

**Act No.    of 20xx**

**Preamble**

This Act may be cited as the –

**BIOSAFETY AND BIOTECHNOLOGY MANAGEMENT BILL, 20xx**

BE IT ENACTED by the Parliament of Antigua and Barbuda as follows:

**Part I.**

**GENERAL PROVISIONS.**

**1. Objectives.**

- (a) To protect the biological diversity and environment of Antigua and Barbuda and the health and safety of people and communities, by preventing or managing the adverse effects of new organisms developed through modern biotechnology;
- (b) In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Act is to ensure an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health;
- (c) To provide a transparent and predictable process for review and decision-making on such LMOs and related activities;
- (d) To provide for the safe handling, transport, use, transfer and release of any LMOs so as to prevent or reduce risks to biological diversity, the environment and human health;
- (e) To Provide for the promotion and management of research and development in the field of biotechnology; and
- (f) To provide for the implementation of the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, and for other matters connected therewith.

**Article 2. Definitions**<sup>[JG1]</sup>.

In this Act, unless the context otherwise requires –

- (a) “accident” - means any incident by which any genetically modified organism may be introduced, either directly or indirectly, into the environment, in the course of their contained use which results, or is likely to result in significant harm to biological diversity, the environment or human health or safety;
- (b) “applicant” means any legal or natural person, whether in Antigua and Barbuda or any other State, who applies for any permit or approval for the handling, transport, use, transfer or release of any LMOs pursuant to the provisions of this Act;

(c) "Biosafety Clearing House" means the information exchange mechanism established under Article 20 of the Cartagena Protocol;

(d) "Cartagena Protocol" means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

(e) "Competent Authority" means the entity responsible for implementation and administration of this Act;

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

(g) "Code" means:

(i) in respect of any LMOs transported by sea, the International Maritime Dangerous Goods (IMDG) Code relating to the carriage of dangerous goods by sea, as amended from time to time, approved by the Maritime Safety Committee of the International Maritime Organisation (IMO); or

(ii) In respect of any LMO transported by air, the Dangerous Goods Regulations relating to the carriage of dangerous goods by air, as amended from time to time, approved by the International Civil Aviation Organisation (ICAO) or the Dangerous Goods Board of the International Air Transport Association (IATA);

(h) "controlled area" means any declared port of entry by air or sea, and includes any area occupied or controlled by the Port Authority;

(i) "deliberate release" means any intentional introduction into the environment of a LMO, or a combination of LMO or products thereof, and includes releases for –

(i) commercial purposes;

(ii) research purposes in field experimentation;

(iii) use in greenhouses, aquaculture facilities, or animal accommodation unless the facility is approved for contained use or disposal of genetically modified organisms;

(j) "environment" includes atmosphere, land, soil, water and all living organisms;

(k) "export" means the intentional transboundary movement of any LMO from the area of national jurisdiction of Antigua and Barbuda to the area of national jurisdiction of another country;

(l) "exporter" means any legal or natural person, whether in Antigua and Barbuda or any other State, who arranges for a LMO to be exported;

(m) "importer" means any legal or natural person, whether in Antigua and Barbuda or any other State, who arranges for a LMO to be exported;

(n) "imported" means the intentional transboundary movement of LMO into the area of national jurisdiction of Antigua and Barbuda from the area of national jurisdiction of another country;

- (o) “risk assessment” means the use of scientific and other appropriate methods to identify and characterise the nature, likelihood of occurrence, and potential magnitude of any hazards, with due regard to the precautionary principle;
- (p) "Living modified organism" (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
- (q) “intentional introduction into the environment” means any deliberate use of LMOs subject to this Act that is not contained use, but does not include LMOs imported for direct use for food or feed or for processing;
- (r) "living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;
- (s) "Modern biotechnology" means the application of:  
(i) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or  
(ii) fusion of cells beyond the taxonomic family,  
that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;
- (t) “National Focal Point” means the entity designated to be responsible on behalf of Antigua and Barbuda for liaison with the Secretariat of the Cartagena Protocol;
- (u) “operator” means any person conducting activities authorized or otherwise allowed under this Act;
- (v) “person” means a juridical or natural person;
- (w) “placing on the market” means action, other than pre-commercial licensing, which makes an LMO or LMOs available to third parties on a commercial basis;
- (x) “registry” means the compilation of LMOs or activities that are authorized, exempted or subject to simplified procedures in accordance with this Act and regularly published by the Competent Authority;
- (y) “risks to human health” means the potential impact on human beings as a direct result of an adverse effect on the conservation and sustainable use of biological diversity;
- (z) “Secretariat of the Cartagena Protocol” means the Secretariat established by Article 31 of the Cartagena Protocol.

### **Article 3. Scope.**

(a) Subject to the exceptions set forth in this Act or provided for by regulation hereunder, this Act shall apply to the contained use, intentional introduction into the environment, and [JP2] import and

export of LMOs that may have an **adverse**<sup>[JG3]</sup> effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

(b) This Act shall not apply to:

- (i) LMOs that are pharmaceuticals for human use;
- (ii) LMOs in transit through but not destined for use in Antigua and Barbuda; and
- (iii) Any other LMOs or categories of LMOs that are exempted under this Act.

## **PART II.**

### **INSTITUTIONAL AND ADMINISTRATIVE ARRANGEMENTS.**

#### **Article 4. Establishment of National Biosafety Board.**<sup>[JP4]</sup>

For the purposes of this Act, there is hereby established a National Biosafety Authority, which shall consist of the following members appointed by the Minister -

- (a) The Department of Environment, which shall be the national focal point and the home of the National Biosafety Clearing House as required under the Cartagena Protocol on Biosafety;
- (b) Plant Protection, which shall perform the functions of the Secretariat in accordance with the requirements of this act and the Cartagena Protocol on Biosafety;
- (c) The Ministry of Foreign Affairs;
- (d) The Ministry of Health;
- (e) The Bureau of Standards;
- (f) The Department of Agriculture;
- (g) The Veterinary and Livestock Division;
- (h) The Office of the Attorney General;
- (i) The Customs and Excise Division;
- (j) The Ministry of Trade;
- (k) Eight independent members who will be appointed based on their personal qualifications, experience and integrity.

#### **Article 5. Establishment of Competent Authority or National Biosafety Authority.**<sup>[JP5]</sup>

(a) The National Biosafety Authority shall be established as the Competent Authority for purposes of the administration of this Act and any regulations promulgated hereunder;

(b) The primary functions of the Competent Authority are:

- (i) To receive, respond to and make decisions on notifications and applications in consultation with the Scientific Advisory Committee and in conformity with the requirements of this Act;
- (ii) To establish administrative mechanisms to ensure the appropriate handling, dissemination, and storage of documents and data in connection with the processing of applications and notifications and other matters covered by this Act; and
- (iii) To promote public awareness and education concerning the activities regulated under this Act, including through the publication of guidance and other materials that explain and elaborate on the risk assessment, risk management and authorization processes.

(c) The **Environment Division** <sup>[JG6]</sup> shall serve as the National Focal Point;

(d) The primary functions of the National Focal Point are:

- (i) To receive, process, and respond to information and notifications from the Secretariat of the Cartagena Protocol; and
- (ii) To facilitate international information sharing as set forth in this Act.

**Article 6. Chair of National Biosafety Authority.**

The Minister shall designate a chairperson and a deputy chairperson from among the members of the National Biosafety Authority.

**Article 7. Deputy Chair of National Biosafety Authority.**

The deputy chairperson appointed by the Minister shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to perform such functions.

**Article 8. Vacancies in National Biosafety Authority.**

- (a) A vacancy in the Authority shall occur when a member:
  - (i) ceases to be an officer within a Government Department or Agency represented;
  - (ii) is absent without leave from more than three consecutive meetings of the Authority;
  - (iii) resigns;
  - (iv) dies.
- (b) The Minister may at any time remove a member of the Authority from office if the Minister is of the opinion that such member is no longer competent to perform duties required under the Act, or has been found guilty of any misconduct by a competent authority.
- (c) A vacancy in the Authority shall be filled as soon as practicable in accordance with the provisions of this act.
- (d) If the Minister is satisfied that any member of the Authority is prevented by illness or any other reason from performing the duties required under the Act, the Minister may appoint any other person suitable to act as the deputy of that member while such member is so prevented, and such deputy shall during the period he or she so acts, perform the functions of the member in whose stead he or she has been appointed so to act.

**Article 9. Meetings<sup>[JG7]</sup> of National Biosafety Board.**

- (a) The National Biosafety Board shall meet at such times as may be necessary to carry out the tasks, functions and responsibilities as required under this Act, and in any event shall meet at least four times in a calendar year. Provision shall be made to facilitate virtual participation.
- (b) The National Biosafety Authority may convene special working groups for the purpose of preparing any document, policy or programme that shall be submitted for the consideration of the Minister.
- (c) At least two weeks prior to convening a meeting of the National Biosafety Board, the Secretariat shall prepare and circulate to members an agenda, unless an emergency meeting is called, outlining items for discussion and approval, which may include policies and programmes that promote biosafety of biotechnology and initiatives that focus on finance, science and technology, education, training and public awareness, capacity building and support for the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*.
- (d) The quorum for any meeting of the National Biosafety Authority shall be a majority of the members and should consist of a minimum of six government agencies, two of which must be the Department of the Environment and Plant Protection and four independent members.
- (e) The National Biosafety Authority may determine its own <sup>[JG8]</sup>procedures to be followed at its meetings and cause minutes to be kept of its proceedings.

- (f) The National Biosafety Authority may co-opt other knowledgeable non-voting persons to serve on the Authority in order to provide advice whenever the Authority deems it necessary.
- (g) The Authority may invite written comment from knowledgeable persons on any aspect of biosafety or biotechnology which lies within the Authority's mandate.
- (h) Formal recommendation of any policy, programme or initiative by the National Biosafety Board [UG9] shall be by majority of Board [UG10] members present at a meeting, providing that matter may be approved unless at least fifty percent of appointed members are present at the meeting.
- (i) Any matter that has been recommended by the National Biosafety Authority shall be transmitted by the Chairperson to Cabinet for approval. Cabinet shall notify the National Biosafety Board on the way forward.

**Article 10. Establishment of Scientific Advisory Committee [UG11].**

- (a) A Scientific Advisory Committee (SAC) shall be established by the Competent Authority, for the purpose of conducting risk assessments and providing scientific and other technical advice and assistance to the Competent Authority. The SAC will include the following technical advisory and testing committee members drawn from CARDI, UWI, PAHO, IICA, CEHI and NGOs.
- (b) The SAC will also take into consideration the rulings of the following international bodies as one component of all the issues that will be considered in arriving at a decision: Codex Alimentarius, The International Plant Protection Convention and The World Organization for Animal Health.
- (c) The SAC will maintain a database of qualified individuals and institutions in the variety of skill areas, to carry out any required risk analysis.
- (d) The responsibilities of the SAC shall include:
  - (i) Conducting risk assessments;
  - (ii) Reviewing risk assessments provided in applications or notifications;
  - (iii) Reviewing risk management measures;
  - (iv) Recommending containment measures, limitations on the duration of authorizations, reporting mechanisms, remedial measures, monitoring procedures and other appropriate and scientifically sound conditions and risk management measures; and
  - (v) Providing such other expert advice and assistance as the Competent Authority may request.
- (e) If necessary, the Technical Advisory Committee (TAC) may invite scientific experts from the following fields to conduct its Risk Assessments:
  - (i) Plant breeding and genetics;
  - (ii) Agronomy;
  - (iii) Weed science;
  - (iv) Plant pathology;
  - (v) Animal breeding and genetics;
  - (vi) Animal pathology;
  - (vii) Environmental toxicology;
  - (viii) Ecology;
  - (ix) Entomology;
  - (x) Virology; and
  - (xi) Microbiology.
- (f) Internal procedures for the operation of SAC and its subcommittees shall be proposed by the SAC and shall be approved by the Competent Authority,

- (i) including designating members and chairpersons of the SAC and its subcommittees, appointing advisors and specifying rules of procedure for the SAC and its subcommittees, and for the participation of advisors in the SAC or its subcommittees;
- (ii) Ensuring the absence of conflicts of interest among members of the SAC and its subcommittees and advisors to the SAC and its subcommittees;
- (iii) Ensuring the protection of confidential information, including a declaration that any information attained by virtue of membership in the SAC or a subcommittee, or appointment as an advisor to the SAC or a subcommittee, shall not be disclosed to others or used for any research, development or commercial purpose without the express written authorization of the Applicant identifying the information as confidential.

[JG12]

### **PART III.**

### **NOTIFICATION AND AUTHORIZATION REQUIREMENTS.** [JG13]

#### **Article 11. Prohibition [JP14] Concerning LMOs. [JP15]**

Where Cabinet has endorsed the recommendation of the National Biosafety Board, the Minister shall, by notice in the Gazette, prohibit –

- (a) the handling, transport, use, transfer and release of any LMOs;
- (b) any activity involving genetically modified organisms, so as to prevent or reduce risks to biological diversity, the environment and human health;
- (c) Prior to issuing any notice prohibiting the import [JP16] of any LMO, the Minister shall give public notice of his or her intention to prohibit the import of such organism;
- (d) The public notice in (c) above shall be published in daily newspapers and shall provide:
  - (i) a description of the organism together with a statement that it is government's intention to prohibit the import of such organism;
  - (ii) that submissions on the proposed prohibition may be made in writing by any person;
  - (iii) the closing date for submissions, which shall not be earlier than thirty calendar days after public notification; and
  - (iv) the address where submissions are to be sent.
- (e) A copy of the public notice shall be lodged with the National Biosafety Clearing House maintained by the Secretariat.
- (f) In addition to the placement of any public notice, the National Biosafety Authority may establish a consultative process with other government ministries, departments or statutory bodies, or with representatives from the academic and business community or the public concerning the proposed prohibition.
- (g) Any person who imports any LMOs that has been prohibited under the provisions of this Act shall be guilty of an offence and liable to the penalties stipulated under the Act.

#### **Article 12. [JP17] Notification [JP18] Requirements and Procedures for Contained Use Activities.**

- (a) No person shall conduct any contained use activities involving LMOs or import LMOs for such purposes without the prior submission of a notification to the Competent Authority as set forth in this Article, except as provided under Article 13(a).
- (b) A notification of intent to conduct activities with LMOs under contained use pursuant to paragraph (a) shall be submitted at least sixty (60) days before the activities covered by the notification are due to begin.



(c) The notification shall include:

- (i) The name and contact information for the Applicant;
- (ii) The location where contained use activities will be undertaken;
- (iii) The name and identity of the LMO or LMOs involved;
- (iv) The nature and purpose of the activities, including such activities as storing, transporting, producing, culturing, processing, destroying, disposing, or using the LMOs in any other way;
- (v) A description of the containment measures to be provided and the suitability of those measures for the LMOs and activities to be undertaken;
- (vi) A description of any potential risks associated with the LMOs and activities to be undertaken; and
- (vii) A description of remedial measures to be undertaken in the event of any unintentional introduction into the environment of the LMOs that may occur as a result of the activities to be conducted.

(d) The Biosafety Clearing House shall advise Cabinet, the Technical Advisory Committee, Department of Environment, and the National Biosafety Board, of the receipt of the application within two weeks.

(e) If the Applicant receives no response within sixty (60) days of the submission of the notification, the proposed activities may commence.

(f) In response to the submission of a notification, the Competent Authority may, in consultation with the SAC, request additional information, including a risk assessment carried out in a scientifically sound manner, in accordance with Annex II and recognized risk assessment techniques. The Competent Authority shall inform the Applicant in writing of the additional information sought and the procedure the Competent Authority will follow in taking further action on the notification.

(g) Where additional information is sought by the Competent Authority under paragraph (e), a final written decision as to whether the proposed activities may proceed shall be provided by the Competent Authority to the Applicant no later than sixty (60) days following receipt of the additional information. In the event the proposed activities are not permitted as requested in the notification, the Competent Authority shall include in its final written decision the reasons for the prohibition or any limitations or conditions that may be placed on the proposed activities. [JG19]

(h) Regulations governing the conduct of contained use activities, including relevant definitions, risk classifications, waste and disposal requirements and procedures, and requirements for risk assessments, shall be promulgated under this Act.

### **Article 13. Authorization Requirements for Intentional Introduction into the Environment.**

(a) The following activities are prohibited unless authorized by the Competent Authority in conformity with this Act:

- (i) The intentional introduction into the environment of an LMO for purposes other than placing on the market; and
- (ii) Placing on the market of an LMO.

(b) No person shall import an LMO for activities subject to paragraph (a) without authorization under this Act.

(c) Persons proposing to export LMOs covered by this Act from Antigua and Barbuda to another country party to the Cartagena Protocol shall:

- (i) Notify the competent authority of the proposed party of import, in writing, prior to the first transboundary movement of an LMO for intentional introduction into the environment



- of the party of import by supplying, at a minimum, information specified in Annex I, in accordance with the Cartagena Protocol and any applicable domestic legislation;
- (ii) Include a declaration that all information provided in such notification is factually correct; and
  - (iii) Prior to shipment, provide to the Competent Authority a copy of the authorization granted by the importing country where authorization is required under the Cartagena Protocol and/or the applicable laws of that country.

#### **Article 14. Application Procedures for Intentional Introduction into the Environment.**

- (a) Any person proposing to intentionally introduce an LMO into the environment shall submit to the Competent Authority an application that complies with the requirements of this Article and describes the activity or activities for which authorization is sought, except as provided under this act.
- (b) Applicants shall include in their submissions:
  - (i) The information specified in Annex I, with the exception of any information the Competent Authority identifies as unnecessary in pre-application consultations;
  - (ii) A risk assessment in conformity with Annex II; and
  - (iii) Any additional information applicants deem relevant to an assessment of the potential risks and/or benefits of the requested activity.
- (c) All applications shall include a declaration that the information contained therein is factually correct.
- (d) An Applicant may withdraw its application at any time prior to the issuance of a final decision by the Competent Authority without prejudice.

#### **Article 15: Confidential Information**

- (a) The Competent Authority shall:
  - (i) Permit the Applicant to identify information provided to the Competent Authority in accordance with the requirements of this Act and any regulations promulgated hereunder, including information contained in notifications, applications and other written submissions, that is to be treated as confidential, with justification for claims of confidentiality to be provided upon request;
  - (ii) Decide whether it accepts as confidential the information designated by the Applicant;
  - (iii) Prior to any disclosure of information identified by the Applicant as confidential, inform the Applicant of its rejection of the claim of confidentiality, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure; and
  - (iv) In the event that an Applicant withdraws or has withdrawn an application, respect the Applicant's claims of confidentiality, including claims for that information on which the Competent Authority and the Applicant disagree as to its confidentiality.
- (b) The Competent Authority shall neither use nor permit the use of confidential information accepted as confidential under paragraph (a) for any purpose not specifically authorized under this Act except with the written consent of the Applicant and shall ensure that such information is protected by all persons involved in handling or reviewing applications or other written submissions under this Act.
- (c) Without prejudice to paragraph (a)(iv) above, the following information shall not be considered confidential:
  - (i) The name and address of the Applicant;

- (ii) A general description of the LMO;
- (iii) A summary of risk assessments performed on the LMO; and
- (iv) Any methods and plans for emergency response.

**Article 16. Acknowledgment and Preliminary Response.**

- (a) Upon receipt of an application, the Competent Authority immediately shall refer the application to SAC for prompt screening for *prima facie* completeness.
- (b) Within thirty (30) days of receipt of the application, based on information provided by SAC, the Competent Authority shall acknowledge receipt of the application and respond, in writing, to the Applicant.
- (c) The preliminary response shall include:
  - (i) The date of receipt of the application; and
  - (ii) Whether the application, *prima facie*, contains the required information or, if not, what additional information within the scope of Annex I is required.
- (d) If additional information is required, the number of days the Competent Authority must wait for the information shall not be included in calculating the timeframe for making a final decision under Article 16(b).

**Article 17. Risk Assessment and Risk Management.**

- (a) The Competent Authority shall ensure that appropriate and adequate risk assessments are carried out for all activities that require authorization.
- (b) Risk assessment, including the auditing of risk assessments, shall be carried out in a scientifically sound manner, in accordance with Annex II and recognized risk assessment techniques. Risk assessments shall take into account available information concerning any potential exposure to the LMO. Such risk assessments shall be based on the information included in the application and any other available scientific evidence.
- (c) The SAC shall audit risk assessments submitted by the Applicant and shall conduct or cause to be conducted any additional risk assessments as required on a case-by-case basis. In carrying out its risk assessment and auditing activities, the SAC shall take into account any risk management measures proposed by the Applicant and any additional risk management measures that may be necessary to minimize any identified risks. Where additional risk assessment is required, it may be undertaken by the Applicant, SAC or other experts at the discretion of the Competent Authority.
- (d) Upon conclusion of the risk assessment and auditing process, the SAC shall provide to the Competent Authority a risk assessment report that gives its opinion, with justifications, on the disposition of the application and indicates any measures or actions that need be taken to ensure the safe use of the LMO. The report should include a summary of the risk assessment that does not include any confidential information subject to protection under Article 15.
- (e) The Competent Authority shall ensure that appropriate mechanisms, measures or strategies are in place to regulate, manage and control risks identified during the risk assessment process.
- (f) The Competent Authority shall provide the risk assessment report described in paragraph (d) to the Applicant within three (3) days of receipt of the report from the SAC. The Applicant may submit comments on the SAC report in writing within thirty (30) days of its receipt of the report. Any such comments shall be provided to the SAC and shall be considered by the Competent Authority, in consultation with the SAC.

**Article 18. Decision-making and Communication of Decision.**

- (a) Following receipt of the risk assessment report, the Competent Authority shall make a final decision concerning the authorization requested in the application.
- (b) Any decision rendered under paragraph (a) shall be based upon:
  - (i) The information submitted by the Applicant;
  - (ii) The risk assessment report prepared by the SAC;
  - (iii) Any written comments provided by the Applicant; and
  - (iv) Any relevant comments submitted by the public.
- (c) In reaching a decision, the Competent Authority also may take into account, consistent with the international obligations of Antigua and Barbuda, 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<sup>[JP20]</sup>.
- (d) Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall not prevent the Competent Authority from making a decision, as appropriate, in order to avoid or minimize such potential adverse effects.
- (e) A final decision shall be made and communicated to the Applicant within one hundred-twenty (120) days of receipt of an application submitted for the intentional introduction into the environment of an LMO for purposes other than placing on the market, and within two hundred-seventy (270) days of receipt of an application submitted for the placing on the market of an LMO.
- (f) The final decision of the Competent Authority shall be recorded in a decision document that:
  - (i) Identifies the Applicant and summarizes the nature of the request;
  - (ii) Describes the procedure followed in reviewing the application;
  - (iii) Includes the summary of the risk assessment conducted by SAC;
  - (iv) States whether the requested activity is authorized, with or without conditions, or whether the requested activity is prohibited; and
  - (v) Provides the reasons for the decision.
- (g) Any specific conditions, limitations or requirements related to the authorization must be clear on the face of the decision document.
- (h) No person shall vary the purpose of the authorized activity as set forth in the decision document unless he obtains authorization from the Competent Authority.
- (i) LMOs or activities authorized under this act shall be included in the registry to be established under Article <sup>???</sup><sup>[JG21]</sup>

#### **Article 19. Review of Risk Assessment Report.**

- (a) The National Biosafety Authority shall review the risk assessment report that has been submitted in pursuance of the requirements of this Act.
- (b) Within two weeks of the receipt of any report mentioned in sub-section (a) above, the National Biosafety Authority shall publish, during two subsequent weeks, in two issues of the daily newspaper circulating in the area where the undertaking would likely be carried out, and the Gazette, a notice to advise the public that copies of the risk assessment report are available for public scrutiny.
- (c) A notice published under the provisions of sub-section (b) above shall state -
  - (i) a summary description of the activity or undertaking involving LMO;
  - (ii) the address where the activity or undertaking is to be carried out;
  - (iii) the place where the report may be inspected;

- (iv) the time limit for the submission of public comments in writing to the National Biosafety Authority.
- (d) A risk assessment report submitted under article 17 shall be open at all reasonable hours for public inspection for a period of not less than one calendar month.
- (e) The National Biosafety Authority shall consider all comments and observations that may be submitted as a result of the public review.
- (f) The National Biosafety Authority may, for the purposes of the review of any report -
  - (i) request any ministry, department, statutory body, non-governmental organisations, or any other person to submit their observations or recommendations in writing concerning any matter contained in a report;
  - (ii) require the applicant to carry out any further study or to submit additional information for the purpose of evaluating any potential for significant risk to Antigua and Barbuda's natural biodiversity, the environment, or human health.

## **Article 20. Decision on Reports.**

- (a) Upon reviewing any comprehensive study report or mediation report, the National Biosafety Authority may:
  - (i) approve the activity or undertaking involving the LMO; or
  - (ii) approve the activity or undertaking involving the LMO subject to conditions; or
  - (iii) where the activity or undertaking involving the LMO may result in impacts that could not be justified, mitigated or managed, refuse a permit for the proposed activity or undertaking.
- (b) [JP22] The National Biosafety Authority shall decline any application for a permit if the LMO results in-
  - (i) any significant displacement of any native species within its natural habitat;
  - (ii) any significant deterioration of natural habitats;
  - (iii) any significant adverse effects on the environment, human health or safety;
  - (iv) any significant adverse effects to Antigua and Barbuda's inherent genetic diversity; or
  - (v) disease, becomes parasitic, or becomes a vector for human health, animal or plant disease that causes any significant effects outlined in paragraphs (b)(i) to (iv) above.
- (c) Any permit issued under sub-section (a)(i) or (ii) above shall contain the following information:
  - (i) the name and contact particulars of the applicant;
  - (ii) the identity of the genetically modified organism that is the subject of the application;
  - (iii) the quantity of genetically modified organism that is the subject of the application;
  - (iv) any special cargo transportation or storage requirements pertaining to any LMO that is the subject of the application; and
  - (v) any conditions or risk management measures that may be imposed by the National Biosafety Authority.
- (d) The National Biosafety Authority shall transmit a copy of any order made pursuant to the provisions of sub-section (?) above to the Secretariat established under this act.

## **Article 21. Issue of Permit.**

- (a) Within seven days of receiving the order issued under the provisions of Article 20 above, the Secretariat shall inform the applicant of the decision of the National Biosafety Authority, and where appropriate, issue the necessary permit. The applicant shall not proceed with any proposed undertaking or activity involving LMO until the following have been received-

- (i) the notice from the Secretariat advising of the decision issued by the National Biosafety Authority; and
- (ii) the permit.
- (b) The order of the National Biosafety Authority and any permit that has been issued under the provisions of Article 20 above, shall be lodged with the National Biosafety Clearing House.
- (c) The National Biosafety Authority may, at any time, cancel a permit that has been issued under sub-section (a) above.
- (d) If any requirement or condition contained in a permit are not strictly complied with, the National Biosafety Authority may issue such directions as may be considered appropriate for the immediate cessation of any activity or undertaking involving LMOs, and for their safe containment.
- (e) Any person who fails to comply with the direction, requirement or condition imposed by the National Biosafety Authority shall be guilty of an offence and liable to the penalties provided under this Act.

#### **Article 22. General Conditions Relating to Permits.**

- (a) Any permit issued under the provisions of this Part shall authorise the holder to undertake on one occasion the type undertaking or activity involving genetically modified organisms to which the permit or certificate relates, and only with the LMO specified in the permit.
- (b) Every permit for an undertaking or activity involving LMOs shall come into force on the date on which it was granted.
- (c) Every permit undertaking or activity involving LMOs shall remain in force for a period of 6 months, or such lesser period as may be specified, unless it is sooner revoked or surrendered.
- (d) A permit shall be personal to the holder, and shall not be transferable to or vest by operation of law in any person other than the holder.
- (e) Any person who is in possession of a permit issued under this part and undertakes any undertaking or activity involving LMOs, they shall before:
  - (i) transporting;
  - (ii) exporting or re-exporting; or
  - (iii) importing or re-importing,any LMOs pursuant to the conditions of any permit, produce the permit to a Customs Officer or other authorised agent, and shall permit such person to inspect the consignment to verify compliance with the requirements and specifications of the permit.
- (f) Any person who fails to comply with any of the requirements of sub-sections above, shall be guilty of an offence and liable on conviction to the penalties provided under this Act.

#### **Article 23. Responsibility for Risk Management Measures.**

- (a) The applicant shall bear all of the costs of the risk assessment.
- (b) It shall be the responsibility of the applicant to implement any risk management measures, including any monitoring programme, protection plan, or mitigation measure that shall constitute the conditions of any permit granted under this Part.
- (c) The Secretariat shall cause to be conducted any inspection that may be necessary to determine whether any undertaking or activity involving LMOs are undertaken in accordance with any risk management measures that shall constitute the conditions of any approval granted under this Part.
- (d) The Secretariat, upon undertaking any inspection as required under the provisions of sub-section (c) above, may cause an action to be initiated before any competent court, where it has been determined that any undertaking or activity involving LMOs has not been undertaken in

accordance with any risk management plan that shall constitute the conditions of any approval granted under this Part.

#### **Part IV.**

### **RISK MANAGEMENT MEASURES**

#### **Article 24. Risk Management Measures – General.**

- (a) It shall be the duty of the Comptroller of Customs and Excise, through officers subordinate to him, to promptly notify the Authority of the arrival in Antigua and Barbuda of any prohibited or restricted genetic material [JP23] and to refuse to release or dispose of the same without authorization, in a form prescribed by regulation under this Act, issued by an authorized officer.
- (b) The provisions of this section apply in addition to any risk management measure that may be imposed in any permit issued by the National Biosafety Authority.
- (c) No LMO may be imported, exported or transported unless it has been certified, marked, packed and stowed in accordance with the requirements set out in the Code [JP24] in respect of that organism and according to the procedures and requirements described in ANNEX VI.
- (d) Any person who imports, exports or transports any LMO that has not been certified, marked, packed or stowed in compliance with the requirements of this Part, shall be guilty of an offence and liable to the penalties provided in this Act.
- (e) Contained use of any genetically modified organisms shall take place in laboratories and installations that are approved under this act, and in accordance with good microbiological practice.
- (f) The user of all LMOs kept for contained use shall ensure that the necessary safety precautions are taken to prevent adverse effects on health and the environment, including measures to limit the detrimental effects of the unintentional release of LMOs.
- (g) Records shall be kept of all contained use of LMOs.
- (h) The documents referred to in sub-section (g) above must be attached to each other while accompanying any LMO in transit.

#### **Article 25. Storage other than in Controlled Areas.**

- (a) Only licensed and registered facilities shall store or process any LMO [JP25].
- (b) The National Biosafety Authority, in consultation with the Ministry of Health and Ministry of Trade, will undertake the licensing and registration of premises [JP26], and for this purpose may establish:
  - (i) standards pertaining to the storage or processing of LMO on any premises;
  - (ii) procedures and requirements for the licensing and registration of premises;
  - (iii) requirements for the training of employees in the safe handling of LMOs.
- (c) The Ministry of Trade, in undertaking the licensing and registration of premises, shall require such premises to carry adequate insurance to cover any foreseeable liability for harm to human health or the environment.
- (d) The person in charge of any premises that is to be used for the storage or processing of any genetically modified organism shall apply in writing to the National Biosafety Authority for permission to use such premises for such purpose.
- (e) Any application for a permit that is submitted shall contain:



- (i) a full and accurate description of the LMOs that are to be stored or processed, including the technical and common name, and where appropriate the United Nations Class; and
  - (ii) a statement of the quantities of LMOs to be stored or processed and the duration of such storage;
  - (iii) the name and location of the place where the LMO is to be stored or processed;
  - (iv) a description of the processing that is to be undertaken on any LMO;
  - (v) a copy of the risk management protocols and emergency measures that operate within the facility.
- (f) Upon receipt of any application, the National Biosafety Authority shall inspect the premises to determine if:
- (i) adequate facilities exist for the safe storage or processing of LMOs;
  - (ii) adequate security, segregation and safety measures exists at the premises; and
  - (iii) employee training in the management of LMO has been undertaken.
- (g) Upon completion of any inspection undertaken, the National Biosafety Authority shall
- (i) refuse permission for the storage or processing of LMO in such premises; or
  - (ii) issue a permit, which may specify conditions.
- (h) Any permit issued shall contain the following information:
- (i) the name and location of the place where the LMO is to be stored or processed;
  - (ii) a full and accurate description of the LMOs that are to be stored or processed, including the technical and common name;
  - (iii) a statement of the quantities to be stored or processed, and the duration of such storage or processing;
  - (iv) any special risk management measures pertaining to any LMO that is to be stored or processed.
- (i) The National Biosafety Authority may, at any time, cancel a permit that has been issued.
- (j) If any requirement or condition contained in a permit are not strictly complied with, the National Biosafety Authority may issue such directions as may be considered appropriate for the immediate cessation of the storage or processing of the LMO.
- (k) Any person who fails to comply with the direction, requirement or condition imposed by the National Biosafety Authority shall be guilty of an offence and liable to the penalties provided under this Act.
- (l) Within seven days of issuing any permit, the National Biosafety Authority shall lodge a copy of the permit with the National Biosafety Clearinghouse.
- (m) Any premises used for the storage or processing of LMO must ensure that all such organisms on the premises are packed, labelled and segregated in accordance with the requirements of this Part, and any direction issued by the National Biosafety Authority.
- (n) The person in charge of any premises used for the storage or processing of LMO shall ensure that LMO storage areas or processing areas are secured against unauthorised access.
- (o) The person in charge of any premises used for the storage or processing of LMO shall maintain material data sheets on any LMO stored or processed on the premises and shall ensure that these sheets are readily accessible in the event of an emergency.
- (p) The person in charge of any premises used for the storage or processing of LMOs shall ensure that an *Emergency Procedures Guide* providing information concerning emergency procedures that are to be employed in the event of any accidental release or other emergency, is kept on the premises and that all employees are trained in emergency procedures.

- (q) The person in charge of any premises used for the storage or processing of LMOs shall ensure that a daily inspection is undertaken by a responsible person of the LMO store areas to assure no accidental release or leakage is occurring.
- (r) The Ministry of Health will carry-out inspections of premises to ensure compliance with any permit, standard and procedures established in this Part, and for this purpose is empowered to execute spot checks to ensure compliance with any such requirements.
- (s) Any person who stores or processes any LMO other than in compliance with the requirements of this section, or in violation of any direction, order or requirement imposed by the National Biosafety Authority, shall be guilty of an offence and liable to the penalties provided under this Act.

#### **Article 26. Duties and Responsibilities.**

- (a) It shall be the duty and responsibility of everyone who may have the custody or care of any LMOs to exercise the utmost care to ensure that harm or damage shall not result to Antigua and Barbuda's natural biodiversity, the environment or human health.
- (b) In the event of an accidental release or spill of any LMO, it shall be the duty and responsibility of everyone who may have the custody or care of any LMO to immediately report such accidental release or spill to the National Biosafety Authority.
- (c) In the event of an accidental release or spill of any LMO, it shall be the duty and responsibility of everyone who may have the custody or care of the LMO to:
- (i) secure the area around the accidental release or spill;
  - (ii) determine whether emergency services are to be called;
  - (iii) assess the situation and respond in appropriate manner;
  - (iv) take reasonable measures to prevent or limit damage and inconvenience.
- (d) Any person who fails to undertake any duty or responsibility required under the provisions of this section shall be guilty of an offence and liable to the penalties provided under this Act.

### **Part V.**

#### **PRE-APPROVED ORGANISMS**<sup>[JP27]</sup>

#### **Article 27. Pre-Approval of LMOs.**

- (a) The National Biosafety Authority shall establish a register of LMOs that have been pre-approved for import into Antigua and Barbuda.
- (b) No LMO may be registered pursuant to sub-section (a) unless the National Biosafety Authority is satisfied –
- (i) a risk assessment has been undertaken by an accredited regional organisation that is competent to undertake scientific assessments to determine that the genetically modified organisms does not cause any significant ecological, social or economic harm in Antigua and Barbuda;

- (ii) there exists information on the interaction between the LMO and natural biodiversity, the environment and human health, including the results of any deliberate release in any other country;
  - (iii) there exists information on any previous approvals of the LMOs in any other country.
- (c) The register of LMOs that have been pre-approved for import into Antigua and Barbuda shall be lodged with the National Biosafety Clearinghouse.
- (d) No application for import shall be required for any LMO that has been registered pursuant to sub-section (a), but any person importing shall notify the National Biosafety Board of the types and quantity to be imported<sup>[UG28]</sup>

**Article 28. Application for Pre-Approval.**

- (a) Any person may apply to the National Biosafety Authority to register LMO for pre-approval.
- (b) Any application under sub-section (a) shall contain –
  - (i) a description of the nature of the application;
  - (ii) a full and accurate description of the LMO;
  - (iii) the risk assessment that has been undertaken by an accredited regional organisation that is competent to undertake scientific assessments to determine that the LMO does not cause any significant ecological, social or economic harm in Antigua;
  - (iv) information on the interaction between the LMO modified organism and natural biodiversity, the environment and human health, including the results of any deliberate release in any other country;
  - (v) information on any previous approvals of the LMOs in any other country.
- (c) Upon receipt of any application, the National Biosafety Authority shall:
  - (i) consult with the Scientific and Technical Advisory Committee;
  - (ii) verify the adequacy of the risk assessment that has been undertaken by an accredited regional organisation; and
  - (iii) give public notice of the application under this Part.
- (d) The public notice required in article 28(c)(iii) above shall be published in daily newspapers and shall provide:
  - (i) a description of the nature of the application;
  - (ii) a full and accurate description of the LMO;
  - (iii) a summary of the findings of any the risk assessment that has been undertaken by an accredited regional organisation.
  - (iv) that submissions on the application may be made in writing by any person;
  - (v) the closing date for submissions, which shall not be earlier than thirty calendar days after public notification; and
  - (vi) the address where submissions are to be sent.
- (e) A copy of the public notice shall be lodged with the National Biosafety Clearinghouse.

### **Article 29. Registration.**

(a) Having satisfied the requirements of Article 28 and upon reviewing any comments from the public, recommendations from the Scientific and Technical Advisory Committee, and any risk assessment report that may have been completed, the National Biosafety Authority shall:

- (i) register the pre-approved LMO which may be subject to conditions concerning appropriate risk management measures; or
- (ii) refuse permission to register the LMO for pre-approval.

(b) Any LMO that has been pre-approved for import into Antigua and Barbuda shall be recorded on the Register of pre-approved LMO contained in the National Biosafety Clearinghouse.

## **Part VI.**

### **EMERGENCY MEASURES**

### **Article 30. Establishment of Accidental Release Control Group.**

(a) In order to co-operate and direct response to any accident release of LMOs within the scope of this Part, the National Biosafety Authority shall establish an Accidental Release Control Group.

(b) The Accidental Release Control Group shall comprise representatives from the Environment Division, the National Office of Disaster Services, the Ministry responsible for Health, the Ministry responsible for Agriculture and Fisheries, the Ministry of Defence, and such other members as the Minister may appoint by notice in the Gazette.

(c) The Minister shall appoint an Accidental Release Commander, who shall direct the activities of the Accidental Release Control Group, and for this purpose shall have such powers and responsibilities as are provided by this Part.

(d) The duties and function of the Accidental Release Control Group shall be to:

- (i) develop appropriate systems for the detection and reporting of accidental release of any LMOs, or of incidents related to the use, transport of LMOs which could result in such accident;
- (ii) ensure prompt response is made in the event of an accidental release of any LMO to either prevent damage to Antigua and Barbuda's natural biodiversity, the environment or human health or to restrict the extent of such damage;
- (iii) ensure that the correct response techniques and risk management measures are used in the event of an accidental release of any LMOs, and that disposal of recovered LMO is carried out in an environmentally acceptable manner;
- (iv) ensure that complete and accurate records are maintained of all expenditures incurred in the event of an accidental release of any LMOs to facilitate cost recovery and the payment of compensation;
- (v) provide adequate protection for public health, safety and welfare, and the protection of the environment in the event of an accidental release of any LMOs;
- (vi) ensure the prompt and efficient mobilization of available manpower and resources, and the orderly deployment of foreign assistance, equipment of personnel which may be offered in the event of an accidental release of any LMO;

(e) The Accidental Release Control Group shall be the sole authority responsible for response to any accident, and shall direct the activities of foreign agencies or parties that may offer assistance in the event of an accident.

(f) The Accidental Release Control Group shall meet at such times and with such frequency as may be necessary to fulfil the duties and responsibilities imposed by this Act, which in any event shall not be less than every six months.

[JG29]

**Article 31. National Accidental Release of LMOs Risk Management Plan.**

(a) A *National Accidental Release of LMOs Risk Management Plan* shall be drawn up by the Accidental Release Control Group which shall describe the established risk management and emergency preparedness measures to be carried out when an accidental release of LMOs has occurred.

(b) The Plan prepared pursuant to the requirements of sub-section (a) above, shall include information and procedures described in Annex V.

**Article 32. Duty to Report Threatened Releases of LMO.** [JP30]

(a) Where there is any significant threat that an accidental release of any LMO may occur, the owner or master of the ship, or the owner or person in charge of the facility, or the occupier of the place on land, as the case may be, shall immediately and by the quickest available means, by radio if possible, report the threatened occurrence to the National Biosafety Authority.

(b) The report required to be made under sub-section (a) shall contain the following information:

- (i) the event to which the threat is attributable;
- (ii) the weather, and where applicable, sea conditions at the time the report is made;
- (iii) the description and quantity of any LMO that may be accidentally released or may escape;
- (iv) the measures being taken to minimise the threat of damage that may occur.

(c) Any person who fails to comply with the requirement of sub-section (a) and (b) above, shall be guilty of an offence and liable to the penalties provided in this Act.

**Part VII.**

**BIOTECHNOLOGY RESEARCH AND DEVELOPMENT**

**Article 33. Policy to Promote and Regulate Biotechnology Research and Development.**

(a) The National Biosafety Authority shall coordinate the development of a national policy to promote and regulate research and development in the field of biotechnology.

(b) The formulation of a *Policy to Promote and Regulate Biotechnology Research and Development* shall be initiated no later than two years after this Act comes into force.

(c) The *Policy to Promote and Regulate Biotechnology Research and Development* shall provide the basis for the establishment, promotion, regulation and management of a viable biotechnology research and development capacity in Antigua and Barbuda, and for this purpose shall balance environmental, economic and social development, and provide the guiding principles for any

subsequent legislative framework that is formulated to regulate biotechnology research and development in Antigua and Barbuda.

(d) Upon initiating the formulation of the *Policy to Promote and Regulate Biotechnology Research and Development*, the National Biosafety Authority shall give public notice of the intention to prepare such a policy.

(e) The public notice outlined in sub-section (d) above shall be published in daily newspapers, and shall provide:

(i) a description of the proposed *Policy to Promote and Regulate Biotechnology Research and Development*;

(ii) that submissions on the policy may be made in writing by any person;

(iii) the closing date for submissions, which shall not be earlier than thirty calendar days after public notification; and

(iv) the address where submissions are to be sent.

(f) A copy of the public notice as provided under sub-sections (d) and (e) shall be lodged with the National Biosafety Clearinghouse.

(g) In addition to the placement of any public notice as provided under sub-sections (d) and (e), the National Biosafety Authority shall establish a consultative process with other government ministries, departments or statutory bodies, and with individuals or representatives from local government bodies, community groups, and non-governmental organizations.

(h) After consideration of submissions, the National Biosafety Authority shall develop a draft of the proposed *Policy to Promote and Regulate Biotechnology Research and Development* which shall be subsequently circulated for public review.

(i) The National Biosafety Authority may make changes to the draft *Policy to Promote and Regulate Biotechnology Research and Development* as a result of submissions made during consultations or the public review undertaken pursuant to the requirements of this section.

(j) The *Policy to Promote and Regulate Biotechnology Research and Development* shall, *inter alia*: include details described in ANNEX IV to this Act.

#### **Article 34. Risk Management Measures for Export.**

(a) Upon receiving a permit the person responsible for the export of any LMO shall correctly complete the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land* and other relevant documentation, as required in this act, and shall sign the statutory declaration on the bottom of such documentation.

(b) The person responsible for the export of any LMO shall ensure that:

(i) the shipment is packed, labelled and marked as required in this act;

(ii) the correct shipping name appears on the package and the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*;

(iii) the correct United Nations number appears on the package and the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*.

(c) The person responsible for the export of any LMOs shall ensure that the requirement concerning the export of such organisms, as provided in the permit issued, are fulfilled.



(d) Notwithstanding the provisions of this Part, any transboundary movement of any LMO shall be covered by insurance, bond or other guarantee as may be required or agreed to by the importing State or any State through whose territorial waters the consignment may transit.

(e) It shall be the responsibility of:

(i) the exporter of any LMO, and

(ii) the master of the vessel or aircraft that is exporting any LMOs;

to ensure that, in the case of an accident occurring during the transboundary movement of the LMOs which is likely to present risk to human health and the environment, the responsible authority in the importing and exporting States are immediately notified.

(f) In any instance where an authorised transboundary movement of any LMOs cannot be completed in accordance with the terms of the permit issued, the LMOs are to be returned to the country of export at the expense of the person responsible for the export of the LMOs.

(g) Notwithstanding the provisions of sub-section (f) above, where an authorised transboundary movement of any LMOs cannot be completed within the terms the permit, the person responsible for the export need not re-import such organisms in instances where alternative arrangements can be made for the disposal or use of the organisms in a manner which is compatible with the environmentally sound management of the organisms as specified in the original permit.

(h) Any person who has obtained a permit shall, when change has occurred in:

(i) the matters set forth in any application ;

(ii) the implementation of any conditions included in a permit issued;

immediately, in writing, notify the National Biosafety Authority of such change and provide such additional information as may be requested.

(i) Any person who exports any LMOs in violation of the provisions and requirements of this Part shall be guilty of an offence and liable to the penalties provided in this Act.

### **Article 35. Simplified Application and Review Procedures.**

(a) The Competent Authority may approve a facility, including an installation or other physical structure, for which no further notification is required for designated types or classes of contained use activities conducted in conformity with applicable laws, regulations and good laboratory practice standards. Procedures and requirements for this purpose shall be established by regulation.

(b) The Competent Authority may exempt any LMOs or activities from the requirements of risk assessment where it determines that sufficient experience or information exists to conclude that the LMOs or activities do not pose a significant risk to the conservation and sustainable use of biological diversity, taking also into account risks to human health.

(c) Where sufficient experience or information exists to conclude that LMOs or activities are not likely to pose a significant risk to the conservation and sustainable use of biological diversity, taking also into account risks to human health, but an exemption under paragraph (b) is not warranted, the Competent Authority may designate types or categories of LMOs or activities that may proceed sixty (60) days after the submission of a notification conforming to paragraph (d).

(d) A notification of intent to conduct an activity for which a designation has been made with respect to an activity or LMO under paragraph (c) shall be submitted to the Competent Authority

at least sixty (60) days before the activity covered by the notification is due to begin and shall include:

- (i) The name and contact information for the person submitting the notification;
  - (ii) The location(s) where the activity will be undertaken;
  - (iii) The name and identity of the LMO involved;
  - (iv) The nature and purpose of the activity;
  - (v) A description of any containment measures to be provided and the suitability of those measures for the LMO and activity to be undertaken; and
  - (vi) A description of remedial measures to be undertaken in the event of any unintentional introduction into the environment of the LMO that may occur as a result of the activity to be conducted.
- (e) If the Applicant subject to notification under paragraph (c) receives no response within sixty (60) days of the submission of the notification, the proposed activities may commence.
- (f) The Competent Authority shall publish notice of any proposal to exempt or apply simplified procedures to LMOs or activities under paragraphs (b) or (c) of this Article and transmit the proposal to the SAC for review.
- (g) The Competent Authority shall make a final decision on proposals under paragraphs (b) and (c) based upon the scientific review conducted by SAC and relevant comments submitted by the public. Any such exemptions or simplified procedures established under this Article shall apply equally to the designated LMOs or activities whether undertaken domestically or imported for such purposes.
- (h) The Competent Authority shall exempt from further regulation under this Act LMOs or categories of LMOs agreed pursuant to Article 7(4) of the Cartagena Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity.
- (i) In addition to or instead of the procedures set forth in this Article, the Competent Authority may enter into bi- or multi-lateral agreements to provide for simplified procedures for trade in specified LMOs.
- (j) LMOs or activities exempted or subject to simplified procedures under paragraphs (b), (c), (h) or (i) of this Article or as a result of a successful petition under Article 36 shall be included in the registry.

#### **Article 36. Petition for Exemption or Simplified Procedures.**

- (a) Any person may petition the Competent Authority to exempt or to apply simplified procedures for LMOs or activities under Article 35(b) or (c) at any time.
- (b) Petitions shall contain the following information:
- (i) Name and address of the Applicant;
  - (ii) Name and description of the LMOs or types and classes of LMOs and/or activities for which exemption or simplified procedures are sought;
  - (iii) A comprehensive discussion of the scientific basis for the requested action accompanied by supporting documentation;
  - (iv) Any information known to the Applicant that would be unfavourable to the petition.

(c) Within ten (10) days of receipt, the Competent Authority shall publish the petition and transmit the petition to the SAC for review.

(d) The Competent Authority shall make a final decision on the petition based upon the scientific review conducted by SAC and relevant comments submitted by the public. The final decision may either approve or deny the petition in whole or in part and shall be communicated in writing to the Applicant within one hundred-twenty (120) days of receipt of the petition by the Competent Authority.

### **Article 37. Review of Decisions.**

(a) The Competent Authority, in consultation with SAC, may review any decision made about any LMO at any time upon obtaining significant new scientific information indicating that the LMOs or activities involved may adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health. The Competent Authority shall inform the Applicant of its intent and reasons for initiating a review of the decision prior to undertaking the review.

(b) Any Applicant may request the Competent Authority to review its decision about an LMO with respect to an activity conducted or proposed to be conducted by the Applicant where the Applicant considers that:

(i) A change in circumstance has occurred that may have a material effect on the outcome of the risk assessment upon which the decision was based; or

(ii) Additional scientific or technical information has become available that may have a material effect on the decision including any conditions, limitations or requirements imposed under an authorization.

(c) If, upon review under paragraphs (a) or (b) in consultation with SAC, the Competent Authority finds that a change is warranted, it may issue an order changing the decision and/or the conditions in the authorization in a manner that is consistent with the validated scientific evidence or other accepted scientific methodology.

(d) A written decision, pursuant to a review conducted under paragraph (a), shall be provided to the Applicant by the Competent Authority within ninety (90) days from the date the Applicant is notified of the review and shall set out the reasons for the decision.

(e) A written decision, in response to a request for review under paragraph (b), shall be provided to the Applicant by the Competent Authority within ninety (90) days of the request and shall set out the reasons for the decision.

### **Article 38. Right of Appeal.**<sup>[JP31]</sup>

(a) An Applicant who remains aggrieved following an appeal under paragraph (a) or who does not receive a response within the timeframe stated in paragraph (b) shall have the right to appeal the decision of the Competent Authority to a competent court.

### **Article 39. Monitoring and Submission of New Information.**

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

#### **Article 40. Public Awareness and Participation.**

- (a) The Competent Authority shall promote awareness and education of the public and those conducting activities subject to the Act concerning biosafety matters through the publication and dissemination of this Act and regulations made hereunder, as well as guidance documents and other material aimed at improving understanding of biosafety and related authorization and notification requirements.
- (b) The Competent Authority shall publish, on a regular basis:
  - (i) Notices concerning proposals for transboundary movement of LMOs; and
  - (ii) Proposed decisions on applications and petitions filed for simplified registration of LMOs.
- (c) Upon request, the Competent Authority shall make available to any person portions of any application or petition subject to paragraph (b)(ii) that do not qualify as confidential information.
- (d) Any person may submit written comments on a proposed decision for any application for placing an LMO on the market or any petition for an exemption within sixty (60) days from the date the notice is posted. Such comments shall be considered as part of the decision-making process. Any comments received by the Competent Authority and responses thereto also shall be made available to the public upon request.
- (e) The Competent Authority shall publish notices of final decisions concerning all applications or petitions and notices concerning the final resolution of any compliance matters in cases involving non-compliance with material provisions of this Act.
- (f) The Competent Authority shall establish and maintain a registry of:
  - (i) LMOs for which authorization is granted, including whether the LMO has been authorized for placing on the market; and
  - (ii) LMOs and activities that are exempted or subject to simplified procedures.
- (g) Any regulations proposed under this Act must be published and a period of sixty (60) days allowed for the submission of written comments by any person. Such comments shall be

considered as part of the regulatory process. Any comments received by the Competent Authority and responses thereto also shall be made available to the public upon request.

**Article 41. International Information Sharing.**

(a) The Competent Authority shall notify the Biosafety Clearing House that its domestic regulations shall apply with respect to any imports of LMOs to the area of national jurisdiction of Antigua and Barbuda.

(b) The Competent Authority shall provide to the Biosafety Clearing House:

- (i) A copy of this Act, including any amendments, decisions, or regulations promulgated hereunder, and any other legislation or national guidelines of relevance to the implementation of the Cartagena Protocol or the management of LMOs;
- (ii) Summaries of risk assessments generated;
- (iii) Final decisions regarding the importation or intentional introduction into the environment of LMOs;
- (iv) Reports concerning national implementation of the Cartagena Protocol in accordance with Article 33 of the Protocol;
- (v) Within thirty (30) days of taking a decision, a copy of the decision describing the changes to the previous decision and the reasons for the decision; and
- (vi) Any other information required under the Cartagena Protocol or other international agreements concerning the subject matter addressed by this Act.

(c) Where the Competent Authority renders a final decision regarding domestic use, including placing on the market, of an LMO that may be subject to export for direct use as food or feed or for processing, it shall ensure that information concerning the authorization of that LMO, as specified in Annex III, is provided to the Biosafety Clearing House established under the Cartagena Protocol within fifteen (15) days of making the decision.

**Article 42. Documentation for LMOs Intended for Intentional Introduction into the Environment.**

(a) LMOs that are imported into or exported from Antigua and Barbuda for intentional introduction into the environment must be accompanied by documentation that:

- (i) Clearly identifies them as LMOs;
- (ii) Specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and
- (iii) Contains a declaration that the movement is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.

(b) Any additional documentation or identification requirements applicable to imports or exports subject to paragraph (a).

**Part VIII.**

## **ENFORCEMENT AND COMPLIANCE**

### **Article 43. Inspections at Ports of Entry or Exit.**

(a) Every person in possession of any LMO as part of his or her personal effects or baggage, shall on arrival in or departure from Antigua and Barbuda, declare such possession to the Customs Officer on duty at the port of entry or exit, and shall:

- (i) permit such officer to inspect and examine any LMO in their possession;
- (ii) afford all reasonable facilities and assistance in carrying out any inspection and examination of any LMO; and
- (iii) produce all permits or relevant documents in respect of the LMO.

(b) Where any person is found to be in possession of any organism that a Customs Officer has reasonable cause to believe or suspect may be a LMO and for which there is no valid permit, that person shall surrender such organism to the officer.

(c) Any person who fails to comply with any of the requirements of sub-sections (a) and (b) above, shall be guilty of an offence and liable on conviction to the penalties provided under this Act.

(d) Any organism surrendered to a Customs Officer pursuant to the requirements of sub-section (b) above shall be immediately conveyed to the National Biosafety Authority.

(e) Should any organism surrendered to a Customs Officer pursuant to the requirements of sub-section (b) above be determined by the National Biosafety Authority not to be a LMO, such organism shall forthwith be released to the person who surrendered the specimen.

(f) Any person who has surrendered an organism pursuant to the provisions of sub-section (b) above, may apply for a permit to export LMO.

### **Article 44. Confiscation of LMOs.**

(a) Where a Customs Officer or inspector finds any LMO

- (i) in or on any ship or aircraft;
- (ii) at any port of entry or exit; or
- (iii) within any parcel, container, packing case, crate, box or package intended for import, export or transshipment,

and which is being transported otherwise than in accordance with the provisions of this Act, the LMO shall be seized and forfeit to State by the Customs Officer or authorised agent, and thereafter delivered into the custody of the Secretariat of the National Biosafety Authority.

(b) Any officer or inspector agent seizing any LMO pursuant to the provisions of sub-section (a) above, may also seize:

- (i) any container, packing case, crate, box, or other form of receptacle holding such LMO; and
- (ii) any thing which the officer has reason to believe may be used as evidence of a breach of the provisions of this Act,

provided that the owner of the items seized under this sub-section may apply to the National Biosafety Authority for the return of any seized item that is not required for evidentiary purposes.

(c) Where the seizure and confiscation of any living modified organism has been ordered, the National Biosafety Authority shall ensure that the organism is properly cared for and housed in



such a fashion such as to minimise the risk of harm to Antigua and Barbuda natural biodiversity, the environment or human health.

(d) Where the confiscation of any illegally imported LMO has been ordered, the National Biosafety Authority may, after consultation with the State where the specimen was obtained, return the LMO at the expense of such State. [JG32]

(e) In any case where a LMO has been seized pursuant to the provisions of sub-section (a) above, and:

(i) the owner cannot be determined; or

(ii) the specimen may die, rot, spoil or otherwise perish,

the Secretariat of the National Biosafety Authority may dispose of the LMO as if it was forfeited to State.

(f) All costs and expenses of and attendant upon any disposal, housing, safe-keeping, or re-export of any LMO that has been seized shall be borne by the owner or the person who had possession thereof, and shall be recoverable from him or her as a debt due to the State, and no compensation shall be payable in respect of such seizure.

## **PART IX. ENFORCEMENT**

### **Article 45. Enforcement. [JG33]**

(a) The Competent Authority may appoint as inspectors such number of persons appearing to him to be qualified for the purposes of ensuring compliance with the Act and its regulations.

(b) The powers of an inspector are, at any reasonable time (or, in a situation in which in the inspector's opinion there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking also into account risks to human health, at any time):

(i) to enter premises, including but not limited to a facility, vessel or property, which the inspector has reason to believe it is necessary for him to enter and to take with him any person duly authorized by the Competent Authority; and

(ii) to take with him any equipment or materials required for any purpose for which the power of entry is being exercised.

(iii) to carry out such tests and inspections (and to make such recordings), as may in any circumstances be necessary;

(iv) to direct that any, or any part of, premises which he has power to enter, or anything in or on such premises, shall be left undisturbed (whether generally or in particular respects) for so long as is reasonably necessary for the purpose of any test or inspection;

(v) to take samples of any organisms, articles or substances found in or on any premises which he has power to enter, and of the air, water or land in, on, or in the vicinity of, the premises;

(vi) in the case of anything found in or on any premises which he has power to enter, which appears to him to contain or to have contained LMOs which have adversely affected or are likely to adversely affect the conservation and sustainable use of biological diversity,

taking also into account risks to human health, to cause it to be dismantled or subjected to any process or test (but not so as to damage or destroy it unless this is necessary).

(c) in the case of anything mentioned in subparagraph (iv) above or anything found on premises which he has power to enter which appears to be a LMO or to consist of or include LMOs, to take possession of it and detain it for so long as is necessary for all or any of the following purposes, namely: [JG34]

- (i) to examine it and do to it anything which he has power to do under that subparagraph;
- (ii) to ensure that it is not tampered with before his examination of it is completed; and
- (iii) to ensure that it is available for use as evidence in any proceedings for an offence;
- (iv) to require the production of, or where the information is recorded in computerised form, the furnishing of extracts from, any records which are required to be kept under this Act or it is necessary for him to see for the purposes of any test or inspection under this Article and to inspect, and take copies of, or of any entry in, the records;
- (v) to require any person to afford him such facilities and assistance with respect to any matters or things within that person's control or in relation to which that person has responsibilities as are necessary to enable the inspector to exercise any of the powers conferred on him by this Article;
- (vi) such other powers as may be necessary for the purposes mentioned in paragraph (a) above which is conferred by regulations made by the Competent Authority.

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

#### **Article 46. Offences and Penalties.**

(a) Any person who contravenes or fails to comply with any condition, restriction, prohibition, reservation or directive imposed or issued in terms of this Act;

(i) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties in terms of this Act or refuses to furnish information as required in terms of this Act to the Secretariat or the National Biosafety Board;

(ii) refuses or fails to furnish information or give an explanation or to reply to the best of his or her ability to a question lawfully demanded from or put to him or her by any inspector in the performance of his or her functions in terms of this Act, or furnishes information, an explanation or a reply to any inspector which is false or misleading, knowing that it is false or misleading; or [JG35]

(iii) falsely holds himself or herself out to be an inspector or any other officer appointed in terms of this Act, shall be guilty of an offence.

(b) A person who exports or imports any LMO in contravention of any requirement or condition specified under the Act, is guilty of an offence and liable upon conviction to a fine of not more than \$???? or to imprisonment for a period of not less than ??? months, or to both such fine and imprisonment;

(c) A person who knowingly, intentionally, or with reckless disregard to human health, safety or the environment

- (i) releases any LMO that results in harm to human health or safety, or severe damage to Antigua and Barbuda's natural biodiversity or the environment;
  - (ii) permits or participates in the transboundary movement of any LMO that results in harm to human health or safety, or severe damage to the environment;
  - (iii) is guilty of an offence and liable upon conviction to a fine of not more than \$???? or to imprisonment for a period of not less than ??? years, or to both such fine and imprisonment.
- (d) Any person convicted of an offence under the Act and not provided under sub-sections (b) and (c), shall-
- (i) on a first conviction be liable to a fine of \$???? or to imprisonment for a period not exceeding ??? months; and
  - (ii) on a second or subsequent conviction be liable to a fine of \$???? or to imprisonment for a period not exceeding ??? months.
- (e) Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty or make any order prescribed by this Act.

#### **Article 47. Limitation Period for Offences.**

A prosecution for an offence under this Act may not be commenced more than three years after:

- (a) the date on which the offence was committed; or
- (b) the date on which evidence of the offence first came for the attention of the Secretariat to the National Biosafety Authority, or any regulatory agency, whichever is the later.

#### **Article 48. Continuing Offence.**<sup>[JG36]</sup>

Where an offence under this Act is committed or continues on more than one day, the person who committed the offence is liable to be convicted for a separate offence for each day on which the offence is committed or continues.

#### **Article 49. Additional Penalties.**

Where an offender has pleaded guilty to, or been convicted of an offence, the court may, in addition to any other punishment that may be imposed under this Act, having regard to the nature of the offence and the circumstances surrounding its commission, make an order-

- (a) prohibiting the offender from doing any act or engaging in any activity that may result in the continuation or repetition of the offence;
- (b) directing the offender to take such action as the court considers appropriate to remedy or avoid any harm to the environment or human health that results or may result from the act or commission that constituted the offence;
- (c) directing the offender to post such bond or pay such amount of money as may be necessary to recover charges associated with any inspection, audit or investigation undertaken in respect of the offence;
- (d) directing the offender to post such bond or pay such amount of money as will ensure compliance with any order made pursuant to this section;
- (e) directing the offender to compensate any affected party, in whole or in part, for any

environmental damage or harm to human health or the cost of any remedial or preventative action taken or caused to be taken as a result of the act or omission that constituted the offence;

(f) directing the seizure and forfeiture of any vessel, aircraft, or vehicle used in the commission of any offence;

(g) requiring the offender to comply with such other reasonable conditions as the court considers appropriate and just in the circumstances.

#### **Article 50. Employee Protection.**

(a) No employer shall:

- (i) dismiss or threaten to dismiss an employee;
- (ii) discipline or suspend an employee;
- (iii) impose a penalty on an employee;

because the employee has reported or proposes to report to any person an act or omission that contravenes, or that the employee has reasonable grounds to believe may contravene this Act.

(b) Any employer who commits any act specified in subsection (a) is guilty of an offence and liable upon conviction to a fine of not more than \$???? or to imprisonment for a period of ??? months, or to both such fine and imprisonment.

#### **Article 51. Civil Claims for Environmental Damage.**

Notwithstanding the results of any criminal proceedings arising under this Act, the Secretariat to the National Biosafety Authority, or a person who has suffered loss or harm as a result of any release of LMO may institute a civil claim for damages in any court, which may include a claim for:

- (a) economic loss resulting from the release of LMOs or from activities undertaken to prevent, mitigate, manage, clean up or remediate any harm from such release;
- (b) medical costs and loss of earnings associated with any human health impact;
- (c) loss of earnings arising from damage to any natural resource;
- (d) loss to, or of any natural environment or resource;
- (e) costs incurred in any inspection, audit or investigation undertaken to determine the nature of any release of LMO, or to investigate response and risk management options.

#### **Article 52. Liability of Corporations and Corporate Directors.**<sup>[JG37]</sup>

(a) Where a corporation commits an offence under this Act, any officer, director, employee or agent of the corporation who directed, authorised, assented to, acquiesced in or participated in the commission of the offence is a party to and guilty of the offence, and is liable to the punishment provided for the offence, whether or not the corporation has been prosecuted or convicted.

(b) A corporation that:

- (i) has caused or contributed to any release of LMO; or
- (ii) owns, manages, or exercises control over any facility or land that has caused or contributed to any release of LMO,

may, in addition to any penalty that may be imposed under this Act or regulations, be liable to a claim for civil damages.

### **Article 53. Corporate Liability in Case of Bankruptcy.**

Where any corporation commits an offence under this Act, any penalty or award of damages against that corporation shall take precedence over any secured or preferred claim lodged in any action for bankruptcy against that corporation.

### **Article 54. Proof of Offence.**

Where the inspection report of the inspector or person carrying out any inspection pursuant to the requirements of this Act, verifies that:

- (i) the condition of the facility or its equipment; or
- (ii) the risk management measures,

do not substantially meet the requirements of this Act or Regulations, or the conditions of any permit issued under the Act, and there are clear grounds for believing that the facility has caused any release of LMO, such report shall be admissible in evidence as *prima facie* proof of the commission of the offence, and the burden of proving, on a balance of probabilities, that the facility has not caused the release shall be upon the owner or person in charge of the facility.

### **Article 55. Procedural Aspects.**

(a) In any prosecution of an offence under this Act it is sufficient proof of the offence to establish that it was committed by an employee or agent of the accused, whether or not the employee or agent is identified or prosecuted for the offence.

(b) A certificate of an analyst stating that the analyst has analysed or examined an organism or substance and stating the result of the analysis or examination is admissible in evidence in any prosecution for an offence under this Act and, in the absence of evidence to the contrary, is proof of the facts contained in the certificate.

(c) Notwithstanding the provisions of subsection (b), the party against whom a certificate of an analyst is produced may, with the leave of the court, require the attendance of the analysts for the purposes of cross-examination.

(d) No certificate of an analysts shall be received in evidence unless the party intending to produce it has given to the party against whom it is intended to be produced reasonable notice of that intention together with a copy of the certificate.

### **Article 56. Enforcement.**

(a) Any person may institute an action before a competent court to compel any ministry, department or statutory agency to undertake any function, action or responsibility that it is lawfully empowered to do under the powers conferred by this Act or Regulations.

(b) It is a condition of every approval, permit, or licence issued under this Act that the holder shall permit inspectors to carry out inspections authorised pursuant to this Act of any place, other than residential premises, to which the approval, permit or licence relates.

(c) An inspector, officer or any person empowered to carry out any duty under this Act may not enter private residential premises except:

- (i) with the consent of the owner; or

- (ii) pursuant to the authority of any search warrant issued under subsection (4).
- (d) Where a Judge is satisfied on evidence under oath by an environmental inspector, officer or any person empowered to carry out any duty under this Act that:
- (i) there are reasonable grounds to believe that an offence under this Act or regulations has been committed; and
  - (ii) the inspector, officer or any person empowered to carry out any duty under this Act may not be able to carry out duties under this Act effectively without a search warrant issued under this section because:
    - (i) the premises to be inspected is a private residence and the consent of the owner has not, or cannot be obtained;
    - (ii) no person is present to grant access to a place that is locked or is otherwise inaccessible;
    - (iii) a person has denied the inspector or administrator access to a place or there is reasonable ground for believing that a person may deny the inspector or officer access to a place;
    - (iv) a person has prevented the inspector, officer or any person empowered to carry out any duty under this Act from doing anything lawfully permitted under the Act;
    - (v) it is impractical, because of the remoteness of the place to be inspected or because of other reason, for the inspector, officer or any person empowered to carry out any duty under this Act to obtain an order under this sub-section without delay if access is denied;
    - (vi) there are reasonable grounds to believe that an attempt by the inspector, officer or any person empowered to carry out any duty under this Act to do anything set out in this Act without the order might defeat the purpose of the inspection or cause an adverse effect,
- the justice may issue an order authorising the inspector, officer or any person empowered to carry out any duty under this Act to do anything that is set out in the order, for the period of time set out in such order.
- (e) An inspector, officer or any person empowered to carry out any duty under this Act may, without a court order or a search warrant, seize anything that is produced, or that is in plain view during an inspection under this section, if the inspector, officer or any person empowered to carry out any duty under this Act has reasonable grounds to believe that there has been an offence committed under this Act and that the thing to be seized will afford evidence as to the commission of the offence.
- (f) In seizing any article under the provisions of subsection (d), the inspector, officer or any person empowered to carry out any duty under this Act shall:
- (i) inform the person in possession of the article of the reason for the seizure;
  - (ii) give the person in possession of the article a receipt for the article that has been seized; and
  - (iii) remove the seized article to a place of safekeeping and deal with the seized article in the same manner as if it were seized pursuant to the authority of a search warrant.

(g) Any person who violates a material provision of this Act or fails to comply with a Cessation Order or regulation issued pursuant to this Act shall be guilty of an offence and shall be liable, upon a conviction or finding of violation by a competent court of law or a duly appointed administrative body, for such fines as may be set by regulation, consistent with those established for violations of similar legislation or regulations, including additional penalties for each day that the offence is continued after legal service of a Cessation Order upon that person.

(h) Any person who repeatedly and knowingly commits offences and is found to be in violation by a competent court of law or duly appointed administrative body under paragraph (a) for such offences may be prohibited from engaging in any further activities subject to this Act.

#### **Article 57. Liability and Redress.**

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

### **PART X. IMPLEMENTATION MEASURES**

#### **Article 58. Regulations.**

(a) Consistent with the objective and scope of this Act, the Competent Authority shall propose and, after public notice and an opportunity for public comment, finalize and publish such regulations as may be necessary for implementing the provisions of this Act.

(b) The Competent Authority shall publish a schedule of fees to cover administrative costs of processing notifications, applications and petitions submitted under this Act.

#### **Article 59. Transitional Provisions.**

(a) Any application pending at the date of the entry into force of this Act shall be subject to the provisions of this Act.

(b) Activities that were ongoing at the date of the entry into force of this Act shall be permitted to continue but shall be subject to the review procedure set forth in this act. [JP38]

#### **Article 60. Review of Act.**

(a) This Act and its regulations shall be reviewed in light of technical and scientific advances and for the purpose of improving the effectiveness of its operation every five years.

(b) Review of the Act and its regulation shall include notice to the public of the review process and an opportunity for the public to comment on proposed changes.

#### **Article 61. Regulations.**

(a) The Minister may make regulations to give effect to any provision of this Act, and in particular and without prejudice to the generality of the foregoing, for all or any of the following:

(i) the application and approval of, and other matters relating to the import, release, contained use, intentional release, placing on the market, of any genetically modified

- organism;
- (ii) designating any organism to which this Act applies;
  - (iii) for the variation of any risk management regime as provided in this Act;
  - (iv) establishing criteria for accreditation or approval of any biotechnology research facility;
  - (v) establishing the storage, handling, and laboratory practices of any biotechnology research facility;
  - (vi) prescribing fees, costs, or expenses for any approvals, risk assessments, investigations, inspections, enforcement done under the Act;
  - (vii) prescribing the labelling, identification, packaging requirements of any LMO;
  - (viii) respecting the format or contents of any permit;
  - (ix) to give effect to any *Policy to Promote and Regulate Biotechnology Research and Development*;
  - (x) prescribing information to be contained in an order to stop work on any development activity or undertaking;
  - (xi) prescribing the procedures for appeal in accordance with this Act; and
  - (xii) with respect to any matter necessary to carry out the intent and purpose of this Part of this Act.
- (b) The Minister may make regulations for carrying into effect the purposes and provisions of this Act and, without prejudice to the generality of the foregoing, for research on, experimentation, importation, exportation, contained use, or release of LMO(s), combinations of LMOs and products thereof.
- (c) Regulations made under this section may without prejudice to the generality of the power conferred by subsection (a) provide for:
- (i) the form and content of applications for experimentation, importation, exportation, contained use, or release of LMO(s), combinations of LMOs and products thereof;
  - (ii) the granting, suspension and refusal, and the duration, of authorizations and licenses under this Act, or regulations and rules made thereunder;
  - (iii) the transport, storage, handling and laboratory practices in relation to LMO(s), combinations of LMOs, or products thereof;
  - (iv) the amount of fees, charges, cost and/or expenses to be imposed and or levied under this Act for granting of license and/or authorization, approval, risk assessment, risk management, investigations, supervision, enforcement and control done under this Act, or regulations and rules made thereunder;
  - (v) the prescription of criteria, parameters or standards for risk assessment and risk management or for such matter required to be done under this Act, or regulations and rules made thereunder;
  - (vi) the form and manners of labeling, identification, packaging of LMO(s) or combinations of LMOs or products thereof;
  - (vii) the form and manner under which simplified procedures may be implemented for certain LMOs with which there is extensive experiment and knowledge or which have been deemed to be at low risk;



(viii) any matter which by this Act is authorized or required or permitted to be prescribed or which is necessary or expedient to be prescribed for carrying this Act, or any regulation and rule made there under, into effect.

## **Part XI.**

### **MISCELLANEOUS AND SUPPLEMENTARY**

#### **Article 62. Other Enactments Apply.**

This Act does not exempt any person, whether or not an approval has been granted under the provisions of this Part, from the requirements imposed by any other law.

#### **Article 63. Commencement.**

This Act shall come into force on the day of its publication in the Gazette.

#### **Article 64. Effective Date.**

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

## **ANNEXES**

Annex I: Information Required in Applications

Annex II: Risk Assessment

Annex III: Information Requirements for Notices to the Biosafety Clearing House

Annex IV: Policy on Promotion and Regulation of Biotechnology Research and Development

Annex V: Accidents

Annex VI: storage and handling and transportation requirements

### **Annex I:**

#### **Information Required in Applications**

1. Name, address and contact details of the exporter.
2. Name, address and contact details of the importer.
3. Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
4. Intended date or dates of the transboundary movement, if known.
5. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
6. Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
7. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
8. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

9. Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
10. Quantity or volume of the living modified organism to be transferred.
11. A previous and existing risk assessment report consistent with Annex II.
12. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal<sup>[UG39]</sup> and contingency procedures, where appropriate
13. Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.
14. Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
15. A declaration that the above-mentioned information is factually correct.

SUGGESTION: SUPPORTING INFORMATION (E.G., RISK ASSESSMENT REPORT) TO BE PROVIDED DIGITALLY ALONG WITH A HARD COPY. A DETERMINATION NEEDS TO BE MADE REGARDING THE PREFERRED FORMAT FOR PROVISION OF INFORMATION.

## **Annex II:**

### **Risk Assessment**

#### **Objective**

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

#### **Use of risk assessment**

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

#### **General principles**

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

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

### **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.

### **Annex III:**

#### **Information Requirements for Notices to the Biosafety Clearing House**

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

### **ANNEX IV:**

#### **(i). *Policy to Promote and Regulate Biotechnology Research and Development***

- (a) establish the Government of Antigua and Barbuda's overall policy objectives in the field of biotechnology research and development, and identify policy directives to achieve these objectives;
- (b) establish standards and procedures to manage and regulate research and development in the field of biotechnology;
- (c) establish standards and operational procedures for facilities engaged in biotechnology research and development and the deliberate release of genetically modified organisms;
- (d) identify methods by which biotechnology research and development and the deliberate release of genetically modified organisms are to be managed;

- (e) identify methods by which genetically modified organisms are to be regulated, controlled and managed so as to support biotechnology research and development in Antigua and Barbuda, including methods to regulate any deliberate release of LMOs;
- (f) establish standards and procedures for the registration and accreditation of facilities for biotechnology research and development in Antigua and Barbuda and within the CARICOM region;
- (g) establish procedures for the safe management, control and eventual disposal of any residue or waste from any facilities for biotechnology research and development in Antigua and Barbuda; and
- (h) identify suitable enforcement mechanisms and appropriate mechanisms to ensure the implementation of the policy, including where appropriate, the use of economic instruments,

and as such shall provide the basis for all sound planning, management and decision making.

**(ii).** The *Policy to Promote and Regulate Biotechnology Research and Development* formulated under the provisions of this Act, shall contain the following:

- (a) an inventory of biotechnology research and development facilities and programs in Antigua and Barbuda;
- (b) an evaluation of historic, current or proposed activities that impact upon the promotion of biotechnology research and development in Antigua and Barbuda and the CARICOM region;
- (c) an evaluation of environmental, trade, economic development, social and human health policies that may impact upon the promotion of biotechnology research and development in Antigua and Barbuda and the CARICOM region;
- (d) an implementation programme outlining mechanisms, programmes, policies, and strategies that are to be established to ensure that biotechnology research and development is carried out in such a manner so as not to adversely impact human health or the carrying capacity of Antigua and Barbuda's natural resources;
- (e) a statement outlining the principle reasons for adopting the objectives and policies of the *Policy to Promote and Regulate Biotechnology Research and Development* and implementation programme;
- (f) a review of the social, environmental and economic impacts of the *Policy to Promote and Regulate Biotechnology Research and Development* and implementation programme;
- (g) mechanisms that are to be employed to manage or mitigate any undesirable social, environmental or economic impact of the policy; and
- (h) mechanisms that are to be employed to monitor and manage the implementation of the *Policy to Promote and Regulate Biotechnology Research and Development* and to ensure its periodic review.

**(iii).** **Approval and Enforcement of Policy on Biotechnology Research and Development**

- (a) The *Policy to Promote and Regulate Biotechnology Research and Development* formulated under the provisions of this Act shall be submitted for approval to the Minister responsible for Environment.
- (b) Upon receipt of the *Policy to Promote and Regulate Biotechnology Research and Development* pursuant to the provisions of sub-section (a) above, the Minister may:
  - (i) refer the Policy to the National Biosafety Board with such recommendations as may be considered necessary to correct any deficiency in the Policy; or
  - (ii) approve the Policy, which approval may contain such **modifications**[JG40] as the Minister considers desirable to give effect to the requirements of this Act.
- (c) Upon approval by the Minister, the *Policy to Promote and Regulate Biotechnology Research and Development* shall be submitted to Cabinet for review and consideration.
- (d) Upon approval by Cabinet, every government ministry, department or statutory body shall observe, and to the extent of its authority, enforce the observance of the *Policy to Promote and Regulate Biotechnology Research and Development*.

### **Orders May Be Made To Implement Policy**

- (iv) The *Policy to Promote and Regulate Biotechnology Research and Development* shall establish the basis for maintaining and protecting Antigua and Barbuda's natural biodiversity, environmental quality and human health, and the Minister may, by Order published in the Gazette, specify requirements to be observed for carrying into effect any aspect of the policy.

## **ANNEX V:**

### **National Accidental Release of Living Modified Organisms Risk Management Plan**

(1)[JG41]

- (a) assess the risk of harm to Antigua and Barbuda's natural biodiversity, the environment or human health that could be caused through an accidental release of living modified organisms under normal conditions and in the case of conceivable types of accidents, as well as the probability of such accidents;
- (b) evaluate what effect the accidental release of any living modified organism have in both the short and long term, in particular it shall be determined how the accidental release will affect use of the natural environment, and the class of activity that will be particularly exposed to the adverse effects from the accidental release;
- (c) detail an organizational plan with precise description of responsibilities and reporting requirements, and the responsibility of individuals in the event of an incident of an accidental release of any living modified organism, or any occurrence or emergency likely to result in significant harm to Antigua and Barbuda's natural biodiversity, the environment or human health;
- (d) inventory a plan of equipment to be utilized for:
  - (i) the discovery, prevention, and abatement, or control of an accidental release of any living modified organism;

- (ii) responding to an actual accidental release of any living modified organism;
  - (iii) the removal of any recovered living modified organism, and the restoration of the natural environment to the state before any accidental release had occurred;
- with a precise description of the nature and type of equipment, its capacity, location, transportation method, correct usage and area of use;
- (e) describe the operational action plan to be deployed, with a precise description of alarm and communications systems, including those required for:
- (i) notifying the appropriate member [JG42] of the Accidental Release Control Group;
  - (ii) determining the roles and responsibility of every member of the accidental release response team;
  - (iii) determining when and in what manner emergency equipment is to be used;
  - (iv) determining the method and measures to be employed to respond to an accidental release;
  - (v) determining the measures for limiting the extent of damage from the accidental release; and
  - (vi) documenting the response and initiating any follow-up action.
- (2) The Accidental Release Control Group shall undertake such action as may be necessary to achieve the required contingency preparedness.
- (3) The accidental release emergency preparedness, shall ensure:
- (a) that any living modified organisms from any accidental release is efficiently collected near the source as quickly as possible; and
  - (b) the initiation of effective measures to combat any accidental release which is threatening Antigua and Barbuda's biodiversity.
- (4) The Accidental Response Commander shall:
- (a) co-ordinate emergency preparedness and response activities, and for this purpose shall react with all available resources according to the *National Accidental Release of Living Modified Organisms Risk Management Plan* as well as with any regional or international risk management program established under the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*; and
  - (b) establish such communications within Antigua and Barbuda's emergency preparedness organizations as are necessary to ensure efficient administration and control of all emergency preparedness resources when any accidental release of living modified organisms has occurred.
- (5) All established technical, operational and organizational measures that constitute the emergency preparedness of the *National Accidental Release of Living Modified Organisms Risk Management Plan* shall be maintained by the Accidental Release Control Group in a state of effective emergency preparedness, and for this purpose regular training shall be carried out to ensure a totally effective mobilization of all emergency preparedness resources, equipment and personnel.

(6) Contingency and response measures implemented when an accidental release of living modified organisms has occurred, shall be documented with a view to accident investigation and the settlement of claims for damage.

### **Response in Events of Accidental Release of LMOs**

**7.**

Upon the receipt of any report involving an accidental release of any living modified organism, or where any accidental release of such organism has come to the attention of the Accidental Release Commander, he shall immediately notify every member, and convene the Accidental Release Control Group.

- (i) The Accidental Release Commander may excuse any member from attending any meeting of the Accidental Release Control Group when his or her presence is not required, subject to the provisions that the representative from the Environment Department does not have the right to withdraw. [JG43]
- (ii) Upon being convened in terms of sub-section (i) above, the Accidental Release Control Group shall:-
  - (a) assess the nature and source of the accidental release;
  - (b) evaluate the potential for harm or damage to any industry, activity, human health, the environment or the economy of Antigua and Barbuda;
  - (c) initiate whatever action may be necessary to respond to the accidental release, including measures to remedy the situation, prevent or reduce any damage, and where necessary co-ordinate the deployment of available personnel and equipment for this purpose;
  - (d) document and record all matters necessary to facilitate cost recovery and the payment of compensation.

**8.** Action initiated by the Accidental Release Control Group in response to an accidental release involving the risk to human life shall ensure, as a priority, that:

- (a) any person having sustained injury is given necessary first aid and is brought to a safe area for treatment; and
- (b) measures to reduce further harm to human health shall be established based on prevailing conditions.

**9.** Where the Accidental Release Commander may consider it necessary, he may appoint an on-site commander, with delegated authority to:

- (a) determine any imminent and substantial threat to public health, safety of the environment from an actual or threatened accidental release of living modified organisms; and
- (b) initiate and co-ordinate the emergency response measures necessary to control any actual or threatened accidental release of living modified organisms.



**10.** Where necessary for the performance of his duties as provided under this Part, the Accidental Release Commander, or any on-site commander appointed in terms of sub-section (5) above, may board and inspect any vessel in Antigua and Barbuda's waters, and may with or without warrant, arrest any person who in his presence or view violates any provisions of this Act or any regulation issued thereunder.

## **ANNEX VI:**

### **1. Labelling**

(a) During transport, import or export each package shall be clearly labelled in English as containing living modified organisms.

(b) The labelling shall also state the species of organism and the name, address and telephone number of both the sender and the recipient.

(c) Any label affixed in accordance with the provisions of sub-section (a) and (b) above must be positioned in the following manner:

(i) on cartons and boxes - at least one label on the side or end;

(ii) on drums and similar containers - at least one label on the side on the upper half;

(iii) on jerricans and similar containers - at least one label on one of the largest surfaces;

(iv) on gas cylinders and small pressure vessels - at least one label positioned near or on the shoulder, and for larger cylinders and pressure vessels where the size or slope makes the label difficult to read a second label should be positioned on the opposite sides of the container;

(v) on pallet loads and open-top containers - except where the class label on the packaging is clearly visible, the label or labels should be positioned in the upper half of each of the two opposite sides of the load, and where the pallet contains a mixed load then all class labels must be placed on both sides.

(d) Every label affixed under the provisions of sub-section (c) above shall be in such a manner that when the LMOs are transported the nature of the consignment is readily recognisable.

### **2. Packaging of Living Modified Organisms**

(a) The packaging of all LMOs shall be –

(i) impervious to both spores and pollen;

(ii) watertight, sealed and fracture-proof, so as to prevent any unintentional leakage of the contents.

(b) There shall always be an inner and an outer container, which shall both be waterproof.

(c) Between the inner and the outer container, there shall be fluid-absorbent material capable of absorbing a quantity of fluid equivalent to that in the container.

(d) If two or more inner containers are carried in the same outer container:

(i) each inner container shall be separately packaged in shock-absorbent and fluid-absorbent material;

- (ii) the outer container shall be watertight, sealed, fracture proof, etc. so as to prevent any unintentional leakage of the contents.

### **3. Documents to Accompany the Transport of LMOs**

All LMOs that are transported, imported, or exported shall be accompanied by the permit issued under this act, which shall at all times be available for inspection by an inspector.

In addition to any delivery slips or invoices that are required for the commercial transaction, the following documents must accompany genetically modified organisms in transit:

- (a) a *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*, which shall:
  - (i) bear a declaration signed by the person who offers the genetically modified organisms for transportation indicating that the goods are fully and accurately described by their proper shipping names and that they are classified, packed, marked, labelled and in proper condition for transport in accordance with the provisions of, where appropriate, the Code or this Part; and
  - (ii) contain, *inter alia*, the following particulars for each individual living modified organism, and in the following order:
    - (i) the Proper Shipping Name;
    - (ii) the Class or organism;
    - (iii) where applicable, the United Nations Number;
    - (iv) the packaging group;
    - (v) the number and type of packages and the total quantity covered by the description;
    - (vi) Additional Handling Information, including the control and emergency temperatures and any other information necessary to ensure that the substance will be segregated correctly and to indicate and additional precautions that must be taken under special circumstance;
    - (vii) the delivery addresses of the consignor and consignee, and contact phone numbers where available.
- (b) a *Consolidated Packing Certificate for Dangerous Goods*, containing information about the packing of the living modified organism goods, except for goods carried in bulk;
- (c) a *Load Plan*, stating where the living modified organisms are located on the ship, aircraft or vehicle, which must be signed by the person loading the goods; and
- (d) an *Emergency Procedures Guide*, providing information concerning emergency procedures that are to be employed in the event of any accidental release or other emergency.
- (e) The documents referred to in sub-section (a) and (b) above must have a characteristic striped border, in red and white.

### **4. Segregation**

- (a) Living modified organisms that are imported or exported by sea or air, which could react or interfere with each other, must be segregated according to the requirements of the Code.

(b) Living modified organisms transported on any road which could react or interfere with each other, must be secured and segregated according to the provisions of section ?? below.

(c) Any person who transports any living modified organism that has not been segregated in compliance with the requirements of sub-sections (a) and (b), shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.

## **5. Importation by Sea**

(1) Where any living modified organism is to be imported into Antigua and Barbuda by sea, the owner or master of the vessel shall, at least 48 hours before the living modified organisms are to be landed, or if this is not practicable, as soon as practicable thereafter, give written notice to the Port Authority at the port in which the living modified organism is to be landed.

(2) The written notice given in compliance with the provisions of sub-section (1) above shall specify:

- (i) the identity of every living modified organism;
- (ii) where applicable, the number on the container transporting the living modified organism;
- (iii) the quantity of each the living modified organism being imported;
- (iv) the vessel on which each the living modified organism is to be carried to Antigua and Barbuda;
- (v) the seaport at which the vessel is to arrive;
- (vi) the estimated time and date of arrival of the vessel; and
- (vii) any special cargo transportation or storage requirements pertaining to any the living modified organism aboard the vessel that is to be imported into Antigua and Barbuda.

(3) The shipping agent for the vessel that will carry the living modified organism to Antigua and Barbuda shall, at least two working days prior to the vessels arrival, lodge with the Port Authority and the National Biosafety Authority a copy of the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*, or where appropriate, the *Dangerous Goods Declaration*.

(4) On receipt of the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*, the Port Authority shall:

- (a) confer with the National Biosafety Board to verify accuracy with any permit issued under section (26) (1); and thereafter:
- (b) allocate transit or storage areas according to the classification and criteria stipulated in the document and shall advise the responsible shipping agent of the allocated location.

(5) The master of any vessel arriving at any controlled area shall surrender to the shipping agent all original *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land* pertaining to any living modified organism aboard the vessel that is to be imported into Antigua and Barbuda.

(6) Upon receipt of the original *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*, the shipping agent shall, before any living modified organism is discharged:

- (i) hand the documents to the stevedore responsible for unloading the vessel; and
- (ii) where appropriate, discuss with the stevedore any special cargo requirements.

(7) It shall be the responsibility of the stevedore to take all appropriate precautions when unloading any living modified organism, and to-

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- (i) ensure that the living modified organisms are stowed in the transit or storage areas allocated by the Port Authority under the provisions of any permit issued under this Act, or according to the classification and criteria stipulated in the permit; and
  - (ii) place all documentation pertaining to the living modified organism in a location adjacent to where the organisms are to be stored within the controlled area.
- (8) The Port Authority shall, in consultation with the National Biosafety Board, issue guidelines and codes of practice concerning:[JG44]
- (a) the storage and management of living modified organism in a controlled area;
  - (b) the establishment of emergency and response procedures in the event of any accidental release of any living modified organism in a controlled area;
  - (c) the establishment of any training requirements or programmes concerning the management, storage or handling of any living modified organism in a controlled area;
  - (d) the establishment of any training requirements or programmes concerning emergency and response procedures in the event of an accidental release of any living modified organism in a controlled area.

## **A SECTION IS REQUIRED FOR LIVING MODIFIED ORGANISMS TRANSPORTED BY AIR**

### **6. Procedures during Unloading of LMO Cargo Transported by Sea**

- (1) During the discharge of any cargo containing LMO the appropriate authority shall ensure that:
  - (a) the container is inspected to ensure no spillage or residue exists;
  - (b) the berth is secure with access permitted only to authorised personnel and emergency services;
  - (c) suitable warning notices are posted.
- (2) During the discharge of any cargo containing living modified organisms the shipping agent and the stevedore shall ensure that:
  - (a) unloading operations are supervised by a properly qualified and trained person; and
  - (b) any mechanical machinery being used to move living modified organisms is operated by a competent operator.
- (3) During the discharge of any living modified organism it shall be the responsibility of the ship's master, the shipping agent and the stevedore to ensure that the discharging vessel operates no more than one crane at any one time.
- (4) In the event of an accidental release or spillage of living modified organism in a controlled area, Customs is to take appropriate action, which shall include:
  - (a) determining the identity of the living modified organism and the quantity of any accidental release or spillage;
  - (b) securing the area to prevent unauthorised access;
  - (c) determining whether emergency services are to be called; and
  - (d) determining, in consultation with the National Biosafety Board, the appropriate method of clean up and disposal.
- (5) During the unloading of any cargo containing living modified organisms, the relevant *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*, or where appropriate the *Dangerous Goods Declaration*, shall be inspected by the shipping agent and the stevedore to ensure that the declaration accurately reflects the nature and quantity of living modified organism being unloaded.

(6) The shipping agent and stevedore undertaking the unloading of any cargo containing living modified organism shall ensure that any consignments that are not to be immediately dispatched to the consignee shall be stored according to conditions and directions given by the National Biosafety Board.

**NOTE: EMERGENCY PROCEDURES SHOULD BE DETERMINED BY THE NATIONAL COMPETENT AUTHORITY. CUSTOMS, IN CONSULTATION WITH THE NATIONAL COMPETENT AUTHORITY, WILL TAKE APPROPRIATE ACTION.**

#### **7. Procedures following Discharge**<sup>[JG45]</sup>

(1) In the event that any discrepancy is determined during or after the discharge of any cargo containing LMO, the shipping agent or the stevedore undertaking the unloading of any such cargo shall immediately notify the Port Authority and Customs.

(2) Upon receiving a notification of any discrepancy under the provisions of sub-section (1), the Port Authority shall ensure that the relevant consignment is placed in a segregated area for assessment by the National Biosafety Board.

(3) The shipping agent shall, in the event of any discrepancy, notify the exporter in the originating country of the nature of the discrepancy.

#### **8. Procedures for the Transport of Living Modified Organisms by Road**

(1) Once a permit has been issued for the transport of any living modified organism under the provisions of section (36) (1), the person responsible for the transportation of the consignment shall provide the driver that is to transport the living modified organism with a copy of:

(a) the permit issued under the provisions of section (36) (1) and

(b) a copy of the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*.

(2) The driver that is to transport the living modified organism shall, upon receiving the documentation specified in sub-section (1) above, inspect the load and documentation to ensure that the consignment complies with the description contained in the documentation.

(3) The driver shall ensure that any required separations are adhered to when loading the living modified organism, and shall ensure that the documentation provided in terms of the provisions of sub-section (1) above is placed in the cab of the vehicle.

(4) When a vehicle is loaded with living modified organisms it must be packed, labelled and segregated in accordance with the requirements of this Part.

(5) All living modified organisms in transit by road must be secured with load restraints to prevent movement of the load during normal operating conditions.

(6) At least one 2-kilogram dry powder fire extinguisher must be carried on any vehicle that transports living modified organism, in addition to any other equipment that may be specified by the Department of Land Transport.

(7) In the event of any spill or accident during the transportation of any living modified organism by road, and where appropriate, it shall be the responsibility of the driver to:

(a) secure the area around the vehicle or spill;

(b) determining whether emergency services are to be called; <sup>[JG46]</sup>

(c) assess the situation and respond in appropriate manner; and

(d) notify the consignor and consignee of the nature of the spill or accident.

(8) In making any guidelines or codes of practice under the provisions of sub-section (7) above, the National Biosafety Board shall ensure the broadest possible consultation.

(9) Upon concluding any guidelines or codes of practice under the provisions of sub-section (8) above, the National Biosafety Board shall lodge a copy with the National Biosafety Clearinghouse.

(10) Any person who fails to comply with the requirements of any guideline or code of practice issued by the Port Authority pursuant to the provisions of sub-section (8) above, shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.

(11) The appropriate authority will carry-out inspections to ensure compliance with any permit, standard and procedures established in this Part, and for this purpose is empowered to execute spot checks to ensure compliance with any such requirements.

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