judicial review, the reasons are critical to the proceedings as they could be the basis of the action. They are also important where the importer wishes a review of the decision under Article 12.

Regarding the aspect of the provision which raises issues that should be considered by the experts, attention is invited to the issue that relates to the conditions which may attach to the decision.

**The Competent Authority advised by the Advisory Body will decide on what those conditions may be. They do not have to do so with finality in one exercise, as the legislation will provide a mechanism that will allow for the addition of other conditions.**
**Review of Decisions**

Decisions under the Protocol may be subject to review by the Party of import on its own initiative, or on the request of the Party of export or the notifier.

The Party of import may on its own initiative, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement.

The decision, and the reasons therefor have to be communicated within thirty days to any notifier who has been previously notified, and the Biosafety Clearing-House.

The Party of export or the notifier may request a review of a decision where it considers that:

- A change in circumstances has occurred that may influence the outcome of the risk assessment on which the decision was based; or
- Additional relevant scientific or technical information has become available.

The Party of import shall respond in writing within ninety days and set out its decision in writing.

The provisions do not address the eventuality of the Party of import requesting further information, and is silent on the effect of the delay.

**The number of days it has to wait for additional information shall not be taken into account.**

The review contemplated in this provision will be conducted by the Body which considered the original notification. In this context, where the public participated in the original decision through its response to a notification of the original application, its participation will take a similar form for the review.

In addition to the procedures set out in the Protocol provision will be made for the notifier to appeal the decision of the Competent Authority. This appellate body will be independent of the original deciding body. It will be composed of a panel of three persons.

**Provision will be made for judicial review of the Panel's decision by the Supreme Court.**

The provisions of the Article and the decisions to the Panel and Judicial Review will be legislated.
Handling, transport, packaging and labeling requirements

Article sets out the handling transport, packaging and labeling requirements. These requirements are not uniform to all LMOs, but vary according to the use of the LMO in question.

The Article provides that each Party shall take necessary measures to require that LMOs that are subject to intentional transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards. This provision relates to both imports and export of LMOs.

It will be observed that the provision obliges the Parties to take into consideration, relevant international rules and standards. It has been observed that these could refer to those rules and standards covering handling, packaging and transport of LMOs and might extend to general international rules and standards governing health, safety, and the environment or international trade. Relevant to this standard setting are those rules and standards promulgated, for example, under the International Plant Protection Convention, by the World Health Organization, or in the United Nations Recommendations on the Transport of Dangerous Goods. 30 Also of importance is the United Nations Guidelines on Consumer Protection.

There will also be rules which may be developed in the future by the Conference of Parties serving as the meeting of the Parties. (Paragraph 3).

The following are the rules relating to the documentation accompanying respective LMOs:

- LMOs that are intended for direct use as food or feed, or for processing shall clearly identify that they “may contain” LMOs and are not intended for intentional introduction into the environment. There must also be a contact point for further information.

- LMOs that are destined for contained use shall be clearly identified as LMOs and any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned, should be specified.

- Regarding LMOs that are intended for intentional introduction into the environment of the Party of import and any other LMOs within the scope of the Protocol, the documentation shall clearly identify them as LMOs; specify

30 IUCU, supra., p.124
the 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 addresses of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

The issue of labeling was identified as a critical issue that should be addressed in the Policy. This issue has not been comprehensively addressed in the Protocol. The matter was addressed by the interested Departments and groups. The relevant Departments include the Bureau of Standards as it regulates appropriate standards of labeling and the Ministry of Health in its regulation of the Food and Drugs Act. This Act regulates labeling, packaging and sale of food and drugs in the Island. The Consumer Affairs Commission is also critical in the development of standards of labeling from the perspective of informing the consumers, and the Ministry of Foreign Affairs and Foreign Trade.

In developing the policy the Committee considered whether the existing rules and standards adequately satisfy the Protocol requirements. In arriving at a decision, the Committee considered that national legislation administered by the Bureau of Standards are already in place and labeling and product identification mechanisms were consistent with the United Nations Guidelines to which Jamaica is a signatory. Furthermore labeling products developed through Genetic Engineering facilitates the process of tracing which is a necessary and vital component of the Policy.

In this respect, the practice in the European Union was considered to be instructive. Labeling provisions are applied to all genetically modified food or feed, irrespective of the detectability of genetically modified DNA or protein. All food and feed which consist of, contain or are produced from GMOs would have to be labeled as such. The purpose is to inform consumers and farmers about the exact nature and characteristics of the food or feed, so they can make informed choices.

Recognizing that Jamaica currently implements international standards relating to labeling and having regard to our trading relationships with respect to the matter of food imports especially, and taking into account the fact that Jamaica is a member of Codex, Jamaica would apply as an interim measure, standards that were developed at the international level. Pending the adoption of detailed requirements such as those which obtain in Europe, the National Codex Committee would examine products and decide on their equivalence.

There will be ongoing efforts to build capacity which will serve not just persons within Jamaica, but can be of benefit to Caribbean Countries.

The provisions which deal with documentation will be implemented in legislation.
Unintentional transboundary movements and emergency measures

Article 17 of the Protocol provides that each Party under whose jurisdiction there is an occurrence resulting in a release that leads, or may lead, to an unintentional transboundary movement of an LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall take appropriate steps to notify potentially affected and affected states, the Biosafety Clearing House and relevant international organizations. The contents of the notification are set out in the Protocol. The Protocol also imposes an obligation to hold immediate consultations with affected States to minimize any significant adverse effects on biodiversity and human health.

The Protocol does not define “unintentional transboundary movement” and therefore this issue may need to be addressed by reference to the existing practice of other Parties.

The Competent Authority shall be responsible for the implementation of this provision.

A training programme will be put in place which will be effective to respond to an accidental release of LMOs in the environment.

This provision will need to be legislated.
Enforcement

The integrity of the regime will be weakened and undermined if there are no adequate measures for monitoring compliance with the provisions of the legislation or with conditions of authorizations, and sanctions which will operate to punish infringements.

Article 25 provides that each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of LMOs carried out in contravention of its domestic measures to implement the Protocol.

The policy adopts as a starting point, the inspections and enforcement regime that exists under the Natural Resources and Conservation Authority Act, recognizing that as science and technology develops, a regime that is specific to biosafety may be elaborated.

The sanctions which may be applied will receive careful attention, as they should bear a close relationship to gravity of the activities that attract their application. In addition, they will also be consistent, as far as possible, with those established for violations of similar legislation.

Persistent offenders will also be prohibited from engaging in any further activities under the legislation.

Recognising that in some respects, the activities may result in environmental damage and could be amenable to the general environmental legal regime, it may be that the breach of a condition of an authorization does not result in damage, but must nevertheless be punished. The practice of other Parties will be examined for useful guidance.

The offences and the penalties must be legislated.

 Liability

The Protocol is silent on the question of civil liability in domestic law. The consideration was whether liability provisions should reflect the general law relating to civil liability, or whether there should be a special regime for LMOs. The international practice is not uniform, however the common elements identified are:

- Liability is imposed for any damage caused by the introduction of the LMO.
• Liability attaches to any person or entity responsible for the harm. Liability also attaches to the officers of a corporation unless they can show that they did all that was possible to prevent the activity in relation to the LMO.
• Liability is for personal injury, damage to property, financial loss and any damage caused to the environment and to biological diversity.
• The responsible persons must bear the costs of reinstatement, rehabilitation, and cleanup measures and for any costs associated with preventative measures.
• Provisions for indemnification.

The Government will enact legislation which will include the elements identified in above.
Section 4

DRAFTING INSTRUCTIONS

Purpose

The purpose of the Legislation on Biosafety is to implement the provisions of the Cartagena Protocol thereby facilitating ratification by Jamaica, which signed the Protocol on June 4, 2001.

Objective

The objective of the Act, taken from Article 1 of the Protocol, is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

Definitions

In this section, the terms which are provided in Article 3 of the Protocol will be defined. In addition the following definitions should be inserted:

1. “Competent authority” means the authority established to implement the administrative functions of the Protocol.
2. “Deliberate release“ means any intentional introduction into the environment of living modified organisms, including any production or use that is not contained use.
3. “Placing on the market,” means supplying or making available LMOs to another person.
4. “Risk assessment” means the evaluation of the direct and indirect risks to human and animal health, the environment and to the socio-economic conditions of Jamaica conducted in accordance with Section ** of this Act.
5. “Protocol” means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity done at Montreal on the twenty-ninth day of January two thousand.

Scope

The legislation will cover the import, export, transit, contained use, deliberate release or placing on the market of any LMOs. Therefore the following activities would be prohibited unless authorized by the Competent Authority:

- The import of an LMO for intentional introduction into the environment;
- The intentional introduction of an LMO into the environment;
• The import of an LMO for contained use.
• The placing of an LMO on the market;
• With respect to export of an LMO to another Party to the Protocol, no person may export an LMO without notifying the Competent Authority.

The Minister may however exempt from the provisions of the Act, LMOs obtained by proven methods of genetic modification which have not proved to entail risk to human health and the environment.

It is also important to exclude from the scope of the legislation, the exclusion contained in the definition of LMOs\(^3\), and pharmaceuticals for humans which are covered by other international agreements\(^2\).

**Jurisdiction**

The Act will apply to the territory of Jamaica, its airspace and areas beyond the territorial sea over which Jamaica exercises sovereignty and sovereign rights in accordance with international law.

**Institutional Arrangements**

This section will treat with the institutional framework in which the entities responsible for policy and those entities that are responsible for the implementation of the administrative arrangements of the legislation are identified.

**Ministerial Directions**

The Minister responsible for Agriculture may give directions to the Competent Authority as to the policy to be followed in implementing the provisions of the Act and any other matter necessary for the implementation of Jamaica’s obligations under the Protocol. Where the subject matter falls within the competence of another Minister, the directions may only be given after consultations with that Minister.

**Competent Authority**

All Parties to the Protocol must designate one or more national competent authorities to be responsible for performing the administrative functions required by the Protocol and which shall be authorized to act on its behalf with regard to those functions.\(^3\)

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\(^3\) Article 3 (h) of the Protocol
\(^2\) Article 5.
\(^3\) Article 19. 21.
Establishment of the Competent Authority.

The Act shall provide that the Natural Resources Conservation Authority established under Section 3 of the Natural Resources Conservation Authority Act is designated as the Competent Authority.

Functions of the Competent Authority

The functions of the Competent authority are primarily set out in the provisions relating to the Advance informed Agreement procedure, such as Articles 8, 9, 10 and 12, provisions regarding confidential information, Article 21, and provisions relating to the monitoring of the implementation of the Protocol by Jamaica.

The following are the principal powers of the Competent Authority:

1. To receive and respond to notifications regarding contained use and deliberate release;
2. To decide on the notifications;
3. To review decisions when requested;
4. To establish administrative procedures to ensure the proper handling of, dissemination, and storage of documents and data in connection with the processing of applications and notifications;
5. To establish appropriate systems to ensure that confidential information is not revealed to unauthorized persons.
6. Determine the financial issues such as the fees that are payable on an application, and whether a bond will be required to be deposited as a condition of approval.
7. To establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling, and transboundary movement of LMOs.
8. To monitor the implementation of the Protocol.

Advisory Body

Under the Protocol, no requirement for an advisory body is mandated. However, an advisory body would need to be established to advise the Competent Authority on, inter alia, whether approval should be given to import living modified organisms taking into account risk to human health and the environment. Similarly, an advisory body would be needed to advise the Competent Authority on decisions to allow or refuse importation although there is lack of scientific certainty due to insufficient scientific relevant 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. The need for a preponderance of scientific persons is evident in the fact that the primary...
concerns of the subject are scientific. This is especially borne out by the fact that only scientific experts can carry out the risk assessments which are required under Article 10, 16, and Annex III.

The legislation will provide for the designation of the National Biosafety Committee as the Advisory Body to advise the Competent Authority on technical and scientific matters and carry out the risk assessments that are to be done. In addition since the decision to allow an activity may also involve socio-economic considerations, if the National Biosafety Committee does not presently have persons representing those disciplines. Provisions should be made to facilitate their representation.

More particularly, the functions of the Advisory body will include:

1. Conducting risk assessments;
2. Reviewing risk assessments provided in notifications;
3. Reviewing risk management measures;
4. Recommending containment measures, remedial measures, financial measures to be imposed and any other matter on which the Competent Authority may require advice.

The Advisory Body will be able to co-op experts in areas it considers necessary in the consideration of any particular matter.

Another area which will be legislated relates to the Competent Authority- National Focal Point.

The issue is addressed in Article 19 of the Protocol. Paragraph 1 speaks to one national focal point which is responsible for liaising with the Secretariat. The Competent National Authority, on the other hand, performs important functions on behalf of the Government. The Protocol provides that the State may designate a single entity to exercise both functions.

The responsible Minister will designate an institution to perform the functions of the National Focal Point under the Protocol. The functions of the National Focal Point will include functions identified for National Focal Points by the Conference of Parties.

**The Regulatory Procedure**

The most fundamental aspect of the Protocol is the Advance Informed Agreement, “AIA” procedure.
The essence of the AIA is that the first intentional transboundary movement of LMOs for intentional introduction into the environment may not be undertaken without notification in writing to the Competent Authority.

The following are the elements of the procedure that are provided for in the provisions of the Protocol.

Article 7 speaks to the application of the AIA. There are other provisions that are relevant. The central Articles are Articles 8, 9, 10 and 12. Other Articles which are relevant are:

1. Article 15 and Annex III (Risk Assessment)
2. Article 19 (Competent Authority)
3. Article 21 (Confidential Information)
4. Article 26 (Socio-economic Considerations)
5. Annex I (Information required in Notifications)

The AIA will be required each time a particular LMO is imported into Jamaica for intentional introduction into the environment. The AIA provided under the Protocol will be modified to govern each import of LMO for contained use.

**Notification and Acknowledgement Procedures**

Any person wishing to export to Jamaica, an LMO for intentional introduction into the environment or for contained use shall provide notification as follows:

Notification
The notification\(^{34}\) shall be provided by either the exporter or the Party of export must satisfy the following:

1. It must be in writing addressed to the national competent authority of the importing Party.
2. It must contain, at a minimum, the information contained in Annex I to the Protocol.
3. Any additional information considered necessary and relevant.

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\(^{34}\) Article 8
The legislation may not be too definitive in the type of information which may be required since there should be scope for providing including information that becomes available or relevant as technology develops.

The Act will provide that an application for intentional introduction into the environment and contained use shall contain:

- The information set out in Annex I of the Protocol;
- Any additional information the applicant considers relevant to the potential risks or benefits of the proposed activity;
- Any other information that may be prescribed; and
- The prescribed fee.

Acknowledgement

The Act will provide that the Competent Authority has to acknowledge the receipt of the notification in writing within 90 days. The acknowledgement shall state

- the date of receipt of the notification;
- whether the notification, prima facie, contains the information required, and if not what further information is required.
- whether the notifier may proceed with the transboundary intentional movement of the LMO.

The Competent Authority should refer the application to the Advisory Body for its assessment of the application and its recommendation.

Decision-making Procedure

The procedure to be followed by a Party of import in reaching its decision whether to permit the first transboundary movement of an LMO for intentional introduction into its territory is contained in Article 10. The procedure will apply mutatis mutandis to an application for contained use.

The Article addresses the basis on which the Party of import should base its decision; the time limit within which the decision should be taken; and the nature of the decision.

Article 15 is also critical to the decision-making process as Article 10 provides that the decisions taken by a Party of import shall be in accordance with that Article. The Article treats with the issue of risk assessment.

\[35\] Article 8
Basis for the Decision

Risk Assessment
The principal basis for the decision is a risk assessment. In the regime under the Protocol, risk assessment is undertaken in accordance with Article 15 and Annex III of the Protocol. Article 15 provides that risk assessments under the Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques.

The criteria to be applied in the risk assessment are set out in the Article and are supplemented by an Annex. Accordingly, risk assessments shall be based, at a minimum, on information provided in accordance with Article 8, and other available scientific evidence in order to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking into account risks to human health.

The legislation will provide that the Competent Authority shall ensure that an applicant shall, at his own expense, carry out a risk assessment in accordance with Annex III of the Protocol and recognized risk assessment techniques, of the impacts and risks posed by the LMO at his own expense.

The legislation will also provide that the Competent Authority may also carry out its own risk assessments for any of the activities within the scope of the legislation. The risk assessments carried out by the Competent Authority shall be in accordance with the provisions of Annex III and any other Guidelines that may be approved by the Advisory Body. (See the Draft Guidelines for the Release of Genetically Modified Organisms (GMOs) into the Environment prepared by the National Biosafety Committee (“Guidelines).  

The Protocol also provides two additional bases on which a decision may be made.

The first relates to the precautionary principle/approach. Paragraph 6 of Article 10 addresses a situation where, having carried out a risk assessment based on information provided in accordance with Annex I, and on the basis of Article 15 and Annex III, the Party of import concludes that there remains a lack of certainty about the extent of potential adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking into account risks to human health. The paragraph is also relevant to a situation where there is insufficient information to carry out a risk assessment. In these cases, a Party of import has the right to base its decision on the

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36 Elements of these provisions may need to be further developed as the language will have to be interpreted for purposes of the legislation.
37 NEPA, Draft Survey Report, National Biosafety Project on Activities, Projects and Biosafety Experts in Jamaica, p.30.
precautionary approach and may prohibit the import or attach conditions based on the precautionary principle/ approach.\(^{38}\)

This provision will be included in the legislation.

The second consideration which may influence a decision would be of the socio-economic type. Article 26 permits the Parties in reaching a decision on import to take into account, consistent with their international obligations, 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.

The legislation will provide that the Competent Authority may, in arriving at its decision, take into account any socio-economic considerations it considers appropriate, provided that they are consistent with Jamaica’s other international obligations.

**Post-decision**

Article 10 provides that having considered the application, the Party of import, shall within ninety days of receipt of the notification, inform the notifier in writing whether the intentional transboundary may proceed either only after written consent has been given; or after no less than ninety days without a subsequent written consent.

The legislation will provide that the Competent Authority shall within ninety days inform the notifier that the import should take place only on express consent. The practice with respect to hazardous waste under the Basel Convention can be useful here.

The Party of import must however, subject to a limited exception\(^{39}\), within 270 days of receipt of the notification, communicate in writing to the notifier and the Biosafety Clearing –House, the decision whether or not to allow the import.

The Competent Authority may either:

- Approve the import with or without conditions, including how the decision will apply to subsequent imports of the same LMO.
- Prohibit the import;

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\(^{39}\) In calculating the period of time in which there must be a response, the number of days it has to wait for additional information shall not be taken into account. Article 10 para.3 ©.
- Request additional relevant information in accordance with Annex I.
- Inform the notifier that there is an extension of a specified time.

Paragraph 4 of the Article provides that except in the case in which consent is unconditional, a decision under paragraph 3 (discussed in the previous paragraph), shall set out the reasons on which it is based.

This provision will have to be included in the legislation.

The reasons given for a decision are important to the review process. Where the importer wishes to have the decision subject to judicial review, the reasons are critical to the proceedings as they could be the basis of the action. They are also important where the importer wishes a review of the decision under Article 12.

The legislation should also provide that the Competent Authority may impose an ongoing obligation on the applicant, to inform it of any new information which may become available about the LMO in question.

**Review of Decisions**

Decisions under the Protocol may be subject to review by the Party of import on its own initiative, or on the request of the Party of export or the notifier.

The legislation will provide that the Competent Authority may on its own initiative, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement.

The Competent Authority shall within thirty days of its decision notify the Biosafety Clearing House and any notifier that has previously notified movements of LMOs referred to in the decision. The Competent Authority shall give reasons for its decision.

The decision, and the reasons therefor have to be communicated within thirty days to any applicant who has been previously notified, and the Biosafety Clearing House.

The legislation will also provide that the Party of export or the notifier may request a review of the decision of the Competent Authority where either the Party of export or the notifier considers that:
• A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or
• Additional relevant scientific or technical information has become available.

The Competent Authority shall respond in writing within ninety days and set out its decision in writing.

The provisions do not address the eventuality of the Party of import requesting further information, and is silent on the effect of the delay. It is however reasonable to provide that the number of days it has to wait for additional information shall not be taken into account.

The review contemplated in this provision should be conducted by the Competent Authority in consultation with the Advisory Body which considered the original notification.

Additionally, provision should be made for the applicant to appeal the decision of the Competent Authority. This appellate body should be independent of the original deciding body. The provisions of the Second Schedule will govern the composition and procedure of the Appellate Body. The Appellate Body may confirm the decision of the Competent Authority; allow the appeal and set aside the decision of the Competent Authority or direct that the Competent Authority reconsider the matter.

The legislation should also provide for judicial review by the Supreme Court.

**Public participation in the decision-making process**

Article 23, paragraph 2, provides that the Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding LMOs and shall make the results of such decisions available to the public while respecting confidential information. This obligation does not impose a standard on public participation but provides each Party with the discretion on how it implements it according to its laws.

This obligation will be implemented in the legislation by requiring the Competent Authority to notify the public on receipt of an application and inviting submissions on the application by a specified date. The public may also be invited to submit views in cases of requests for reviews. A useful precedent may be found in the Food and Drugs Act.
The Competent Authority should also inform the public on any decisions relating to release into the environment of LMOs, and provide access to information derived from Laboratory research and field tests.
Confidential Information

Under Article 21, the notifier has a right to request that information he identifies in his submission as part of the AIA procedure be treated as confidential. He however must give justification for his request if the Party of imports asks for it.

Where the Party decides that the information identified by the notifier does not qualify for confidential treatment, the information may not be disclosed before the notifier has been notified of the decision, with reasons if so requested, and there is an opportunity for consultation and review.

Once there is agreement that the information is confidential the importing Party has the following obligations:

4 Protect the confidential information received in the context of the AIA in a manner no less favourable than its treatment of confidential information in connection with domestically produced LMOs.

5 Ensure that the information is not used for a commercial purpose except with the written consent of the notifier.

6 Where a notifier withdraws or withdraws a notification, respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to confidentiality.

The following information shall not be considered confidential:

5 The name and address of the notifier;

6 A general description of the LMO;

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

8 Any methods and plans for emergency response.

The provisions on confidentiality will have to be legislated in their entirety. The Act should also provide that the members of the Competent Authority and the Advisory Body will give some form of undertaking to keep the information confidential.

In areas of comparable legislation, every person who has an official relationship in the administration of the legislation has an obligation for secrecy and is
expected to subscribe to a declaration to deal with as secret and confidential, information relating to applicants for licences etc.

**Procedure for LMOs intended for direct use as food or feed, or for processing**

The following should be included in the legislation. The Minister may, after consultation with the Minister responsible for Health determine the conditions under which LMOs intended for direct use as food or feed or for processing will be imported into the Island.

A person may apply to the Competent Authority for authorization to release a LMO for food or feed or for processing. The applicant shall provide with the application the information in Annex II of the Protocol. The provision of any information which is false constitutes an offence. Where the Competent Authority decides that an LMO may be placed on the domestic market, and that it may be subject to transboundary movement for use as food or feed or for processing, the Competent Authority shall within fifteen days of making the decision inform the Parties to the Protocol through the Biosafety Clearing House. The information shall contain the elements included in Annex II to the Protocol.

**Handling, transport, packaging and labeling requirements**

Article 18 sets out the handling transport, packaging and labeling requirements. These requirements are not uniform to all LMOs, but vary according to the use of the LMO in question.

The Article provides that each Party shall take necessary measures to require that LMOs that are subject to intentional transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.

It will be observed that the provision obliges the Parties to take into consideration, relevant international rules and standards. It has been observed that these could refer to those rules and standards covering handling, packaging and transport of LMOs and might extend to general international rules and standards governing health, safety, and the environment or international trade. Relevant to this standard setting are those rules and standards promulgated, for example, under the International Plant Protection Convention, by the World Health Organization, or in the United Nations Recommendations on the Transport of Dangerous Goods. 40

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40 IUCU, supra. p.124
There will also be rules which may be developed in the future by the Conference of Parties serving as the meeting of the Parties. (Paragraph 3).

The following are the rules relating to the documentation accompanying respective LMOs:

- LMOs that are intended for direct use as food or feed, or for processing shall clearly identify that they “may contain” LMOs and are not intended for intentional introduction into the environment. There must also be a contact point for further information.

- LMOs that are destined for contained use shall be clearly identified as LMOs and any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned, should be specified.

- Regarding LMOs that are intended for intentional introduction into the environment of the Party of import and any other LMOs within the scope of the Protocol, the documentation shall clearly identify them as LMOs; specify the 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 addresses of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

The provisions which deal with documentation will need to be implemented in legislation.
In this regard, assistance is offered by the treatment of plants imported into the Island under the Plants (Importation) Control Regulations, 1997.

Other relevant legislation in this area would be the Standards Act as it regulates appropriate standards of labeling and the Food and Drugs Act This Act regulates labeling, packaging and sale of food and drugs in the Island.

Unintentional transboundary movements and emergency measures

Article 17 of the Protocol provides that each Party under whose jurisdiction there is an occurrence resulting in a release that leads, or may lead, to an unintentional transboundary movement of an LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall take appropriate steps to notify
potentially affected and affected states, the Biosafety Clearing House and relevant international organizations. The contents of the notification are set out in the Protocol. The Protocol also imposes an obligation to hold immediate consultations with affected States to minimize any significant adverse effects on biodiversity and human health.

The Protocol does not define "unintentional transboundary movement" and therefore this issue may need to be addressed by reference to the existing practice of other Parties.

The Protocol also does not contain provisions which treat with the obligations of the persons who have responsibility for the source of the unintended release.

In particular, the legislation will provide that the Competent Authority shall ensure that before any release or contained use is carried an emergency plan is prepared for the protection of human and animal health and the environment and that in the event of an accident the appropriate services are informed of the plan.

The legislation should provide that any person who has knowledge of the unintentional release should immediately notify the Competent Authority.

Any accident shall be reported to the Competent Authority immediately and the information relating to the circumstances of the accident and details relating to the identity and other relevant facts of the LMO involved should be provided.

**Enforcement**

The integrity of the regime will be weakened and undermined if there are no adequate measures for monitoring compliance with the provisions of the legislation or with conditions of authorizations, and no sanctions which will operate to punish infringements.

Article 25 provides that each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of LMOs carried out in contravention of its domestic measures to implement the Protocol.

The legislation will provide for an inspections and enforcement regime similar to that which exists under the Natural Resources and Conservation Authority Act, and provide that the Competent Authority may make rules under this section for securing better enforcement of the objectives of the Act.

In particular, the legislation will provide for the immediate cessation of any activity covered by an authorization if the Competent Authority determines on the basis of scientific evidence that there is an imminent danger posed to the conservation
and sustainable use of biological diversity, taking into account risks to human health.

Cessation orders may also be issued where there is a material infringement or breach of the conditions or requirements attached to an authorization.

An important element in the regime will be that relating to monitoring. Accordingly, the Competent Authority will have the responsibility to monitor activities authorized under the Act and require from all persons conducting activities under the Act, information relating to their activities which will enable the Competent Authority to undertake its functions of monitoring under the Act.

The sanctions which may be applied should however receive careful attention, as they really should bear a close relationship to the activities that attract their application and should as far as possible be consistent with comparable breaches under similar legislation.

**Liability**

The Protocol is silent on the question of civil liability in domestic law. The consideration was whether liability provisions should reflect the general law relating to civil liability, or whether there should be a special regime for LMOs. The international practice is not uniform, however the common elements identified are:

- Liability is imposed for any damage caused by the introduction of the LMO.
- Liability attaches to any person or entity responsible for the harm. Liability also attaches to the officers of a corporation unless they can show that they did all that was possible to prevent the activity in relation to the LMO.
- Liability is for personal injury, damage to property, financial loss and any damage caused to the environment and to biological diversity.
- The responsible persons must bear the costs of reinstatement, rehabilitation, and cleanup measures and for any costs associated with preventative measures.
- Provisions for indemnification.

The legislation will enact these elements.
Appendix I

CARTAGENA PROTOCOL ON BIOSAFETY TO
THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

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

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

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

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

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

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

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

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

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

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

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

Have agreed as follows:
Article 1

OBJECTIVE

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

Article 2

GENERAL PROVISIONS

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

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

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

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

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

Article 3

USE OF TERMS

For the purposes of this Protocol:

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

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

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

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

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

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

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

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

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

   b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

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

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

**Article 4**

**SCOPE**

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
Article 5

PHARMACEUTICALS

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

Article 6

TRANSIT AND CONTAINED USE

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

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

Article 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

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

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

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

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
Article 8

NOTIFICATION

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

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

Article 9

ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

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

2. The acknowledgement shall state:

   (a) The date of receipt of the notification;

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

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

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

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

Article 10

DECISION PROCEDURE

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

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

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

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

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

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

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

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

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

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

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

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

Article 11

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

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

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

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.
4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

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

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

(a) A risk assessment undertaken in accordance with Annex III; and
(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

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

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

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12

REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.
2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

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

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

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

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

**Article 13**

**Simplified Procedure**

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

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

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

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

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

**Article 14**

**Bilateral, Regional and Multilateral Agreements and Arrangements**

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

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

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

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.
Article 15

RISK ASSESSMENT
1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.
3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16

RISK MANAGEMENT
1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.
2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.
3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.
4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.
5. Parties shall cooperate with a view to:
   (a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
   (b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17

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

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

3. Any notification arising from paragraph 1 above, should include:
   (a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;
   (b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;
   (c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;
   (d) Any other relevant information; and
   (e) A point of contact for further information.

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

**Article 18**

**HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION**

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

2. Each Party shall take measures to require that documentation accompanying:
   (a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;
(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and
(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

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

Article 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

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

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

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

Article 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:
(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

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

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

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

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

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

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

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

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

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

Article 21

CONFIDENTIAL INFORMATION

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

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

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

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

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

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

(a) The name and address of the notifier;
(b) A general description of the living modified organism or organisms;
(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
(d) Any methods and plans for emergency response.

Article 22

CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

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

Article 23

PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:
(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

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

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

Article 24

NON-PARTIES

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

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

Article 25

ILLEGAL TRANSBOUNDARY MOVEMENTS

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

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

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

Article 26

SOCIO-ECONOMIC CONSIDERATIONS

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

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

Article 27

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

Article 28

FINANCIAL MECHANISM AND RESOURCES
1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.
2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.
3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.
4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.
5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.
6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.
Article 29

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

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.
3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.
4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:
   (a) Make recommendations on any matters necessary for the implementation of this Protocol;
   (b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;
   (c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;
   (d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;
   (e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and
   (f) Exercise such other functions as may be required for the implementation of this Protocol.
5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.
6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the
Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

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

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

Article 30

SUBSIDIARY BODIES
1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.
3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31

SECRETARIAT
1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.
2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.
3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties
serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32

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

Article 33

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

Article 34

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

Article 35

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

Article 36

SIGNATURE

Article 37

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

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

Article 38

RESERVATIONS

No reservations may be made to this Protocol.

Article 39

WITHDRAWAL

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

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

Article 40

AUTHENTIC TEXTS

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

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

DONE at Montreal on this twenty-ninth day of January, two thousand.
INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.
(b) Name, address and contact details of the importer.
(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
(d) Intended date or dates of the transboundary movement, if known.
(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
(j) Quantity or volume of the living modified organism to be transferred.
(k) A previous and existing risk assessment report consistent with Annex III.
(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.
(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
(o) A declaration that the above-mentioned information is factually correct.
ANNEX II
INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.
(b) The name and contact details of the authority responsible for the decision.
(c) Name and identity of the living modified organism.
(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
(e) Any unique identification of the living modified organism.
(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
(i) Approved uses of the living modified organism.
(j) A risk assessment report consistent with Annex III.
(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
Annex III

RISK ASSESSMENT

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

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

General principles
3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.
4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.
5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology
7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.
8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:
   (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
   (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
(c) An evaluation of the consequences should these adverse effects be realized;

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

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

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

Points to consider

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

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

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

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

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

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

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

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

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

Biotechnology Glossary

**Amplicon**: A specific sequence of DNA that is produced by a DNA-amplification technology such as the Polymerase Chain Reaction (PCR) technique.

**Biolistic® Gene Gun**: The word "biolistic" was coined from the words "biological" and "ballistic" (pertaining to a projectile fired from a gun). Used to shoot pellets that are coated with genes (e.g., for desired traits) into plant seeds or plant tissues, in order to get those plants to then express the new genes.

**Biotechnology**: The means or way of manipulating life forms (organisms) to provide desirable products for man's use.

**Cell Fusion**: The combining of cell contents of two or more cells to become a single cell.

**Chromosomes**: Discrete units of the genome carrying many genes, consisting of (histone) proteins and a very long molecule of DNA. Found in the nucleus of every plant and animal cell.

**Clone (an organism)**: A group of individual organisms (or cells) produced from one individual cell through asexual processes that do not involve the interchange or combination of genetic material.

**Clone (a molecule)**: To create copies of a given molecule.

**Deoxyribonucleic Acid (DNA)**: The chemical building blocks (molecules) of which genes (i.e., paired nucleotide units that code for a protein to be produced by a cell's machinery, such as its ribosomes) are constructed. DNA is the carrier of genetic information, which is encoded in the sequence of bases; it is present in chromosomes and chromosomal material of cell organelles such as mitochondria and chloroplasts, and also present in some viruses.

**Electroporation**: A process utilized to introduce a foreign gene into the genome of an organism. Electroporation uses a brief direct-current (dc) electrical pulse to cause formation of "micropores" (tiny holes) in the surface of cells or protoplasts suspended in a solution (water) containing DNA sequences (genes). After the gene(s) enter cell via the temporarily created micropores, the electrical pulse ceases, and the micropores close so that the gene(s) cannot depart the cell. The cell then incorporates (some) of the new genetic material (genes) into its genetic complement (genome), and produces whatever product (i.e., a protein) the newly introduced gene codes for.
Gene: A natural unit of the hereditary material, which is the physical basis for the transmission of the characteristics of living organisms from one generation to another. The basic genetic material is fundamentally the same in all living organisms: it consists of chain-like molecules of nucleic acids- deoxyribonucleic acid (DNA) in most organisms and ribonucleic acid (RNA) in certain viruses- and is usually associated in a linear arrangement that (in part) constitutes a chromosome.

Gene Amplification: The copying of segments (e.g., genes) within the DNA or RNA molecule. This can be done by polymerase chain reaction (PCR).

Genetic Engineering: The manipulation and alteration of the genetic material (constitution) of an organism in such a way as to allow it to produce endogenous proteins with properties different from those of the traditional (historic/typical), or to produce entirely different (foreign) proteins altogether. Some other words often applicable to the same process are gene splicing, gene manipulation, or recombinant DNA technology (techniques).

Gene Silencing: The suppression of gene expression.

Gene Splicing: The enzymatic attachment (joining) of one gene (or part of a gene) to another; also removal of introns and splicing of exons during mRNA synthesis.

Genome: The entire hereditary material in a cell.

GEO: Genetically engineered organism

GMO: Genetically manipulated organism, or genetically modified organism.

LMO: Living modified organism.

Metabolic Engineering: The selective, deliberate alteration of an organism's metabolic pathway(s) via genetic engineering of the genes that define/control the organism's metabolism.

Nuclear Transfer: A method of cloning a living organism, in which that organism's entire genetic information is conveyed via transfer of an (adult) cell nucleus into an unfertilized egg (from another animal of the same species) whose nucleus had previously been removed.

Plasmid: An independent, stable, self-replicating piece of DNA in bacterial cells that is not a part of the normal cell genome. Plasmids are commonly used in recombinant DNA experiments as acceptors of foreign DNA.
Polymerase Chain Reaction (PCR): A reaction that uses the enzyme DNA polymerase to catalyze the formation of more DNA strands from an original one by the execution of repeated cycles of DNA synthesis.

Promoter: A promoter is a region of DNA (deoxyribonucleic acid) which lies "upstream" of the transcriptional initiation site of a gene. The promoter controls where (e.g., which portion of a plant, which organ within an animal, etc.) and when (e.g., which stage in the lifetime of an organism) that the gene is expressed.

Protoplast Fusion: Refers to the practice of fusing two living cells together by first making each cell into a protoplast, then fusing-together the two in order to result in a (combined) cell which possesses traits from both of the original cells.

Recombinant DNA (rDNA): DNA formed by the joining of genes (genetic material) into a new combination.
Reston Endonucleases: A class of enzymes that cleave (i.e. cut) DNA at a specific and unique internal location along its length, and are naturally produced by bacteria.

Shotgun Cloning Method: A technique for obtaining the desired gene that involves "chopping up" the entire genetic complement of a cell using restriction enzymes, then attaching each (resultant) DNA fragment to a vector and transferring it into a bacterium, and finally screening those (engineered) bacteria to locate the bacteria that are producing the desired product (e.g., a protein).

Tissue Culture: The growth and maintenance of cells from higher organisms in vitro, that is, in a sterile test tube or petri dish environment which contains the nutrients necessary for cell growth.

Transgene: A "package" of genetic material (i.e., DNA) that is inserted into the genome of a cell via gene splicing techniques.

Transgenic: An organism whose gamete cells (sperm/egg) contain genetic material originally derived from an organism other than the parents, or in addition to the parental genetic material.

Transposition: Movement of a gene or set of genes from one site in the genome to another without a reciprocal exchange (of DNA).

Vector: The agent used to carry new genes into cells.
Appendix III

Experts with whom Consultations were held

Mrs. Winsome Townsend          NEPA
Mrs. Laleta Davis-Mattis        NEPA
Ms. Yvette Strong               NEPA
Mrs. Joy Crawford               Ministry of Agriculture
Mrs. Merlene Bardowell          Office of the Prime Minister
Dr. Florence Young              Ministry of Agriculture
Ms. Carol Thomas                Ministry of Agriculture
Dr. Audia Barnett               Scientific Research Council
Dr. Elaine Fisher               Scientific Authority
Ms. Leonie Barnaby              Ministry of Land and Environment
Mr. Esmond Reid                 Ministry of Foreign Affairs and Foreign Trade
Mr. Gladstone Rose              Bureau of Standards
Mrs. Hyacinth Lindsay           Chief Parliamentary Counsel
Mrs. Erica Monroe               Office of the Chief Parliamentary Counsel