

DOMINICA BIOSAFETY AND BIOTECHNOLOGY MANAGEMENT ACT 2004

Part 1 PRELIMINARY

1. Preamble
2. Definitions
3. Application of Act
4. Purpose of Act
5. Precautionary Principle
6. Act Binds the State

Part 2 ADMINISTRATION

7. Establishment of National Biosafety Authority
8. Chair of National Biosafety Authority
9. Deputy Chair of National Biosafety Authority
10. Functions of National Biosafety Authority
11. Duties of National Biosafety Authority
12. Vacancies in National Biosafety Authority
13. Meetings of National Biosafety Authority
14. Secretariat to National Biosafety Authority
15. Functions of Secretariat
16. Scientific and Technical Advisory Committee
17. Functions of Scientific and Technical Advisory Committee
18. Conflict of Interest
19. Inspectors
20. Powers of Inspectors
21. Establishment of National Biosafety Clearinghouse
22. Confidentiality

Part 3 PROHIBITED ORGANISMS

23. Prohibition Concerning Genetically Modified Organisms
24. Public Notice of Intent to Prohibit Importation
25. Control of Genetically Modified Organism
26. Import of Genetically Modified Organisms
27. Application for Export Permit
28. Import Permit
29. Risk Management Measures for Export

Part 4 RISK ASSESSMENT

30. Risk Assessment and Risk Management System
31. Prohibition on Handling, Transportation, Use, Transfer or Release of Genetically Modified Organism without Permit.
32. Application for a Permit
33. Risk Assessment Process
34. Review of Risk Assessment Report
35. Decision on Reports

36. Issue of Permit
37. General Conditions Relating to Permits
38. Responsibility for Risk Management Measures

Part 5
RISK MANAGEMENT MEASURES

39. Risk Management Measures – General
40. Labelling
41. Packaging of Genetically Modified Organism
42. Documents to Accompany the Transport of Genetically Modified Organisms
43. Segregation
44. Importation by Sea
45. Procedures during Unloading of GMO Cargo Transported by Sea
46. Procedures following Discharge
47. Procedures for the Transport of Genetically Modified Organisms by Road
48. Storage other than in Controlled Areas
49. Duties and Responsibilities

Part 6
PRE-APPROVED ORGANISMS

50. Pre-Approval of Genetically Modified Organisms
51. Application for Pre-Approval
52. Contents of Application
53. Approval Process
54. Public Notice
55. Registration of Public Notice
56. Decision on Application
57. Registration of Pre-Approved Organisms

Part 7
EMERGENCY MEASURES

58. Establishment of Accidental Release Control Group
59. National Accidental Release of Genetically Modified Organisms Risk Management Plan
60. Response in Events of Accidental Release of Genetically Modified Organisms
61. Duty to Report Threatened Releases of genetically Modified Organisms

Part 8
BIOTECHNOLOGY RESEARCH AND DEVELOPMENT

62. Policy to Promote and Regulate Biotechnology Research and Development
63. Formulation of Policy
64. Approval and Enforcement of Policy on Biotechnology Research and Development
65. Orders May Be Made To Implement Policy

Part 9
APPEALS

66. Appeals

Part 10
ENFORCEMENT AND COMPLIANCE

- 67. Inspections at Ports of Entry or Exit
- 68. Confiscation of Genetically Modified Organisms.
- 69. Offences and Penalties
- 70. Limitation Period for Offences
- 71. Continuing Offence
- 72. Additional Penalties
- 73. Employee Protection
- 74. Civil Claims for Environmental Damage
- 75. Liability of Corporations and Corporate Directors
- 76. Corporate Liability in Case of Bankruptcy
- 77. Proof of Offence
- 78. Procedural Aspects
- 79. Enforcement

Part 11
MISCELLANEOUS AND SUPPLEMENTARY

- 80. Other Enactments Apply
- 81. Delegation of Powers
- 82. Transitional Provisions
- 83. Regulations
- 84. Commencement

BIOSAFETY AND BIOTECHNOLOGY MANAGEMENT ACT

COMMONWEALTH OF DOMINICA

Act No. of 2004

An Act to make provision for:

- (a) the safe handling, transport, use, transfer and release of any genetically modified organisms so as to prevent or reduce risks to biological diversity, the environment and human health;
- (b) the promotion and management of research and development in the field of biotechnology;
- (c) the implementation of the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*,
and for other matters connected therewith.

BE IT ENACTED by the Parliament of the Commonwealth of Dominica as follows:

Part 1 PRELIMINARY

Preamble

1. This Act may be cited as the –

BIOSAFETY AND BIOTECHNOLOGY MANAGEMENT BILL, 2004

Definitions

2. In this Act, unless the context otherwise requires –

“accident” - as provided in Part 8 means any incident by which any genetically modified organism may be introduced, either directly or indirectly, into the environment, which results, or is likely to result in significant harm to biological diversity, the environment or human health or safety;

“applicant” means any legal or natural person, whether in Dominica or any other State, who applies for any permit or approval for the handling, transport, use, transfer or release of any genetically modified organisms pursuant to the provisions of this Act;

“Code” means:

- (a) in respect of any genetically modified organism 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

- (b) in respect of any genetically modified organism 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);

"contained use" means any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a closed system in which physical barriers are employed, either alone or together with chemical and/or biological barriers, to limit contact between the organism on the one hand and humans and the environment on the other;

"controlled area" as provided in Part 5 means any declared port of entry by air or sea, and includes any area occupied or controlled by the Port Authority;

"deliberate release" means any intentional introduction into the environment of a genetically modified organism, or a combination of genetically modified organisms 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;

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

"export" means intentional transboundary movement of any genetically modified organism to Dominica;

"exporter" means any legal or natural person, whether in Dominica or any other State, who arranges for a living modified organism to be exported;

"genetically modified organism" means micro-organisms, plants and animals whose genetic composition has been modified by the use of gene or cell technology, more specifically -

- (i) an organism derived from the formation of a combination of genetic material by artificial techniques, or
- (ii) an organism inheriting such combination of genetic material, or
- (iii) an organism that results from the replication of an organism described in paragraph (i), and

and includes living modified organisms, or such other matter as may be prescribed by the Minister;

“import” means intentional transboundary movement of any genetically modified organism to Dominica;

“importer” means any legal or natural person, whether in Dominica or any other State, who arranges for a living modified organism to be imported;

“living modified organism” means any living organisms that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

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

“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 overcomes natural physiological reproductive or recombination barriers and that are not techniques used in natural breeding and selection;

“Minister” means the Minister responsible for the Environment;

“officer” means a person designated or appointed under section 19 who is authorised to carry out functions as an officer or inspector under the –

- (i) Animal (National and International Movement and Diseases Prevention) Act, 2004;
- (ii) Customs and Excise Act;
- (iii) Fisheries Act;
- (iv) Food Safety Act, 2004;
- (v) Forestry and Wildlife Act;
- (vi) Fresh Produce Act;
- (vii) Standards Act;
- (viii) Plant Health Act;
- (ix) Plant Protection and Quarantine Act, 2004.

“organism” means any multicellular, uncellular, subcellular or cellular entity capable of replication or of transferring genetic material whether by natural or artificial processes, or such other entity or matter as may be prescribed by the Minister;

“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 as articulated in section 5;

“Secretariat” means the organization charged with the administration of this Act pursuant to section 14;

Application of Act

3. (1) This Act shall apply to-

- (a) the development, production, release, transport, use and application of genetically modified organisms (including viruses and bacteriophages);
 - (b) the genetic modification of organisms; and
 - (c) the use of gene therapy.
- (2) This Act shall not apply to the production with the aid of cell technology of -
- (a) genetically modified plant cells when the same result can be obtained by means of traditional methods of cultivation, or
 - (b) animal cells in culture where the cell material has been obtained from different individuals of the same species and where the cells could have been produced by natural reproduction, and the use of such plant or animal cells.

Purpose of Act

4. The purpose of this Act is to protect the biological diversity and environment of Dominica and the health and safety of people and communities, by preventing or managing the adverse effects of new organisms developed through modern biotechnology.

Precautionary Principle

5. (1) All persons exercising functions, powers and duties under this Act shall take into account the need for caution in managing the risks of adverse effects to biological diversity, the environment and human health, particularly where there is scientific or technical uncertainty about those effects.
- (2) Persons responsible for handling, transport, use, transfer and release of genetically modified organisms shall ensure that the conditions stated in this Act are complied with, and otherwise show due care and take reasonable measures to ensure that handling, transport, use, transfer and release are carried out without adverse effects on biological diversity, the environment and human health.

Act Binds the State

6. This Act binds the State.

Part 2

ADMINISTRATION

Establishment of National Biosafety Authority

7. For the purposes of this Act, there is hereby established a National Biosafety Authority, which shall consist of not more than ten members appointed by the Minister representing the following -
- (a) The Environment Coordinating Unit within the Ministry of Agriculture and the Environment, which shall perform the functions of the Secretariat as provided under section 14;
 - (b) The Ministry of Foreign Affairs, Trade and Marketing;
 - (c) The Environmental Health Department within the Ministry of Health;
 - (d) The Dominica Bureau of Standards;
 - (e) The Fisheries Development Division within the Ministry of Agriculture and the Environment;
 - (f) The Forestry, Wildlife & Parks Division within the Ministry of Agriculture and the Environment;
 - (g) The Livestock Development Unit within the Ministry of Agriculture and the Environment;
 - (h) The Attorney General's Office within the Ministry of Legal Affairs, Immigration and Labour;
 - (i) The Plant Protection Unit within the Ministry of Agriculture and the Environment;
 - (j) The Department of Customs;
 - (k) Non-governmental organizations;
 - (l) The private sector.

Chair of National Biosafety Authority

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

Deputy Chair of National Biosafety Authority

9. The deputy chairperson appointed by the Minister under section 7 shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to perform such functions.

Functions of National Biosafety Authority

10. The National Biosafety Authority shall:

- (a) advise the Minister, other Ministries and appropriate bodies, on all aspects concerning the development, production, transport, use, application and release of genetically modified organisms;
- (b) ensure that all activities with regard to the development, production, transport, use, application and release of genetically modified organisms are performed in accordance with the provisions of this Act;
- (c) perform such other duties and responsibilities as required by the Minister to provide for the implementation of the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*.

Duties of National Biosafety Authority

11. In order to perform the functions provided in section 10, the National Biosafety Authority may -

- (a) require any applicant to:
 - (i) provide such information as may be necessary to undertake any risk assessment or risk management process required under the Act;
 - (ii) use designated facilities for the development, production, use or application of genetically modified organisms or to release such organisms into the environment;
 - (iii) submit to the National Biosafety Authority through the Secretariat, an assessment of the risk and, where required, an assessment of the impact on national biodiversity, the environment or human health of such development, production, use, application or release, as the case may be;
- (b) require the Secretariat or the Scientific and Technical Advisory Committee established pursuant to section 16 to examine the conformity of an application to the requirements of this Act;
- (c) require the Secretariat to maintain a register of –
 - (i) all applications made pursuant to the requirements of this Act;
 - (ii) the particulars of all genetically modified organisms that have been approved pursuant to the requirements of this Act;
 - (iii) the particulars of all facilities involved in the contained use or the trial release of genetically modified organisms;
 - (iv) the names and addresses of persons concerned with the contained use or trial release of genetically modified organisms;
 - (v) the names and addresses of persons listed on the Roster of Experts established pursuant to section 21 (2) (a).

- (d) require notification by the applicant of any intended change in the type of activities or release involving genetic modification of organisms being undertaken at facilities for which approval was granted under the provisions of this Act, in which case the Authority may require the applicant to apply for a new permit;
- (e) require the Secretariat to arrange for the inspection of facilities where activities with or the release of genetically modified organisms are being undertaken;
- (f) require the Secretariat to arrange for the inspection of all activities that may be necessary, including contained use, trial release and general release to ensure compliance with that all terms and conditions attached to a permit issued under this Act;
- (g) after consideration of the risk assessment, and in consultation with the Scientific and Technical Advisory Committee established pursuant to section 16, approve, subject to the provisions of this Act and any other law and in accordance with such terms and conditions as the Authority may deem necessary, the use of the facilities concerned for the purpose for which the application was made, or the handling, transport, use, transfer or release of genetically modified organisms into the environment, and authorize the Secretariat to issue a permit accordingly;
- (h) require that the applicant or any user immediately notify the Secretariat both orally and in writing of any accident involving genetically modified organisms and require that the Secretariat be supplied with information on the circumstances of the accident, the identity and quantity of genetically modified organisms released, any information necessary to assess the impact of the accident on national biodiversity, the environment or human health, and the emergency measures taken to avoid or mitigate any adverse impact of such accident;
- (i) require the Secretariat to appoint a panel to enquire into and report on the causes of an accident, and to make recommendations to the Minister with a view to avoiding similar accidents in the future and with a view to limiting the adverse impact of such accidents;
- (j) inform any other country of any accident that may have an impact on that country's national biodiversity, environment or human health;
- (k) co-operate or enter into agreements with any person or institution to undertake any risk assessment or risk management process required under this Act upon such conditions as the Authority and the person or institution concerned may agree upon;
- (l) promote co-operation between Dominica and any other country with regard to research, development and technology transfer in the field of the genetic modification of organisms;
- (m) with the consent of the Minister approve and publish guidelines for all uses of genetically modified organisms;
- (n) advise the Minister on-

- i. restrictions and prohibitions that should be established on the handling, transport, use, transfer and release of any genetically modified organisms;
 - ii. the exercise of the necessary control of imports or transboundary movement of any genetically modified organisms;
 - iii. the development, production, use, application, release and distribution of genetically modified organisms;
 - iv. the authorisation or notification of contained uses of any genetically modified organisms;
 - v. the authorisation of trial or general releases of any genetically modified organisms;
 - vi. the control measures to be taken in the event of an accident of any genetically modified organisms;
 - vii. any other matter with regard to genetically modified organisms;
- (o) make recommendations to the Minister on the appointment of members to the Scientific and Technical Advisory Committee pursuant to section 16.

Vacancies in National Biosafety Authority

12. (1) A vacancy in the Authority shall occur when a member
- (a) ceases to be an officer within a Government Department or Agency listed in section 6;
 - (b) is absent without leave from more than three consecutive meetings of the Authority;
 - (c) resigns;
 - (d) dies.
- (2) 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.
- (3) A vacancy in the Authority shall be filled as soon as practicable in accordance with the provisions of section 3.
- (4) Whenever 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.

Meetings of National Biosafety Authority

13. (1) The National Biosafety Authority 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.
- (2) 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.
- (3) At least two weeks prior to convening a meeting of the National Biosafety Authority, the Secretariat established pursuant to section 14 shall prepare and circulate to members an agenda 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*.
- (4) The quorum for any meeting of the National Biosafety Authority shall be a majority of the members.
- (5) The National Biosafety Authority may determine its own procedures to be followed at its meetings and cause minutes to be kept of its proceedings.
- (6) The National Biosafety Authority may co-opt other knowledgeable persons to serve on the Authority in order to provide advise whenever the Authority deems it necessary.
- (7) The Authority may invite written comment from knowledgeable persons on any aspect of biosafety or biotechnology which lies within the Authority's mandate.
- (8) Formal approval of any policy, programme or initiative by the National Biosafety Authority shall be by general consensus of those members present at a meeting, providing that matter may be approved unless at least fifty percent of appointed members are present at the meeting.
- (9) Any matter that has been approved by the National Biosafety Authority shall be transmitted by the Chairperson to the Minister for consideration.

Secretariat to National Biosafety Authority

14. (1) The Environmental Coordinating Unit within the Ministry of Agriculture and the Environment acting in the capacity as Secretariat to the National Biosafety Authority, is charged with the administration of this Act.
- (2) The Secretariat to the Authority may exercise such powers and perform such duties as may be conferred upon or delegated or assigned under this Act or by the Authority.

Functions of Secretariat

15. The Secretariat shall subject to the instructions of and the conditions laid down by the Authority-
- (a) issue a permit as required or prescribed under this Act or Regulations;
 - (b) where it has been ascertained or there are reasonable grounds for believing that genetically modified organisms are being imported or locally produced or used contrary to the provisions of this Act or the conditions of a permit issued thereunder-
 - (i) serve a notice upon any person by whom or on whose behalf genetically modified organisms are being so imported into, produced or used in Dominica for the removal of such genetically modified organisms to a place or facility and in a manner prescribed by the National Biosafety Authority; and
 - (ii) authorize an inspector to destroy such genetically modified organisms or cause it to be destroyed, subject to procedures and other provisions as set out in Regulations under this Act;
 - (c) with just cause, amend or withdraw a permit issued under this Act;
 - (d) furnish an inspector with a certificate of appointment;
 - (e) require the cessation of any genetic modification activity at facilities where the provisions of this Act or the conditions of a permit have not been or are not being complied with; and
 - (f) ensure that appropriate measures are undertaken by all users at all times with a view to the protection of the national biodiversity, the environment or human health from hazards

Scientific and Technical Advisory Committee

16. (1) There is hereby established a Scientific and Technical Advisory Committee which shall consist of not less than six persons appointed by the Minister after the recommendation of the National Biosafety Authority for a period not exceeding five years.
- (2) The National Biosafety Authority shall, in recommending members for appointment to the Scientific and Technical Advisory Committee, endeavour to achieve representation from relevant fields of expertise involved with genetically modified organisms, social and environmental impact assessment, and risk management.
- (3) The Minister shall, in consultation with and upon the recommendation of the National Biosafety Authority, designate any member of the Scientific and Technical Advisory Committee as chairperson.

- (4) In the absence of the chairperson the remaining members of the Committee shall elect an acting chairperson from their number.
- (5) The acting chairperson shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to do so.
- (6) A member of the Committee whose period of office has expired shall be eligible for reappointment.

Functions of Scientific and Technical Advisory Committee

17. (1) The Scientific and Technical Advisory Committee shall-
 - (a) act as the national scientific and technical advisory body on all matters concerning or related to the genetic modification of organisms;
 - (b) advise, on request of the Minister, the National Biosafety Authority, other Ministries and appropriate bodies, on matters concerning the genetic modification of organisms and, inter alia, advise them on-
 - (i) all aspects relating to the introduction of genetically modified organisms into the environment;
 - (ii) proposals for specific activities or projects concerning the genetic modification of organisms;
 - (iii) all aspects concerning the contained use of genetically modified organisms;
 - (iv) the importation and exportation of genetically modified organisms; and
 - (v) proposed regulations and written guidelines;
 - (c) liaise through the relevant national departments with international groups or organisations concerned with biosafety; and
 - (d) invite written comments from knowledgeable persons on any aspect of the genetic modification of organisms which lies within the Committee's brief.
- (2) The Committee may appoint subcommittees to deal with specific matters as required.

Conflict of Interest

18. A person appointed to the Scientific and Technical Advisory Committee shall immediately excuse themselves as a member of the Committee if a subject matter is in issue in which he or she has any direct or indirect interest or if, for any other reason, there is or there is likely to be a conflict of interest as a result of his or her participation in the proceedings of the Committee.

Inspectors

19. (1) The Secretariat may appoint any officer, or with the approval of the Minister, any person who is not an officer, as an inspector to exercise and perform the functions referred to in section 20.
- (2) Every inspector shall be furnished with –
- (i) a certificate signed by the Secretariat stating that he or she has been appointed as inspector under this Act; and
 - (ii) an identity card containing a recent photograph of the inspector.
- (3) An inspector shall, at the request of any person affected by the exercise or performance of a function by such an inspector, exhibit the certificate and identity card referred to in sub-section (2) to such a person.
- (4) The Instrument of Appointment for any inspector appointed under the provisions of this Act shall be published by way of notice in the *Gazette*.

Powers of Inspectors

20. (1) An inspector may, on the authority of a warrant issued in terms of sub-section (2), conduct an investigation to determine whether the provisions of this Act are being or have been complied with, and may, for that purpose during normal office hours and without giving prior notice, enter any place or facility in respect of which he or she has reason to believe that a contravention of the provisions of this Act is taking place -
- (a) to inspect any activity or process carried out in or upon such place or facility in connection with any activities referred to in this Act;
 - (b) to request any information regarding such an activity or process from the owner or person in charge of such place or facility or from any person carrying out or in charge of the carrying out of such activities;
 - (c) to seize any appliance, book, statement or document and take samples of material or substances which appear to provide proof of a contravention of any provision of this Act; and
 - (d) to give notice to the owner of any material, substance, appliance, book, statement or document seized under paragraph (c) or to the person who had control over it immediately before any seizure under subparagraph (c) to remove the seized items at such person's own cost within a period and to a place specified in such notice.
- (2) A warrant referred to in sub-section (1) shall be issued by a magistrate or other judicial officer who has jurisdiction in the area in which the place or facility in question is situated, and shall only be issued if it appears from information on oath that there are reasonable grounds to believe that any material, substance,

appliance, book, statement or document that may relate to a contravention of this Act, is upon or in such place or facility.

- (3) A warrant issued in terms of this sub-section (2) shall be executed with strict regard to decency and order.
- (4) If no criminal proceedings are instituted in connection with any item referred to in sub-section (2), seized in terms of sub-section (1)(c), or if it appears that such item is not required at any trial for the purpose of evidence or an order of court, that item shall be returned as soon as possible to the person from whom it was seized.
- (5) After the conclusion of criminal proceedings any item seized in terms of sub-section (1)(c) and which served as an exhibit in proceedings in which a person was convicted, shall be handed over to the inspector to be destroyed or otherwise dealt with as instructed by the Secretariat.
- (6) Where any person obstructs, assaults, threatens or delays any officer in the execution of his duties under the Act or Regulations, the officer may arrest that person without a warrant.
- (7) Any person arrested under the provisions of sub-section (6) shall be taken with all practicable speed before a magistrate and shall not be detained without a warrant longer than is necessary.
- (8) An inspector may, at any time, order that any:
 - (a) genetically modified organism; or
 - (b) any organism suspected of being a genetically modified organism, that is imported into Dominica, be held at a particular place until an inspection, examination, analysis or risk assessment, as applicable, is conducted.
- (9) Where an inspector suspects that any genetically modified organism presents a risk of harm to Dominica's biodiversity, the environment or human health, he shall:
 - (a) seize the genetically modified organism and take such steps as are necessary to reduce the risk of harm;
 - (b) immediately notify the National Biosafety Authority.
- (10) No action shall be brought against any inspector in respect of anything done or omitted to be done by him in good faith in the execution of his powers and duties under this Act or any regulations made thereunder.

Establishment of National Biosafety Clearinghouse

21. (1) The Secretariat shall establish and maintain a National Biosafety Clearinghouse in order to facilitate the exchange of information on biosafety and modern biotechnology in Dominica, and provide public access to notices, applications and other information pursuant to the requirements of this Act.

- (2) The National Biosafety Clearinghouse, shall include, *inter alia*, the following -
- (a) a roster of experts that shall include the names, contact particulars and relevant biographical information of all individuals in Dominica with expertise in –
 - (i) genetically modified organisms;
 - (ii) biodiversity management and conservation;
 - (iii) environmental management;
 - (iv) social and environmental impact assessment; and
 - (v) risk assessment and management.
 - (b) national biosafety laws and guidelines;
 - (c) a list of genetically modified organisms that have been approved for import or export;
 - (d) all applications lodged pursuant to the provisions of this Act;
 - (e) a summary of emergency measures that have been established to manage the accidental release of any genetically modified organism into the environment;
 - (f) such other information as may be required to give effect to the requirements of this Act.
- (3) While not in any manner limiting the requirements of sub-section (2) above, the National Biosafety Clearinghouse shall contain:
- (a) current guidelines and codes of practice concerning the handling, transport, use, transfer and release of any genetically modified organisms;
 - (b) any national emergency response plans for genetically modified organisms;
 - (c) all documents produced, collected or submitted with respect to:
 - (i) the handling, transport, use, transfer and release of any genetically modified organisms;
 - (ii) the registration of any facility involved in modern biotechnology, and shall be capable of providing immediate information concerning any guideline, code of practice or response plan in the event of any enquiry.
- (4) The public shall have access to any record or document filed in the National Biosafety Clearinghouse, except for such documents or records as may be restricted for reasons of public security by the Minister by publication of a notice in the Gazette.

Confidentiality

22. (1) No person shall disclose any information acquired by him or her through the exercise of his or her powers or the performance of his or her duties in terms of this Act, except-
- (a) in so far as it is necessary for the proper application of the provisions of this Act;
 - (b) for the purposes of any legal proceedings under this Act;
 - (c) when ordered to do so by any competent court; or
 - (d) if he or she is authorised to do so by the Minister.
- (2) The National Biosafety Authority shall decide, after consultation with the applicant, which information will be kept confidential and shall inform the applicant of its decision.
- (3) Notwithstanding the provisions of sub-section (2), the following information shall not be kept confidential -
- (a) the description of the genetically modified organisms, the name and address of the applicant, and the purpose of the use or release and the location of use;
 - (b) the methods and plans for the monitoring of the genetically modified organisms and for emergency measures in the case of an accident; and
 - (c) the risk assessment of foreseeable significant impacts, in particular any pathogenic or ecologically disruptive impacts.
- (4) Notwithstanding the provisions of sub-section (3), the National Biosafety Authority may, after consultation with the applicant and if the Authority is satisfied on the grounds of information furnished by the applicant that certain information should be withheld in order to protect the intellectual property of the applicant, withhold such information for the period needed to protect such rights.
- (5) If, for whatever reasons, the applicant withdraws an application, any party who has knowledge of the details of the application must respect the confidentiality of the information supplied.

Part 3 PROHIBITED ORGANISMS

Prohibition Concerning Genetically Modified Organisms

23. The Minister may, on the recommendation of the National Biosafety Authority, by notice in the Gazette, prohibit –

- (a) the handling, transport, use, transfer and release of any genetically modified organisms;
- (b) any activity involving genetically modified organisms, so as to prevent or reduce risks to biological diversity, the environment and human health.

Public Notice of Intent to Prohibit Importation

24. (1) Prior to issuing any notice prohibiting the import of any genetically modified organism under the provisions of section 23 above, the Minister shall give public notice of his or her intention to prohibit the import of such organism.
- (2) The public notice outlined in sub-section (1) above shall be published in local 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.
- (3) A copy of the public notice as provided under sub-sections (1) and (2) shall be lodged with the National Biosafety Clearinghouse maintained by the Secretariat.
- (4) In addition to the placement of any public notice as provided under sub-sections (1) and (2), 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.
- (5) Any person who imports any genetically modified organism that has been prohibited under the provisions of section 23 shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.

Control of Genetically Modified Organism

25. (1) No person shall import, export, transport, use, store, sell, dispose of or otherwise control any genetically modified organism except as may be provided in Part 4 of the Act.
- (2) Any person who imports, exports, transports, stores, uses, sells, disposes of or otherwise controls any genetically modified organism except as may be provided in this Part of the Act, shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.

- (3) All genetically modified organisms shall, upon importation into Dominica, be subject to inspection by an inspector at the port of entry.
- (4) If upon inspection carried out in accordance with sub-section (3), the inspector determines that the imported genetically modified organism is not accompanied by a permit issued under this Act or any relevant documentation required by the Act or any regulations made thereunder, or presents any risk to Dominica's biodiversity, the environment or human health, the inspector shall immediately notify the National Biosafety Authority which may require by written notice served on the importer that the imported organism be:
 - (a) re-exported;
 - (b) confiscated; or
 - (c) destroyed by any means specified in the notice.
- (5) The National Biosafety Authority may forgo notice and carry out any of the actions listed under sub-section (4) where in its opinion destruction of the genetically modified organism is urgently required or the giving of notice is impracticable.
- (6) Where imported genetically modified organisms lie unclaimed in the port of entry for two weeks or more after their entry into Dominica, the National Biosafety Authority may take action to destroy such organisms.
- (7) The costs and responsibility for any action taken under sub-sections (4), (5), or (6), shall be borne by the importer, except where in exceptional cases the government determines that for reason of expediency the Government should take responsibility for the associated costs.
- (8) The Government of Dominica shall bear no liability for the destruction or disposal of genetically modified organisms imported into Dominica in contravention of this Act.

Import or Export of Genetically Modified Organism

26. (1) No genetically modified organism shall be exported to Dominica, or from Dominica to any State unless:
- (a) Dominica or the State that is to receive the genetically modified organism as the case may be, possesses the technical capacity and the facilities and suitable risk assessment and risk management systems to ensure that the handling, transport, use, transfer and release of any genetically modified organisms does not cause any significant ecological, social or economic harm; and
 - (b) the consent in writing in advance has been received from Dominica or such State to the specific import.
- (2) Any person who exports any genetically modified organism in violation of the provisions of sub-section (1) above shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.

Application for Export Permit

27. (1) Subject to the provisions of section 48 (4), any person who wishes to export any genetically modified organism under the provisions of section 24 shall notify –
- (a) the National Biosafety Authority in Dominica; or
 - (b) the State that is to import the genetically modified organism;
- and request written consent to export such organisms to Dominica or such State, as the case may be.
- (2) The notification transmitted under the provisions of sub-section (1) above shall contain -
- (a) a full and accurate description of the genetically modified organisms to be exported, which shall include the technical and common name and a statement of the quantities to be exported;
 - (b) information relating to the conditions of release, contained use, or placing on the market, and where appropriate, the receiving environment for the genetically modified organism;
 - (c) the name of the State that is to receive the genetically modified organisms and documentary proof that such State possesses the technical capacity and the facilities and suitable risk assessment and risk management systems to ensure that the handling, transport, use, transfer and release of any genetically modified organisms does not cause any significant ecological, social or economic harm;
 - (d) confirmation of the existence of a contract between the applicant and the recipient in the State to which the genetically modified organism is to be exported, specifying the environmentally sound manner in which the genetically modified organisms in question is to be handled;
 - (e) a report documenting any risk assessment that has been undertaken in the country of export to determine that the genetically modified organisms does not cause any significant ecological, social or economic harm;
 - (f) information on the interaction between the genetically modified organism and natural biodiversity, the environment and human health, including the results of any deliberate release in the country of export or other country;
 - (g) information on any previous approvals or rejections of the genetically modified organisms;
 - (h) a description of any risk management measures that are required for the safe transport, use, handling of such genetically modified organism, including –
 - (i) information concerning marking, labelling, packaging, storage and segregation requirements;
 - (ii) information on monitoring, control, disposal and waste management procedures;
 - (iii) emergency response plans to address any unintentional release.
- (3) Any person who submits an application under the provisions of sub-section (2) above which to his knowledge contains any false or mis-leading information, shall

be guilty of an offence and liable on conviction to the penalties provided under Part 10 of the Act.

- (4) Upon receipt of any application under the provisions of sub-section (1) (a) above, the National Biosafety Authority shall:
 - (a) determine whether the genetically modified organisms has been pre-approved for import pursuant to the provisions of section 31;
 - (b) consult with the Scientific and Technical Advisory Committee;
 - (c) determine that a comprehensive risk assessment be undertaken pursuant to the provisions of section 31 (1) at the expense of the applicant; and
 - (d) give public notice of the application under this Part.
- (5) The public notice required in sub-section (4)(d) above shall be published in local newspapers and shall provide:
 - (a) a description of the nature of the application;
 - (b) a full and accurate description of the genetically modified organism that is to imported;
 - (c) information concerning the location, time and method of use of the genetically modified organism that is to be imported;
 - (d) a statement concerning any significant impact on natural biodiversity, the environment or human health that may result from the use of the genetically modified organism that is to be imported;
 - (e) any risk management or environmental monitoring or management plans that are to be established;
 - (f) that submissions on the application may be made in writing by any person;
 - (g) the closing date for submissions, which shall not be earlier than thirty calendar days after public notification; and
 - (h) the address where submissions are to be sent.
- (6) A copy of the public notice as provided under sub-sections (4) (d) shall be lodged with the National Biosafety Clearinghouse established pursuant to section 21.

Import Permit

28. (1) Having satisfied the requirements of section 27 (4) 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:
 - (a) refuse permission for the import of any genetically modified organisms; or
 - (b) request further information concerning the proposed export; or
 - (c) issue a permit, which may specify conditions including the nature and extent of any risk management regime or insurance coverage that shall be required.
- (2) Any permit issued under sub-section (1) (c) above shall contain the following information:

- (a) the identity of every genetically modified organism being imported, including, where appropriate, the United Nations Class;
 - (b) the quantity of each genetically modified organism being imported;
 - (c) the vessel or aircraft on which the genetically modified organism is to be carried to Dominica;
 - (d) the seaport or airport at which the genetically modified organism is to arrive;
 - (e) the transportation route, and estimated time and date of arrival of the aircraft or vessel that is to transport the genetically modified organism; and
 - (f) any special cargo transportation or storage requirements pertaining to any genetically modified organism that is to be exported to Dominica.
- (3) The National Biosafety Authority may for just cause, at any time, cancel a permit that has been issued under sub-section (1) (c) above.
- (4) 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 export of the genetically modified organism, and for their removal from Dominica.
- (5) 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 in Part 10 of the Act.
- (6) Within seven days of issuing any permit under the provisions of sub-section (1) above, the National Biosafety Authority shall:
- (a) lodge a copy of the permit with the National Biosafety Clearinghouse established pursuant to section 21; and
 - (b) transmit a copy to the relevant authority in the State that is to export the genetically modified organism.

Risk Management Measures for Export

29. (1) Upon receiving a permit as provided in section 28 (1) (c) the person responsible for the export of any genetically modified organism shall correctly complete the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land* and other relevant documentation, as provided in Part 5 above, and shall sign the statutory declaration on the bottom of such documentation.
- (2) The person responsible for the export of any genetically modified organism shall ensure that:
- (a) the shipment is packed, labelled and marked as required in Part 5;
 - (b) the correct shipping name appears on the package and the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land* as required in Part 5;
 - (c) the correct United Nations number appears on the package and the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*.

- (3) The person responsible for the export of any genetically modified organisms shall ensure that the requirement concerning the export of such organisms, as provided in the permit issued pursuant to section 28 (1) (c) above, are fulfilled.
- (4) Notwithstanding the provisions of this Part, any transboundary movement of any genetically modified organisms 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.
- (5) It shall be the responsibility of:
 - (a) the exporter of any genetically modified organisms: and
 - (b) the master of the vessel or aircraft that is exporting any genetically modified organisms;to ensure that, in the case of an accident occurring during the transboundary movement of the genetically modified organisms which is likely to present risk to human health and the environment, the responsible authority in the importing and exporting States are immediately notified.
- (6) In any instance where an authorised transboundary movement of any genetically modified organisms cannot be completed in accordance with the terms of the permit issued pursuant to section 28 (1) (c), the genetically modified organisms are to be returned to the country of export at the expense of the person responsible for the export of the genetically modified organisms.
- (7) Notwithstanding the provisions of sub-section (6) above, where an authorised transboundary movement of any genetically modified organisms 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.
- (8) Any person who has obtained a permit under the provisions of section 28 (1) (c) shall, when change has occurred in:
 - (a) the matters set forth in any application made pursuant to section 15;
 - (b) the implementation of any conditions included in a permit issued under section 28 (2);immediately, in writing, notify the National Biosafety Authority of such change and provide such additional information as may be requested.
- (9) Any person who exports any genetically modified organisms in violation of the provisions and requirements of this Part shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.

Part 4

RISK ASSESSMENT

Risk Assessment and Risk Management System

30. (1) The National Biosafety Authority shall establish and maintain an effective risk assessment and risk management system to ensure that:
- (a) the handling, transport, use, transfer and release of any genetically modified organisms in Dominica does not cause any significant ecological, social or economic harm;
 - (b) the promotion of any biotechnology research or development does not cause any undesirable impact upon Dominica's natural biodiversity, environment or human health.
- (2) Any risk assessment or risk management system that shall be established pursuant to the provisions of sub-section (1) shall, where possible, be based on the Canadian Standards Association *Risk Management Guidelines for Decision-Makers* (CAN/CSA-Q850-97), or equivalent standard.

Prohibition on Handling, Transportation, Use, Transfer or Release of Genetically Modified Organism without Permit.

31. (1) No person may handle, transport, use, transfer, or release any genetically modified organism without a permit.
- (2) Any person who handles, transports, uses, transfers, or releases any genetically modified organism in violation of the provisions of sub-section (1) above shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.

Application for a Permit

32. (1) Any person who wishes to undertake the handling, transport, use, transfer and release of any genetically modified organisms in Dominica shall apply in writing to the National Biosafety Authority.
- (2) Any application for a permit that is submitted under the provisions of sub-section (1) shall contain –
- (a) a full and accurate description of the genetically modified organism, which shall include the technical and common name and a statement of the quantities to be exported;
 - (b) information relating to the conditions of release, contained use, or placing on the market, and where appropriate, the receiving environment for the genetically modified organism;
 - (c) the name of the organisation that is to use the genetically modified organisms and documentary proof that such organisation possesses the technical capacity and the facilities and suitable risk assessment and risk management systems to ensure that the handling, transport, use, transfer

- and release of any genetically modified organisms does not cause any significant ecological, social or economic harm;
- (d) a report documenting any risk assessment that has been undertaken to determine that the genetically modified organisms does not cause any significant ecological, social or economic harm;
 - (e) information on the interaction between the genetically modified organism and natural biodiversity, the environment and human health, including the results of any deliberate release in any other country;
 - (f) information on any previous approvals or rejections of the genetically modified organism;
 - (g) a description of any risk management measures that are required for the safe transport, use, handling of such genetically modified organism, including –
 - (i) information concerning marking, labelling, packaging, storage and segregation requirements;
 - (ii) information on monitoring, control, disposal and waste management procedures;
 - (iii) emergency response plans to address any unintentional release.
- (3) Any person who submits an application under the provisions of sub-section (2) above which to his knowledge contains any false or mis-leading information, shall be guilty of an offence and liable on conviction to the penalties provided under Part 10 of the Act.
- (4) Upon receipt of any application under the provisions of sub-section (1) (a) above, the National Biosafety Authority shall:
- (a) determine whether the genetically modified organisms has been pre-approved for use in Dominica pursuant to the provisions of section 48;
 - (b) consult with the Scientific and Technical Advisory Committee;
 - (c) determine that a comprehensive risk assessment be undertaken pursuant to the provisions of section 33 (1) at the expense of the applicant; and
 - (d) give public notice of the application under this Part.
- (5) The public notice required in sub-section (4)(d) above shall be published in local newspapers and shall provide:
- (a) a description of the nature of the application;
 - (b) a full and accurate description of the genetically modified organism;
 - (c) information concerning the location, time and method of use of the genetically modified organism;
 - (d) a statement concerning any significant impact on natural biodiversity, the environment or human health that may result from the use of the genetically modified organism;
 - (e) any risk management or environmental monitoring or management plans that are to be established;
 - (f) that submissions on the application may be made in writing by any person;
 - (g) the closing date for submissions, which shall not be earlier than thirty calendar days after public notification; and
 - (h) the address where submissions are to be sent.

- (10) A copy of the public notice as provided under sub-sections (4) (d) shall be lodged with the National Biosafety Clearinghouse established pursuant to section 21.

Risk Assessment Process

33. (1) The risk assessment process shall include:
- (a) an assessment by the Scientific and Technical Advisory Committee to determine whether the genetically modified organism is likely to cause any significant impact on Dominica's natural biodiversity, the environment or human health; or
 - (b) an assessment by an accredited regional organisation that is competent to undertake scientific assessments to determine that the genetically modified organism does not cause any significant ecological, social or economic harm in Dominica;
- and the design and implementation of a risk management program that may include an environmental or human health protection plan and monitoring programme.
- (2) Any risk assessment that shall be undertaken pursuant to the provisions of sub-section (1) shall be at the expense of the applicant.
- (3) In undertaking any risk assessment for any application under this Act, the Scientific and Technical Advisory Committee or the accredited regional organisation, as appropriate, shall identify and characterize the nature, likelihood of occurrence, and potential magnitude of any hazards to Dominica's natural biodiversity, the environment or human health.
- (4) Notwithstanding the provisions of sub-section (3), any risk assessment for any application under this Act, shall identify -
- (a) the nature and scope of the undertaking or activity involving the genetically modified organism;
 - (b) any potential for interaction between the genetically modified organism and natural biodiversity, the environment and human health, including the results of any deliberate release in any other country;
 - (c) whether the undertaking or activity involving the genetically modified organism will cause any significant environmental, social or human health impacts;
 - (d) the significance of any environmental, social or human health impacts;
 - (e) whether there exists any technically or economically feasible measures that would manage, minimise, reduce or eliminate any significant adverse environmental, social or human health impacts;
 - (f) the appropriate risk management measures that are required for the safe transport, use, handling of such genetically modified organism, including:
 - (i) marking, labelling, packaging, storage and segregation requirements;
 - (ii) monitoring, control, disposal and waste management procedures;
 - (iii) emergency response plans to address any unintentional release.

- (g) the nature of any public concerns relating to the undertaking or activity involving the genetically modified organism.
- (5) Once the Scientific and Technical Advisory Committee or the accredited regional organisation, as appropriate, has completed the risk assessment as outlined in sub-sections (3) and (4), and determined whether the undertaking or activity involving the genetically modified organism will cause significant environmental, social or human health impact that cannot be managed or mitigated, the report documenting the risk assessment that has been undertaken shall be referred to the National Biosafety Authority.

Review of Risk Assessment Report

34. (1) The National Biosafety Authority shall review the risk assessment report that has been submitted in pursuance of the requirements of this Act.
- (2) Within two weeks of the receipt of any report mentioned in sub-section (1) above, the National Biosafety Authority shall publish, during two subsequent weeks, in two issues of the local newspaper circulating in the area where the undertaking would likely be carried out, and in the Gazette, a notice to advise the public that copies of the risk assessment report are available for public scrutiny.
 - (3) A notice published under the provisions of sub-section (1) above shall state -
 - (a) a summary description of the activity or undertaking involving genetically modified organism;
 - (b) the address where the activity or undertaking is to be carried out;
 - (c) the place where the report may be inspected;
 - (d) the time limit for the submission of public comments in writing to the National Biosafety Authority.
 - (4) A risk assessment report submitted under section 33 (5) shall be open at all reasonable hours for public inspection for a period of not less than one calendar month.
 - (5) The National Biosafety Authority shall consider all comments and observations that may be submitted as a result of the public review.
 - (6) The National Biosafety Authority may, for the purposes of the review of any report -
 - (a) 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;
 - (b) 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 Dominica's natural biodiversity, the environment, or human health.

Decision on Reports

35. (1) Upon reviewing any comprehensive study report or mediation report, the National Biosafety Authority may:
- (a) approve the activity or undertaking involving the genetically modified organism; or
 - (b) approve the activity or undertaking involving the genetically modified organism subject to conditions; or
 - (b) where the activity or undertaking involving the genetically modified organism may result in impacts that could not be justified, mitigated or managed, refuse a permit for the proposed activity or undertaking.
- (2) The National Biosafety Authority shall decline any application for a permit if the genetically modified organisms is likely to cause:
- (a) any significant displacement of any native species within its natural habitat;
 - (b) any significant deterioration of natural habitats;
 - (c) any significant adverse effects on the environment, human health or safety;
 - (d) any significant adverse effects to Dominica's inherent genetic diversity; or
 - (e) disease, be parasitic, or become a vector for human health, animal or plant disease that causes any significant effects outlined in paragraphs (a) to (d) above.
- (3) Any permit issued under sub-section (1) (a) or (c) above shall contain the following information:
- (a) the name and contact particulars of the applicant;
 - (b) the identity of the genetically modified organism that is the subject of the application;
 - (c) the quantity of genetically modified organism that is the subject of the application;;
 - (d) any special cargo transportation or storage requirements pertaining to any genetically modified organism that is the subject of the application;
- and any conditions or risk management measures that may be imposed by the National Biosafety Authority.
- (4) The National Biosafety Authority shall transmit a copy of any order made pursuant to the provisions of sub-section (4) above to the Secretariat established pursuant to section (7) (a).

Issue of Permit

36. (1) Within seven days of receiving the order issued under the provisions of section 35 (4) above, the Secretariat shall inform the applicant of the decision of the National Biosafety Authority, and where appropriate, issue the necessary permit.
- (2) The applicant shall not proceed with any proposed undertaking or activity involving genetically modified organisms until –

- (a) the notice from the Secretariat advising of the decision issued by the National Biosafety Authority; and
 - (b) the permit,
have been received.
- (3) The order of the National Biosafety Authority and any permit that has been issued under the provisions of sections 35 (4) and 36 (1) above, shall be lodged with the National Biosafety Clearinghouse.
- (4) The National Biosafety Authority may for just cause, at any time, cancel a permit that has been issued under sub-section (1) above.
- (5) 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 genetically modified organisms, and for their safe containment.
- (6) 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 in Part 10 of the Act.

General Conditions Relating to Permits

37. (1) Any permit issued under the provisions of this Part shall authorise the holder to undertake on one occasion the type of undertaking or activity involving genetically modified organisms to which the permit or certificate relates, and only with the genetically modified organism specified in the permit.
- (2) Every permit for an undertaking or activity involving genetically modified organisms shall come into force on the date on which it was granted.
- (3) Every permit undertaking or activity involving genetically modified organisms 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.
- (4) 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.
- (5) Where any person who is in possession of a permit issued under this part, undertakes any undertaking or activity involving genetically modified organisms, he shall before:
- (a) transporting;
 - (b) exporting or re-exporting; or
 - (b) importing or re-importing,
- any genetically modified organisms 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.

- (6) Any person who fails to comply with any of the requirements of sub-section (5) above, shall be guilty of an offence and liable on conviction to the penalties provided under Part 10 of the Act.

Responsibility for Risk Management Measures

38. (1) 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.
- (2) The Secretariat shall cause to be conducted any inspection that may be necessary to determine whether any undertaking or activity involving genetically modified organisms are undertaken in accordance with any risk management measures that shall constitute the conditions of any approval granted under this Part.
- (3) The Secretariat, upon undertaking any inspection as required under the provisions of sub-section (2) above, may cause an action to be initiated before any competent court, where it has been determined that any undertaking or activity involving genetically modified organisms has not been undertaken in accordance with any risk management plan that shall constitute the conditions of any approval granted under this Part.

Part 5 RISK MANAGEMENT MEASURES

Risk Management Measures - General

39. (1) 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.
- (2) No genetically modified organisms 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 in respect of that organism.
- (3) Any person who imports, exports or transports any genetically modified organism 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 Part 10 of the Act.
- (4) Contained use of any genetically modified organisms shall take place in laboratories and installations that are approved pursuant to section 48, and in accordance with good microbiological practice.
- (5) The user of all genetically modified organisms 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 genetically modified organisms.

- (6) Records shall be kept of all contained use of genetically modified organisms.

Labelling

40. (1) During transport, import or export each package shall be clearly labelled in English as containing genetically modified organisms.
- (2) The labelling shall also state the species of organism and the name, address and telephone number of both the sender and the recipient.
- (3) Any label affixed in accordance with the provisions of sub-section (1) and (2) above must be positioned in the following manner:
- (a) on cartons and boxes - at least one label on the side or end;
 - (b) on drums and similar containers - at least one label on the side on the upper half;
 - (c) on jerricans and similar containers - at least one label on one of the largest surfaces;
 - (d) 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;
 - (e) 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.
- (4) Every label affixed under the provisions of sub-section (3) above shall be in such a manner that when the genetically modified organisms are transported the nature of the consignment is readily recognisable.

Packaging of Genetically Modified Organism

41. (1) The packaging of all genetically modified organisms shall be –
- (a) impervious to both spores and pollen;
 - (b) watertight, sealed and fracture-proof, so as to prevent any unintentional leakage of the contents.
- (2) There shall always be an inner and an outer container, which shall both be waterproof.
- (3) 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.

- (4) If two or more inner containers are carried in the same outer container:
 - (a) each inner container shall be separately packaged in shock-absorbent and fluid-absorbent material;
 - (b) the outer container shall be watertight, sealed, fracture proof, etc. so as to prevent any unintentional leakage of the contents.

Documents to Accompany the Transport of Genetically Modified Organisms

42. (1) All genetically modified organisms that are transported, imported, or exported shall be accompanied by the permit issued pursuant to section 36 (1) which shall at all times be available for inspection by an inspector.
- (2) 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 genetically modified organism, and in the following order:
 - (A) the Proper Shipping Name;
 - (B) the Class or organism;
 - (C) where applicable, the United Nations Number;
 - (D) the packaging group;
 - (E) the number and type of packages and the total quantity covered by the description;
 - (F) 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;
 - (G) 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 genetically modified organism goods, except for goods carried in bulk;
 - (c) a *Load Plan*, stating where the genetically 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.
- (3) The documents referred to in sub-section (2)(a) and (2)(b) above must have a characteristic striped border, in red and white.
- (4) The documents referred to in sub-section (2) above must be attached to each other while accompanying any genetically modified organism in transit.

Segregation

- 43. (1) Genetically 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.
- (2) Genetically 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 47 below.
- (3) Any person who transports any genetically modified organism that has not been segregated in compliance with the requirements of sub-sections (1) and (2), shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.

Importation by Sea

- 44. (1) Where any genetically modified organism is to be imported into Dominica by sea, the owner or master of the vessel shall, at least 48 hours before the genetically 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 genetically modified organism is to be landed.
- (2) The written notice given in compliance with the provisions of sub-section (1) above shall specify:
 - (a) the identity of every genetically modified organism;
 - (b) where applicable, the number on the container transporting the genetically modified organism;
 - (c) the quantity of each the genetically modified organism being imported;
 - (d) the vessel on which each the genetically modified organism is to be carried to Dominica;
 - (e) the seaport at which the vessel is to arrive;
 - (f) the estimated time and date of arrival of the vessel; and
 - (g) any special cargo transportation or storage requirements pertaining to any the genetically modified organism aboard the vessel that is to be imported into Dominica.

- (3) The shipping agent for the vessel that will carry the genetically modified organism to Dominica 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 Authority 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 genetically modified organism aboard the vessel that is to be imported into Dominica.
- (6) Where the National Biosafety Authority is satisfied that there has been a failure on the part of the master of any vessel in a prescribed port area to comply with a requirement of this Act or the regulations, or with a condition imposed pursuant thereto, the Authority may cause the vessel to be detained until compliance with any requirements specified by the National Biosafety Authority.
- (7) The National Biosafety Authority shall forthwith deliver, in writing, to the captain of the vessel particulars of the non-compliance.
- (8) Upon receipt of the original *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*, the shipping agent shall, before any genetically modified organism is discharged from the vessel:
 - (i) hand the documents to the stevedore responsible for unloading the vessel; and where appropriate
 - (ii) discuss with the stevedore any special cargo requirements.
- (9) It shall be the responsibility of the stevedore to take all appropriate precautions when unloading any genetically modified organism, and:
 - (i) ensure that the genetically modified organism 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 genetically modified organism in a location adjacent to where the organisms are to be stored within the controlled area.
- (10) The Port Authority may, in consultation with the National Biosafety Authority, issues guidelines and codes of practice concerning:

- (a) the storage and management of genetically modified organism in a controlled area;
 - (b) the establishment of emergency and response procedures in the event of any accidental release of any genetically modified organism in a controlled area;
 - (c) the establishment of any training requirements or programmes concerning the management, storage or handling of any genetically 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 genetically modified organism in a controlled area.
- (11) In making any guidelines or codes of practice under the provisions of sub-section (10) above, the National Biosafety Authority shall ensure the broadest possible consultation.
- (12) Upon concluding any guidelines or codes of practice under the provisions of sub-section (11) above, the National Biosafety Authority shall lodge a copy with the National Biosafety Clearinghouse.
- (13) 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 (12) above, shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.
- (14) 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.

Procedures during Unloading of GMO Cargo Transported by Sea

45. (1) During the discharge of any cargo containing genetically modified organism 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 from a vessel of any cargo containing genetically modified organism 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 genetically modified organisms is operated by a competent operator.
- (3) During the discharge from a vessel of any genetically 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 genetically modified organism in a controlled area, the Port Authority is to take appropriate action, which shall include:
 - (a) determining the identity of the genetically 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 Authority, the appropriate method of clean up and disposal.
- (5) During the unloading of any cargo containing genetically 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 genetically modified organism being unloaded.
- (6) The shipping agent and stevedore undertaking the unloading of any cargo containing genetically 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 Authority.

Procedures following Discharge

46. (1) In the event that any discrepancy is determined during or after the discharge of any cargo containing genetically modified organism, the shipping agent or the stevedore undertaking the unloading of any such cargo shall immediately notify the Port Authority, the Department of Customs and the National Biosafety Authority.
- (2) Upon receiving a notification of any discrepancy under the provisions of subsection (1), the Port Authority shall ensure that relevant consignment is placed in a segregated area for assessment by the National Biosafety Authority.
- (3) The shipping agent shall, in the event of any discrepancy, notify the exporter in the originating country of the nature of the discrepancy.

Procedures for the Transport of Genetically Modified Organisms by Road

47. (1) The provisions of this section shall come into force and effect no later than twelve months after the enactment of this Act.
- (2) Only licensed and certified drivers shall transport genetically modified organisms on any road.
- (3) The Transport Board will undertake the licensing and registration of drivers under

the provisions of sub-section (2), and for this purpose shall, in consultation with the National Biosafety Authority, establish procedures and requirements for licensing, registration and training, and for the endorsement of licences for any registered driver.

- (4) Any driver licensed to transport genetically modified organisms shall have his or her licence endorsed to this effect, and shall be required to carry their licence and genetically modified organism transport permit at all times when carrying such organisms.
- (5) The Transport Board, in undertaking the licensing and registration of drivers under the provisions of sub-section (3), shall –
 - (a) limit the number of drivers that will be registered to transport genetically modified organisms; and
 - (b) require such drivers to carry adequate insurance to cover any foreseen harm to human health or the environment that may result from an accidental release of any genetically modified organisms that is being transported by road.
- (6) The Transport Board will only issue a licence under the provisions of sub-section (3) once the driver has satisfactorily passed an established training program on the handling and transportation of genetically modified organisms, which shall be undertaken every two years.
- (7) Any person who wishes to transport any genetically modified organisms in bulk upon any road shall apply in writing to the Transport Board.
- (8) Any application for a permit that is submitted under the provisions of sub-section (7) shall contain:
 - (a) a full and accurate description of the genetically modified organisms to be transported including the technical and common name, and where applicable, the United Nations Class;
 - (b) a statement of the quantities to be transported;
 - (c) the name and location of the place from where the genetically modified organisms is to be transported; and
 - (d) the name and location of the place to where the genetically modified organisms is to be transported.
- (9) Upon receipt of any application under the provisions of sub-section (7), the Transport Board, shall verify that the location to where the genetically modified organisms are to be transported is, as appropriate, a controlled area, or is licensed pursuant to the requirements of section 48, and thereafter may, in consultation with the National Biosafety Authority:
 - (a) refuse permission for the transportation of any organism; or
 - (b) issue a permit, which may specify conditions.
- (10) Any permit issued under sub-section (9) shall contain the following information:
 - (a) the identity of every genetically modified organism being transported,

- including, where appropriate, the United Nations Class;
- (b) the quantity of each genetically modified organism being transported;
 - (c) the vehicle on which each genetically modified organism is to be transported;
 - (d) the route which shall be used for the transportation of the genetically modified organisms;
 - (e) any special transportation or storage requirements pertaining to any genetically modified organism that is to be transported by road; and
 - (f) the particulars of the person to whom the permit is issued.
- (11) Any route specified in terms of sub-section (10) (d) should, where practicable, be planned to minimise risk to human health and the environment.
 - (12) The Transport Board may for just cause, at any time, cancel a permit that has been issued under sub-section (9) (b).
 - (13) If any requirement or conditions contained in a permit are not strictly complied with, the Transport Board may issue such directions as may be considered appropriate for the immediate cessation of the transportation of the genetically modified organism.
 - (14) Any person who fails to comply with the direction, requirement or condition imposed by the Transport Board is guilty of an offence and liable upon conviction to the penalties provided in Part 10 of the Act.
 - (15) Within seven days of issuing any permit under the provisions of subsection (9), the Transport Board shall lodge a copy of the permit with the National Biosafety Clearinghouse established pursuant to section 21.
 - (16) The Transport Board will carry-out inspections of drivers and vehicles 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.
 - (17) Any person who transports on any road any genetically modified organisms other than in compliance with the requirements of this section is guilty of an offence and liable upon conviction to the penalties provided in Part 10 of the Act.
 - (18) Any driver convicted under the provisions of subsection (17), in addition to any other penalty imposed, may be prohibited from carrying out the business of transporting genetically modified organisms for a period of time.
 - (19) Any application or permit that may be required under the provisions of this section may be sent by means of a faxed copy, on condition that the original is immediately dispatched by the quickest possible means.
 - (20) Once a permit has been issued for the transport of any genetically modified organism under the provisions of sections 36 (1) and 47 (9), the person

responsible for the transportation of the consignment shall provide the driver that is to transport the genetically 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*.
- (21) The driver who is to transport the genetically modified organism shall, upon receiving the documentation specified in sub-section (20) above, inspect the load and documentation to ensure that the consignment complies with the description contained in the documentation.
- (22) The driver shall ensure that any required separations are adhered to when loading the genetically modified organism, and shall ensure that the documentation provided in terms of the provisions of sub-section (20) above is placed in the cab of the vehicle.
- (23) When a vehicle is loaded with genetically modified organisms, such organism must be packed, labelled and segregated in accordance with the requirements of this Part.
- (24) All genetically modified organisms in transit by road must be secured with load restraints to prevent movement of the load during normal operating conditions.
- (25) At least one 2 kilogram dry powder fire extinguisher must be carried on any vehicle that transports genetically modified organism, in addition to any other equipment that may be specified by the Transport Board.
- (26) In the event of any spill or accident during the transportation of any genetically 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;
 - (c) assess the situation and respond in an appropriate manner; and
 - (d) notify the consignor and consignee of the nature of the spill or accident.

Storage other than in Controlled Areas

48. (1) Only licensed and registered facilities shall store or process any genetically modified organism.
- (2) The National Biosafety Authority, in consultation with the Ministry of Health and the Labour Division, will undertake the licensing and registration of premises under the provisions of sub-section (2) above, and for this purpose may establish:
- (a) standards pertaining to the storage or processing of genetically modified organism on any premises;
 - (b) procedures and requirements for the licensing and registration of premises;
 - (c) requirements for the training of employees in the safe handling of genetically modified organism.

- (3) The Labour Division, in undertaking the licensing and registration of premises under the provisions of sub-section (3) above, shall require such premises to carry adequate insurance to cover any foreseeable liability for harm to human health or the environment.
- (4) 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.
- (5) Any application for a permit that is submitted under the provisions of sub-section (1) above shall contain:
 - (a) a full and accurate description of the genetically modified organism that are to be stored or processed, including the technical and common name, and where appropriate the United Nations Class; and
 - (b) a statement of the quantities of genetically modified organisms to be stored or processed and the duration of such storage;
 - (c) the name and location of the place where the genetically modified organism is to be stored or processed;
 - (d) a description of the processing that is to be undertaken on any genetically modified organism;
 - (e) a copy of the risk management protocols and emergency measures that operate within the facility.
- (6) Upon receipt of any application under the provisions of sub-section (6) above, the National Biosafety Authority shall inspect the premises to determine if:
 - (a) adequate facilities exist for the safe storage or processing of genetically modified organism;
 - (b) adequate security, segregation and safety measures exists at the premises; and
 - (c) employee training in the management of genetically modified organism has been undertaken.
- (7) Upon completion of any inspection undertaken under the provisions of sub-section (6) above, the National Biosafety Authority shall
 - (i) refuse permission for the storage or processing of genetically modified organism in such premises; or
 - (ii) issue a permit, which may specify conditions.
- (8) Any permit issued under sub-section (7) (ii) above shall contain the following information:
 - (a) the name and location of the place where the genetically modified organism is to be stored or processed;
 - (b) a full and accurate description of the genetically modified organism that are to be stored or processed, including the technical and common name;
 - (c) a statement of the quantities to be stored or processed, and the duration of such storage or processing;

- (d) any special risk management measures pertaining to any genetically modified organism that is to be stored or processed.
- (9) The National Biosafety Authority may for just cause, at any time, cancel a permit that has been issued under sub-section (7) (ii) above.
- (10) 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 genetically modified organism.
- (11) 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 in Part 10 of the Act.
- (12) Within seven days of issuing any permit under the provisions of sub-section (7) (ii) above, the National Biosafety Authority shall lodge a copy of the permit with the National Biosafety Clearinghouse established under section 21.
- (13) Any premises used for the storage or processing of genetically modified organism 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.

- (14) The person in charge of any premises used for the storage or processing of genetically modified organism shall ensure that genetically modified organism storage areas or processing areas are secured against unauthorised access.
- (15) The person in charge of any premises used for the storage or processing of genetically modified organism shall maintain material data sheets on any genetically modified organism stored or processed on the premises and shall ensure that these sheets are readily accessible in the event of an emergency.
- (16) The person in charge of any premises used for the storage or processing of genetically modified organisms 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.
- (17) The person in charge of any premises used for the storage or processing of genetically modified organism shall ensure that a daily inspection is undertaken by a responsible person of the genetically modified organism store areas to assure no accidental release or leakage is occurring.
- (18) Notwithstanding the provisions of sections 20 and 79, the Labour Division and the Environmental Health Department 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.
- (19) Any person who stores or processes any genetically modified organism 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 in Part 10 of the Act.

Duties and Responsibilities

49. (1) It shall be the duty and responsibility of everyone who may have the custody or care of any genetically modified organism to exercise the utmost care to ensure that harm or damage shall not result to Dominica's natural biodiversity, the environment or human health.
- (2) In the event of an accidental release or spill of any genetically modified organism, it shall be the duty and responsibility of everyone who may have the custody or care of any genetically modified organism to immediately report such accidental release or spill to the National Biosafety Authority.

- (3) In the event of an accidental release or spill of any genetically modified organism, it shall be the duty and responsibility of everyone who may have the custody or care of the genetically modified organism to:
 - (a) secure the area around the accidental release or spill;
 - (b) determining whether emergency services are to be called;
 - (c) assess the situation and respond in appropriate manner;
 - (d) take reasonable measures to prevent or limit damage and inconvenience.
- (4) 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 Part 10 of the Act.

Part 6

PRE-APPROVED ORGANISMS

Pre-Approval of Genetically Modified Organisms

50. (1) The National Biosafety Authority may establish a register of genetically modified organisms that have been pre-approved for import into Dominica.
- (2) No genetically modified organism may be registered pursuant to sub-section (1) unless the National Biosafety Authority is satisfied –
- (a) 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 Dominica;
 - (b) there exists information on the interaction between the genetically modified organism and natural biodiversity, the environment and human health, including the results of any deliberate release in any other country;
 - (c) there exists information on any previous approvals of the genetically modified organisms in any other country.
- (3) The register of genetically modified organisms that have been pre-approved for import into Dominica shall be lodged with the National Biosafety Clearinghouse established pursuant to section 21.
- (4) No application for import shall be required under the provisions of sections 26 and 27 for any genetically modified organism that has been registered pursuant to sub-section (1).

Application for Pre-Approval

51. (1) Any person may apply to the National Biosafety Authority to register genetically modified organisms for pre-approved pursuant to the provisions of section 50 (1).

Contents of Application

52. Any application under sub-section (1) shall contain –
- (a) a description of the nature of the application;
 - (b) a full and accurate description of the genetically modified organism;
 - (c) the risk assessment that 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 Dominica;
 - (d) information on the interaction between the genetically modified organism and natural biodiversity, the environment and human health, including the results of any deliberate release in any other country;
 - (e) information on any previous approvals of the genetically modified organisms in any other country.

Approval Process

53. Upon receipt of any application under the provisions of section 52, the National Biosafety Authority shall:
- (a) consult with the Scientific and Technical Advisory Committee;
 - (b) verify the adequacy of the risk assessment that has been undertaken by an accredited regional organisation pursuant to section 50 (2) (a); and
 - (c) give public notice of the application under this Part.

Public Notice

54. The public notice required in section 53 (c) above shall be published in local newspapers and shall provide:
- (a) a description of the nature of the application;
 - (b) a full and accurate description of the genetically modified organism;
 - (c) a summary of the findings of any the risk assessment that has been undertaken by an accredited regional organisation pursuant to section 50 (2) (a);
 - (d) that submissions on the application may be made in writing by any person;
 - (e) the closing date for submissions, which shall not be earlier than thirty calendar days after public notification; and
 - (f) the address where submissions are to be sent.

Registration of Public Notice

55. A copy of the public notice as provided under section 54 shall be lodged with the National Biosafety Clearinghouse established pursuant to section 21.

Decision on Application

56. Having satisfied the requirements of section 53 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:

- (a) register the pre-approved genetically modified organism pursuant to the provisions of section 50 (1) which may be subject to conditions concerning appropriate risk management measures; or
- (b) refuse permission to register the genetically modified organisms for pre-approved pursuant to the provisions of sub-section (1).

Registration of Pre-Approved Organisms

57. Any genetically modified organism that has been pre-approved for import into Dominica pursuant to the provisions of section 50 (1) shall be recorded on the Register of pre-approved genetically modified organisms contained in the National Biosafety Clearinghouse established pursuant to section 21.

Part 7 EMERGENCY MEASURES

Establishment of Accidental Release Control Group

58. (1) In order to co-operate and direct response to any accident release of genetically modified organisms within the scope of this Part, the National Biosafety Authority shall establish an Accidental Release Control Group.
- (2) The Accidental Release Control Group shall comprise representatives from the Environmental Co-ordinating Unit, the Ministry responsible for Regional Planning, the Ministry responsible for Finance, the Fisheries Division, the Ministry of Health, the Ministry of Defence, and such other members as the Minister may appoint by notice in the Gazette.
- (3) 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.
- (4) The duties and function of the Accidental Release Control Group shall be to:
- (a) develop appropriate systems for the detection and reporting of accidental release of any genetically modified organisms, or of incidents related to the use, transport of genetically modified organisms which could result in such accident;
 - (b) ensure prompt response is made in the event of an accidental release of any genetically modified organisms to either prevent damage to Dominica's natural biodiversity, the environment or human health or to restrict the extent of such damage;

- (c) ensure that the correct response techniques and risk management measures are used in the event of an accidental release of any genetically modified organisms, and that disposal of recovered genetically modified organism is carried out in an environmentally acceptable manner;
 - (d) ensure that complete and accurate records are maintained of all expenditures incurred in the event of an accidental release of any genetically modified organisms to facilitate cost recovery and the payment of compensation;
 - (d) provide adequate protection for public health, safety and welfare, and the protection of the environment in the event of an accidental release of any genetically modified organisms;
 - (e) 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 genetically modified organisms; and
 - (f) develop, implement and keep under review the "*Dominica Accidental Release of Genetically Modified Organisms Risk Management Plan*".
- (5) 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.
- (6) 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.

National Accidental Release of Genetically Modified Organisms Risk Management Plan

59. (1) A *National Accidental Release of Genetically Modified Organisms 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 genetically modified organisms has occurred.
- (2) The Plan prepared pursuant to the requirements of sub-section (1) above, shall:
- (a) assess the risk of harm to Dominica's natural biodiversity, the environment or human health that could be caused through an accidental release of genetically 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 genetically 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 genetically modified organism, or any occurrence or emergency likely to result in significant harm to Dominica'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 genetically modified organism;
 - (ii) responding to an actual accidental release of any genetically modified organism;
 - (iii) the removal of any recovered genetically 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 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.
- (3) The Accidental Release Control Group shall undertake such action as may be necessary to achieve the required contingency preparedness.
- (4) The Minister in consultation with and on the recommendations of the National Biosafety Authority, the may issue instructions concerning changes in approved risk management measures and emergency plans, and if necessary for the protection of human life, property or the environment, issue directives to revoke, amend or withdraw any part of the *National Accidental Release of Genetically Modified Organisms Risk Management Plan* prepared pursuant to the requirements of sub-section (1).
- (5) The accidental release emergency preparedness, as provided under sub-section (4) above, shall ensure:
- (a) that any genetically 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 Dominica's natural biodiversity, the environment or human health.
- (6) 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 Genetically 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 Dominica's emergency preparedness organizations as are necessary to ensure efficient administration and control of all emergency preparedness resources when any accidental release of genetically modified organisms has occurred.
 - (7) All established technical, operational and organizational measures that constitute the emergency preparedness of the *National Accidental Release of Genetically 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.
 - (8) Contingency and response measures implemented when an accidental release of genetically 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 Genetically Modified Organisms

- 60. (1) Upon the receipt of any report involving an accidental release of any genetically modified organism, or where any incidental 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.
- (2) 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 Environmental Co-ordinating Unit does not have the right to withdraw.
- (3) Upon being convened in terms of sub-section (1) 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 of the economy of Dominica;

- (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.
- (4) 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.
- (5) 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 genetically modified organisms; and
 - (b) initiate and co-ordinate the emergency response measures necessary to control any actual or threatened accidental release of genetically modified organisms.
- (6) 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 Dominica'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.
- (7) In the event of any release of any genetically modified organism that presents a significant threat to Dominica's biodiversity, the environment or human health, the Minister may declare a State of Emergency.

Duty to Report Threatened Releases of Genetically Modified Organisms

61. (1) Where there is any significant threat that an accidental release of any genetically modified organism 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.
- (2) The report required to be made under sub-sections (1) shall contain the following information:
- (a) the event to which the threat is attributable;
 - (b) the weather, and where applicable, sea conditions at the time the report is made;

- (c) the description and quantity of any genetically modified organism that may be accidentally released or may escape;
 - (d) the measures being taken to minimise the threat of damage that may occur.
- (3) Any person who fails to comply with the requirement of sub-section (1) and (2) above, shall be guilty of an offence and liable to the penalties provided in Part 10 of the Act.

Part 8

BIOTECHNOLOGY RESEARCH AND DEVELOPMENT

Policy to Promote and Regulate Biotechnology Research and Development

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

Formulation of Policy

63. (1) 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.
- (2) 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 Dominica, 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 Dominica.
- (3) 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.
- (4) The public notice outlined in sub-section (3) above shall be published in local newspapers, and shall provide:
- (a) a description of the proposed *Policy to Promote and Regulate Biotechnology Research and Development*;
 - (b) that submissions on the policy may be made in writing by any person;
 - (c) the closing date for submissions, which shall not be earlier than thirty calendar days after public notification; and
 - (d) the address where submissions are to be sent.

- (5) A copy of the public notice as provided under sub-sections (3) and (4) shall be lodged with the National Biosafety Clearinghouse.
- (6) In addition to the placement of any public notice as provided under sub-sections (3) and (4), 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.
- (7) 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.
- (8) 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.
- (9) The *Policy to Promote and Regulate Biotechnology Research and Development* shall, inter alia:
 - (a) establish the Government of Dominica'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 Dominica, including methods to regulate any deliberate release of genetically modified organisms;
 - (f) establish standards and procedures for the registration and accreditation of facilities for biotechnology research and development in Dominica 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 Dominica; 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.

- (10) 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 Dominica;
 - (b) an evaluation of historic, current or proposed activities that impact upon the promotion of biotechnology research and development in Dominica 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 Dominica 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 Dominica'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.

Approval and Enforcement of Policy on Biotechnology Research and Development

64. (1) 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.
- (2) Upon receipt of the *Policy to Promote and Regulate Biotechnology Research and Development* pursuant to the provisions of sub-section (1) above, the Minister may:
- (a) refer the Policy to the National Biosafety Authority with such recommendations as may be considered necessary to correct any deficiency in the Policy; or
 - (b) approve the Policy, which approval may contain such modifications as the Minister considers desirable to give effect to the requirements of this Act.

- (3) Upon approval by the Minister, the *Policy to Promote and Regulate Biotechnology Research and Development* shall be submitted to Cabinet for review and consideration.
- (4) 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

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

Part 9 APPEALS

Appeals

66. (1) A person who feels aggrieved by any decision or action taken by the National Biosafety Authority, the Secretariat or an inspector in terms of this Act may, within the period and in the manner prescribed by Regulations under the Act, and upon the payment of the prescribed fee, appeal against such decision or action to the Minister, who shall appoint an appeal board for the purpose of the appeal concerned.
- (2) An appeal board established pursuant to sub-section (1) shall consist of the person or persons who has or have expert knowledge and who is or are otherwise suitable to decide on the issues of the appeal concerned.
- (3) If an appeal board consisting of more than one person is appointed, the Minister shall designate one of the members as chairperson of that appeal board.
- (4) A person appointed under sub-section (3), shall recuse himself or herself as a member of the appeal board if he or she has any direct or indirect interest in the subject matter of the appeal or if, for any other reason, there is or there is likely to be a conflict of interests as a result of his or her participation in the proceedings of the appeal board.
- (5) There may be paid to a member of an appeal board who is not in the full-time employment of the State, from money appropriated by Government for such purpose, such remuneration or allowances as the Minister, with the concurrence of the Minister of Finance, may determine.
- (6) An appeal board established pursuant to sub-section (1) may –

- (a) confirm, set aside or amend the decision or action concerned which is the subject of the appeal;
 - (b) refer the relevant matter back to the Secretariat for reconsideration by the National Biosafety Authority; or
 - (c) make such other order as it may deem fit.
- (7) If a decision or action which is the subject of an appeal-
- (a) is set aside, the fee referred to in sub-section (1) shall be refunded to the appellant concerned; or
 - (b) is amended, such portion of the fee referred to in sub-section (1) as the appeal board concerned may determine, shall be refunded to the appellant.
- (8) The decision of an appeal board, together with the reasons therefor, shall be reduced to writing, and copies thereof shall be furnished to the Minister, whereupon the Minister may take such further action as he or she may deem necessary.

Part 10

ENFORCEMENT AND COMPLIANCE

Inspections at Ports of Entry or Exit

67. (1) Every person in possession of any genetically modified organism as part of his or her personal effects or baggage, shall on arrival in or departure from Dominica, declare such possession to the Customs Officer or inspector on duty at the port of entry or exit, and shall:
- (a) permit such officer to inspect and examine any genetically modified organism in their possession;
 - (b) afford all reasonable facilities and assistance in carrying out any inspection and examination of any genetically modified organism; and
 - (c) produce all permits or relevant documents in respect of the genetically modified organism.
- (2) Where any person is found to be in possession of any organism that a Customs Officer or inspector has reasonable cause to believe or suspect may be a genetically modified organism, and for which there is no valid permit, that person shall surrender such organism to the officer.
- (3) Any person who fails to comply with any of the requirements of sub-sections (1) and (2) above, shall be guilty of an offence and liable on conviction to the penalties provided under Part 10 of the Act.

- (4) Any organism surrendered to a Customs Officer or inspector pursuant to the requirements of sub-section (2) above shall be immediately conveyed to the National Biosafety Authority.
- (5) Should any organism surrendered to a Customs Officer or inspector pursuant to the requirements of sub-section (2) above be determined by the National Biosafety Authority not to be a genetically modified organism, such organism shall forthwith be released to the person who surrendered the specimen.
- (6) Any person who has surrendered an organism pursuant to the provisions of sub-section (2) above, may apply for a permit to re-export genetically modified organism as provided in section 27.

Confiscation of Genetically Modified Organisms.

68. (1) Where a Customs Officer or inspector finds any genetically modified organism:
- (a) in or on any ship or aircraft;
 - (b) at any port of entry or exit; or
 - (c) 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 genetically modified organism 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.
- (2) Any officer or inspector seizing any genetically modified organism pursuant to the provisions of sub-section (1) above, may also seize:
- (a) any container, packing case, crate, box, or other form of receptacle holding such genetically modified organism; and
 - (b) 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, and which does not pose any harm to Dominica's biodiversity, the environment or human health..
- (3) Where proceedings are instituted within the time provided under this Act, and at the final conclusion of those proceedings the court orders the forfeiture of any genetically modified organism that was seized and detained, it shall be disposed of as the National Biosafety Authority may direct.
- (4) 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 `Dominica's natural biodiversity, the environment or human health.

- (5) Where the confiscation of any illegally imported genetically modified organism has been ordered, the National Biosafety Authority may, after consultation with the State where the specimen was obtained, return the genetically modified organism at the expense of such State.
- (6) In any case where a genetically modified organism has been seized pursuant to the provisions of sub-section (1) above, and:
 - (a) the owner cannot be determined; or
 - (b) the specimen may die, rot, spoil or otherwise perish,the Secretariat of the National Biosafety Authority may dispose of the genetically modified organism as if it was forfeited to State.
- (7) All costs and expenses of and attendant upon any disposal, housing, safe-keeping, or re-export of any genetically modified organism 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.

Offences and Penalties

69. (1) Any person who-
 - (a) contravenes or fails to comply with any condition, restriction, prohibition, reservation or directive imposed or issued in terms of this Act;
 - (b) 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 Authority;
 - (c) 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
 - (d) 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.
- (2) A person who exports or imports any genetically modified organism in contravention of any requirement or condition specified under the Act, is guilty of an offence and liable upon conviction to a fine not exceeding \$100,000 or to imprisonment for a period of not exceeding five years, or to both such fine and imprisonment.
- (3) A person who knowingly, intentionally, or with reckless disregard to human health, safety or the environment:

- (a) releases any genetically modified organism that results in harm to human health or safety, or severe damage to Dominica's natural biodeiversity or the environment;
- (b) permits or participates in the transboundary movement of any genetically modified organism that results in harm to human health or safety, or severe damage to the environment;

is guilty of an offence and liable upon conviction to a fine not exceeding \$500,000 or to imprisonment for a period of not exceeding 10 years, or to both such fine and imprisonment.

- (4) Any person convicted of an offence under the Act and not provided under subsections (2) and (3) , shall-
 - (a) on a first conviction be liable to a fine not exceeding \$50,000 or to imprisonment for a period not exceeding 2 years; and
 - (b) on a second or subsequent conviction be liable to a fine not exceeding \$100,000 or to imprisonment for a period not exceeding 5 years.

Limitation Period for Offences

- 70. 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, which ever is the later.

Continuing Offence

- 71. 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.

Additional Penalties

- 72. 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.

Employee Protection

73. (1) No employer shall:
- (a) dismiss or threaten to dismiss an employee;
 - (b) discipline or suspend an employee;
 - (c) 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.
- (2) Any employer who commits any act specified in sub-section (1) is guilty of an offence and liable upon conviction to a fine of not exceeding \$30,000 or to imprisonment for a period not exceeding 1 year, or to both such fine and imprisonment.

Civil Claims for Environmental Damage

74. 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 genetically modified organism may institute a civil claim for damages in any court, which may include a claim for:
- (a) economic loss resulting from the release of genetically modified organisms 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 genetically modified organism, or to investigate response and risk management options.

Liability of Corporations and Corporate Directors

75. (1) 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.
- (2) A corporation that:
- (a) has caused or contributed to any release of genetically modified organism; or
 - (b) owns, manages, or exercises control over any facility or land that has caused or contributed to any release of genetically modified organism,
- may, in addition to any penalty that may be imposed under this Act or regulations, be liable to a claim for civil damages as provided in section 74.

Corporate Liability in Case of Bankruptcy

76. 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.

Proof of Offence

77. Where the inspection report of the inspector or person carrying out any inspection pursuant to the requirements of this Act, verifies that:
- (a) the condition of the facility or its equipment; or
 - (b) 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 genetically modified organism, 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.

Procedural Aspects

78. (1) 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.
- (2) 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.

- (3) Notwithstanding the provisions of sub-section (2), 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.
- (4) 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.

Enforcement

- 79.
- (1) 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.
 - (2) 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 a residential premises, to which the approval, permit or licence relates.
 - (3) An inspector, officer or any person empowered to carry out any duty under this Act may not enter a private residential premises except:
 - (a) with the consent of the owner; or
 - (b) pursuant to the authority of any search warrant issued under sub-section (4).
 - (4) Where a justice is satisfied on evidence under oath by an inspector, officer or any person empowered to carry out any duty under this Act that:
 - (a) there are reasonable grounds to believe that an offence under this Act or regulations has been committed; and
 - (b) 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 can not 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 officer 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.

- (5) 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 any thing 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.
- (6) In seizing any article under the provisions of sub-section (5), the inspector, officer or any person empowered to carry out any duty under this Act shall:
 - (a) inform the person in possession of the article of the reason for the seizure;
 - (b) give the person in possession of the article a receipt for the article that has been seized; and
 - (c) 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.

Part 11

MISCELLANEOUS AND SUPPLEMENTARY

Other Enactments Apply

- 80. 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.

Delegation of Powers

- 81. The Minister may, subject to such conditions as he or she may determine, in writing delegate any power conferred upon him or her by this Act, other than a power referred to in section 64 (2), to an officer employed by the department, but shall not be divested of

any power so delegated and may amend or set aside any decision of the delegate made in the exercise of such power.

Transitional Provisions

82. Any genetically modified organism that is being imported into Dominica at the time of the enactment of this Act shall be subject to the provisions of section 23 and Part 4.

Regulations

83 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:

- (a) 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;
- (b) designating any organism to which this Act applies;
- (c) for the variation of any risk management regime as provided in this Act;
- (d) establishing criteria, procedures and protocols for the safe destruction, temporary storage or disposal of any genetically modified organisms;
- (e) establishing criteria for accreditation or approval of any biotechnology research facility;
- (f) establishing the storage, handling, and laboratory practices of any biotechnology research facility;
- (g) establishing sampling and analytical procedures and protocols for any risk assessment regime as provided in the Act;
- (h) prescribing fees, costs, or expenses for any approvals, risk assessments, investigations, inspections, enforcement done under the Act;
- (i) prescribing the labelling, identification, packaging requirements of any genetically modified organism;
- (j) respecting the format or contents of any permit;
- (k) to give effect to any *Policy to Promote and Regulate Biotechnology Research and Development* approved under the provisions of Part 8;
- (l) prescribing information to be contained in an order to stop work on any development activity or undertaking;
- (m) prescribing the procedures for appeal in accordance with Part 9 of this Act; and
- (n) with respect to any matter necessary to carry out the intent and purpose of this Part of this Act.

Commencement

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