**BIOSAFETY BILL**

**EXPLANATORY MEMORANDUM**

**PRELIMINARY**

**Clause 1: Short title and commencement**

The Minister responsible for biodiversity and biosafety will administer this Bill. For this reason, the Bill will come into force on a date to be fixed by the Minister by Order published in the *Gazette* according to clause 1 of the Bill. However, clause 1(3) allows the Minister to fix a different date for commencement of products of living modified organisms specified in Part B of Schedule 1.

**Clause 2: Interpretation**

In clause 2 of the Bill, the definitions of the words used throughout the Bill are provided. The definition of the words “export”, “import”, “modern biotechnology” and “transboundary movement” are reproduced from the Cartagena Protocol. Other words such as, “contained use”, “living modified organism”, “intentional introduction into the environment”, “placing on the market” and “risks to human health” are defined.

**Clause 3: Application**

Clause 3 of the Bill indicates the matters to which the Bill will apply.

**Clause 4: The Crown**

Under clause 4 of the Bill, the Bill is binding on the Crown.

**PART I**

**ADMINISTRATION**

**Clauses 5-10**

Clause 5 of the Bill designates Competent National Authorities for the purposes of the Bill. The Sustainable Development and Environment Division of the Ministry responsible for biodiversity and biosafety is the focal point for Saint Lucia under clause 6 of the Bill. The functions of the Sustainable Development and Environment Division of the Ministry responsible for biodiversity and biosafety are also identified in clause 6 of the Bill. The functions of the Sustainable Development and Environment Officer and the Public Education Specialist are stated in clauses 7 and 8 of the Bill. The functions of the Information Technology Officer and inspectors are in clauses 9 and 10 of the Bill.

**Clauses 11-26**

A Biosafety Committee is established in clause 11 of the Bill. The remaining provisions (clauses 12-26), therefore, make provision for the constitution of the Committee, disqualification from the Committee, functions of the Committee, meetings of the Committee, Scientific and Technical Advisory Sub-Committee, declaration of interest and abstention from voting, signing of documents and decisions, and annual report of the Committee.

**PART II**

**CATEGORIES OF LICENCES**

**Division 1**

*Contained use licence*

**Clauses 27-30**

In clause 27 of the Bill, a person may only conduct contained use activities in a laboratory, installation or other physical structure if they obtain a licence for contained use. The responsibilities of a licensee are highlighted in clauses 28-30 and consist of safety precautions, good microbiological practice and the keeping of records.

**Division 2**

*Direct use as food, feed or processing licence*

**Clauses 31-33**

Within clause 31 of the Bill provision is made for authorisation for direct use as food, feed or processing. The labeling requirements for direct use as food, feed or processing are identified in clause 32 of the Bill. The labeling of pharmaceuticals is dealt with in clause 33 of the Bill.

**Division 3**

*Intentional introduction into the environment licence*

**Clauses 34**

An intentional introduction into the environment licence is provided for in clause 34 of the Bill.

**Division 4**

*Import licence*

**Clauses 35-37**

In clause 35 of the Bill, a person must obtain an import licence to import a living modified organism into Saint Lucia. The advance informed agreement procedure set out in clause 36 of the Bill must be followed for all imports. The Committee may grant or refuse an import licence in accordance with clause 37 of the Bill.

**Division 5**

*Export licence*

Clause 38 of the Bill makes provision for an export licence.

**Division 6**

*Transit and Trans-shipment licence*

In clause 39 of the Bill a licence is required for the transit and trans-shipment of living modified organisms.

**Division 7**

*General*

**Clauses 40-52**

An applicant can identify information that should be treated as confidential by clause 40 of the Bill. By virtue of clause 41 of the Bill an applicant may withdraw an application and in clause 42 of the Bill an application may be cancelled in the circumstances identified. In addition, provision is made for the precautionary principle, review of decision, validity, effect of a licence, the keeping of records and furnishing of information, placing on the market in clauses 43-48 of the Bill. In clauses 49 and 50 of the Bill the documentation for import or export and the suspension or revocation of a licence are provided for. The right of appeal against a decision of the Committee and exemptions are provided for in clauses 51 and 52.

**PART III**

**RISK ASSESSMENT, RISK MANAGEMENT AND RISK**

**COMMUNICATION**

Clauses 53-55 of Part III of the Bill provide for risk assessment, risk management and risk communication.

**PART IV**

**UNINTENTIONAL INTRODUCTION INTO THE ENVIRONMENT AND**

**EMERGENCY MEASURES**

In clause 56 provisions are made for unintentional introduction into the environment and in clause 57 the determination of emergency measures is provided for.

**PART V**

**ENFORCEMENT**

Part V of the Bill deals with enforcement. Consequently, clauses 58-68 provides for powers of an inspector, application for warrant, obstruction of inspector, forfeiture by consent, forfeiture by the court, release of forfeited property, cessation notice and imposition of additional risk management measures, notice to remedy cause of contravention, power to enter and execute remedial works, payment of compensation for loss or damage, injunction, and appeal.

**PART VI**

**COMPLAINTS**

**Clauses 69-78**

A complaint may be made by members of the public under clause 69 of the Bill. The complaint will then be submitted to an Inspector in accordance with clause 70 of the Bill. Notification, disposal, frivolous complaints, inspector to investigate complaints and review of the inspector’s report are dealt with in clauses 71-75 of the Bill. An application for review may be made under clause 76 of the Bill and the inspector is to furnish relevant material for such review by clause 77 of the Bill. A review by the Committee must be carried out in accordance with clause 78 of the Bill.

**PART VII**

**TRIBUNAL**

A Biosafety Tribunal is established in clause 79 of the Bill and the remaining clauses of Part VIII of the Bill which consists of clauses 80-90 includes provisions for the constitution, functions, tenure, temporary members, resignations and other matters relating to the hearings, deliberations and decisions of the Tribunal and the validity of their proceedings.

**PART VIII**

**BIOSAFETY FUND**

Part VIII of the Bill established a Biosafety Fund in clause 91 of the Bill. The administration of the Fund is provided for in clause 92 of the Bill. The preparation of financial statements and the audit of such financial statements and the annual report are provided for in clauses 93 and 94 of the Bill.

**MISCELLANEOUS**

In Part IX of the Bill miscellaneous provisions are provided in clauses 95-101. This Part therefore deals with publication, the register, protection, safety measures, appeals, amendment of schedules and regulations.

**SCHEDULE 1**

A list of living modified organisms to be regulated upon commencement of the Bill is presented in Part A and the products to be regulated at a later date are presented in Part B of Schedule 1.

**SCHEDULE 2**

Schedule 2 of the Bill contains the text of the Cartagena Protocol.

**Biosafety Act**

**SAINT LUCIA**

**No. of 2016**

**ARRANGEMENT OF SECTIONS**

Sections

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1. Short title and commencement

2. Interpretation

3. Application

4. The Crown

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1. Competent National Authority

6. Sustainable Development and Environment Division

7. Functions of Sustainable Development and Environment Officer

8. Public Education Specialist

9. Information Technology Officer

10. Inspectors

11. Establishment of Committee

12. Constitution of Committee

13. Disqualification

14. Functions of Committee

15. Powers of Committee

16. Tenure

17. Revocation of appointment

18. Alternate members

19. Resignation

20. Vacancy

21. Decisions not invalidated

22. Meetings of the Committee

23. Declaration of interest and abstention from voting

24. Signing of documents and decisions

25. Annual report of Committee

26. Biosafety Scientific and Technical Advisory Sub-Committee

**PART II**

**CATEGORIES OF LICENCES**

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*Contained use*

27. Contained use licence

28. Safety precautions

29. Microbiological practice

30. Records

**Division 2**

*Direct use as food, feed or processing licence*

31. Direct use as food, feed or processing licence

32. Labelling for direct use as food, feed or processing

33. Labelling for pharmaceuticals

**Division 3**

*Intentional introduction into the environment licence*

34. Intentional introduction into the environment licence

**Division 4**

*Import licence*

35. Import licence

36. Advanced informed agreement procedure

37. Grant or refusal of import licence

**Division 5**

*Export licence*

38. Export licence

**Division 6**

*Transit and Trans-shipment licence*

39. Transit and Trans-shipment licence

**Division 7**

*General*

40. Confidentiality

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43. Precautionary approach

44. Review of decision

45. Validity

46. Effect of licence

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48. Placing on the market

49. Document for import or export

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**PART III**

**RISK ASSESSMENT, RISK MANAGEMENT AND RISK**

**COMMUNICATION**

53. Risk assessment

54. Risk management

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**PART IV**

**UNINTENTIONAL INTRODUCTION INTO THE ENVIRONMENT AND**

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56. Unintentional introduction into the environment

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**PART V**

**ENFORCEMENT**

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60. Forfeiture by consent

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**COMPLAINTS**

69. Complaints by public

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**TRIBUNAL**

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82. Tenure

83. Temporary member

84. Resignation

85. Revocation of appointment

86. Publication in the *Gazette*

87. Secretary of Tribunal

88. Remuneration of members of Appeals Tribunal

89. Hearings, deliberations and decisions

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92. Administration of the Fund

93. Preparation of financial statements

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**MISCELLANEOUS**

95. Publication

96. Register

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100. Amendment of Schedules

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**SCHEDULE 1**

**SCHEDULE 2**

**Biosafety Act**

**SAINT LUCIA**

**No. of 2016**

**A**

**BILL**

**ENTITLED**

**AN ACT** to regulate living modified organisms, to implement the Cartagena Protocol on Biosafety and for related matters.

**BE IT ENACTED** by the Queen’s Most Excellent Majesty by and with the advice and consent of the House of Assembly and the Senate of Saint Lucia, and by the Authority of the same, as follows:

**PRELIMINARY**

**Short title and commencement**

1. (1) This Act may be cited as the Biosafety Act, 2016.

(2) This Act shall come into force on a date to be fixed by the Minister by Order published in the *Gazette*.

(3) Notwithstanding subsection (2), Part B of Schedule 1 shall come into force on a later date to be fixed by the Minister by Order published in the Gazette.

**Interpretation**

2. In this Act -

“advanced informed agreement procedure” means the process set out in section 36;

“agent” includes an independent contractor;

“applicant” means a person or country or agent of such person or country who submits an application under this Act;

“application” means an application made for a licence under sections 27, 31, 34, 35, 38 or 39;

“application fee” means a prescribed amount to be submitted with an application under this Act;

“biosafety” means the prevention of large-scale loss of biological integrity, focusing on ecology and human health;

“Sustainable Development and Environment Division” means the Sustainable Development and Environment Division in the Ministry responsible for biodiversity and biosafety that is responsible for biodiversity and biosafety;

“Biosafety Clearing House” means the information exchange mechanism or portal established under article 20 of the Protocol;

“biosafety website” means the biosafety website created under section 6(3);

“Committee” means the Biosafety Committee established under section 11;

“Competent National Authority” means the Competent National Authority designated under section 5;

“contained use” means any operation or activity, in which a living modified organism is produced, grown, stored, destroyed or used in some other way in a laboratory, installation or other physical structure in which stringent physical barriers are employed, either alone or together with chemical or biological barriers, to limit contact between the living modified organism on the one hand and humans and the environment on the other hand;

“control” includes –

(a) a method to restrict the dissemination or persistence of the living modified organism or its genetic material in the environment;

(b) a method for disposal of the living modified organism or its genetic material in the environment;

(c) data collection, including studies to be conducted about the living modified organism;

(d) a method to restrict the geographic area in which the living modified organism is proposed to be used;

“damage” means an adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health, that –

(a) is measurable or otherwise observable taking into account, wherever available, scientifically-established baselines that takes into account any other human induced variation and natural variation; and

(b) is significant on the basis of factors, such as –

(i) the long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time,

(ii) the extent of the qualitative or quantitative changes that adversely affect the components of biological diversity,

(iii) the reduction of the ability of components of biological diversity to provide goods and services,

1. the extent of any adverse effects on human health in the context of the Protocol;

“direct use as food, feed or processing” includes activities that result in –

1. living modified organisms for human consumption;
2. living modified organisms for processing edible oils;
3. living modified organisms for feeding to animals;
4. living modified organisms used in industrial processing in the production of plastics and oils;

“export” means intentional trans-boundary movement from Saint Lucia to another country;

“exporter” means a person who arranges for a living modified organism to be exported;

“import” means intentional transboundary movement into Saint Lucia from another country;

“importer” means a person who arranges for a living modified organism to be imported;

“Information Technology Officer” means a person in the Ministry responsible for Biodiversity and Biosafety appointed by the Public Service Commission to act as the Information Technology Officer for the Sustainable Development and Environment Division;

“inspector” means –

1. a person assigned as an inspector to a Competent National Authority;
2. a person appointed under any law relating to biosafety to inspect, monitor or ensure compliance of such law;

“intentional introduction into the environment” –

(a) means any deliberate release of a living modified organism for which no specific containment measures are in place to limit their contact with and to provide a high level of consideration for safety for the general population and the environment; and

(b) includes-

(i) the use of living modified organisms in field trials;

(ii) the growing of agricultural living modified organisms in close proximity to natural plants to cross pollinate;

(iii) the release of transgenic fish into open waters;

(c) does not include a living modified organism imported for direct use for food, feed or for processing;

“licence” means a licence issued under section 27, 31, 34, 35, 38 or 39;

“licensee” means a person who is issued a licence;

“limit” includes a restriction on –

1. the scope of the contained use, direct use as food, feed or processing, intentional introduction into the environment, import, export, transit or trans-shipment;
2. the scale of the contained use, direct use as food, feed or processing, intentional introduction into the environment, import, export, transit or trans-shipment;
3. the location of the contained use, direct use as food, feed or processing, intentional introduction into the environment, import, export, transit or trans-shipment;
4. the duration of the contained use, direct use as food, feed or processing, intentional introduction into the environment, import, export, transit, or trans-shipment;
5. the person who is permitted to conduct the contained use, direct use as food, feed or processing, intentional introduction into the environment, import, export, transit or trans-shipment of the living modified organism;

“living modified organism” –

1. means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids that possess a novel combination of genetic material obtained through the use of modern biotechnology;
2. includes the products listed in Schedule 1;

“Minister” means the Minister responsible for Biodiversity and Biosafety matters;

“modern biotechnology” means the application of -

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

(b) fusion of cells beyond the taxonomic family;

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

“notification” means a notice **made under this Act;**

“notifier” means a person who makes a notification under this Act;

“operator” means any person or agent of such person in direct or indirect control of a living modified organism;

“person” includes corporate bodies and unincorporated bodies;

“placing on the market” means making a living modified organism available to third parties whether in return for payment or free of charge but does not include a living modified organism that will be exclusively used for contained use;

“precautionary approach” means the way of dealing with the grant of a licence by the Committee under section 43(2);

“Protocol” means the Cartagena Protocol on Biosafety the text of which is set out in Schedule 2;

“Public Education Specialist” means a person in the Ministry responsible for Biodiversity and Biosafety appointed by the Public Service Commission to act as Public Education Specialist for the Sustainable Development and Environment Division;

“risk assessment” means the process and criteria set out in section 53;

“risks to human health” means the potential impact on human beings and on the conservation and sustainable use of biological diversity as a direct result of -

(a) a living modified organism;

(b) a causal chain of events, through mechanisms, such as, interactions with other organisms, transfer of genetic material, or changes in use or management;

(c) direct or indirect effects observed on the immediate release of the living modified organism;

(d) direct or indirect effects observed at a later stage of release of the living modified organism or after termination of the release of the living modified organism;

“Secretariat” means the body internationally responsible for executing biodiversity activities;

“Secretary” means –

1. in relation to the Committee, the Sustainable Development and Environment Officer under section 12(1)(e); or
2. in relation to the Tribunal, the recording Secretary appointed under section 87(1);

“Sub-Committee” means the Biosafety Scientific and Technical Advisory Sub-Committee established under section 26;

“Sustainable Development and Environment Officer” means a person in the Ministry responsible for Biodiversity and Biosafety appointed by the Public Service Commission to act as the Sustainable Development and Environment Officer in the Sustainable Development and Environment Division;

“transboundary movement” means the transfer of a living modified organism from Saint Lucia to another country or into Saint Lucia from another country;

“Tribunal” means the Biosafety Tribunal established under section 79;

“unique identifier” means the nine-digit alphanumeric code that is given to each transgenic or genetically engineered plant that is approved for commercial use, including planting and food or feed use under the Organisation for Economic Cooperation and Development published guidance for the designation of a unique identifier for transgenic plants.

**Application**

3. (1) This Act applies to -

(a) the transboundary movement and movements within Saint Lucia, transit, handling, production and use of all living modified organisms that may cause damage or risks to human health;

(b) a living modified organism that is a pharmaceutical not covered by an international agreement and that is for human and animal use;

(c) fish, insects and other living modified organisms.

(2) This Act does not apply to a living modified organism that is exempted under section 52.

**The Crown**

4. This Act binds the Crown.

**PART I**

**ADMINISTRATION**

**Competent National Authority**

5. (1) The –

1. Chief Veterinary Officer or his or her delegated alternate;
2. Plant Protection and Plant Quarantine Services;
3. Ministry responsible for Health;
4. Ministry responsible for Commerce; and
5. Pesticides and Toxic Chemicals Control Board;

are each designated as a Competent National Authority for the purposes of this Act.

 (2) Notwithstanding subsection (1), the Minister may, on the recommendation of the Committee, by Order published in the Gazette, designate a body as a Competent National Authority as the Minister considers necessary.

 (3) Each Competent National Authority shall –

1. submit applications to the Sustainable Development and Environment Officer;
2. grants licences in accordance with this Act;
3. maintain records of application and licences;
4. monitor and enforce this Act.

**Sustainable Development and Environment Division**

6. (1) The Sustainable Development and Environment Division shall serve as the national focal point for biosafety for Saint Lucia and shall perform the functions specified in subsection (2).

(2) The functions of the Sustainable Development and Environment Division includes -

1. to liaise with the Secretariat;

(b) to receive, process, and respond to information and notifications from the Secretariat;

(c) to facilitate national, regional and international information sharing;

(d) to carry out the policies of the Committee;

(e) to receive applications, notifications, petitions and complaints made under this Act;

(f) to submit the applications, notifications, petitions and complaints referred to in paragraph (e) to the Committee for consideration;

(g) to submit decisions of the Committee to the Competent National Authority.

 (3) The Sustainable Development and Environment Division shall keepa national biosafety website for the purpose of sharing national information on biosafety matters.

(4) The website created under subsection (3) shall be linked to -

(a) regional biosafety websites for collaboration on matters related to risk assessment and risk management; and

(b) the Biosafety Clearing-House.

(5) The Sustainable Development and Environment Division shall provide to the national biosafety website and the Biosafety Clearing-House -

1. a copy of this Act, including any amendments, decisions made under this Act or regulations made under this Act, and any other legislation or national guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available or for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;
2. any bilateral, regional or multilateral agreement and arrangement of relevance to the implementation of the Protocol or management of living modified organisms;

(c) summaries of risk assessments generated under section 53 including, where appropriate, relevant information regarding products, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) final decisions regarding the importation for intentional introduction into the environment of living modified organisms;

(e) reports concerning national implementation of the Protocol;

(f) within thirty days of taking a decision under section 43, a copy of the decision describing the changes to the previous decision and the reasons for the decision;

(g) within fifteen days of making final decisions regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing, a copy of that decision;

(h) final decisions regarding the importation or release of living modified organisms;

1. any decision regarding the transit through Saint Lucia of a living modified organism;

(j) within two hundred and seventy days of receipt of an application for intentional transboundary movement of living modified organisms, decisions regarding such movement;

(k) within thirty days of reviewing and changing of decisions regarding an intentional transboundary movement, decisions of such reviews and changes with the reasons for the decision;

(l) cases in which intentional transboundary movement to Saint Lucia may take place at the same time as the licence is issued to the applicant;

(m) imports of living modified organisms to Saint Lucia to be exempted from the advance informed agreement procedure;

(n) decisions that specific laws apply to imports to Saint Lucia;

(o) information concerning cases of illegal transboundary movements pertaining to Saint Lucia.

 (6) The decision referred to in subsection (5)(g) must contain, at a minimum, the information specified in Annex II of the Protocol.

 (7) The Sustainable Development and Environment Division shall provide a copy of the information under subsection (5)(g), in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House.

 (8) Subsections (5)(g), (6) and (7) do not apply to decisions regarding field trials.

**Functions of Sustainable Development and Environment Officer**

7. (1) The functions of the Sustainable Development and Environment Officer are –

(a) to establish guidelines for effective biosafety management in Saint Lucia under the direction of the Committee;

(b) to liaise with enforcement agencies identified by the Committee to collaborate with it and the Sustainable Development and Environment Division in enforcing this Act in the execution of their duties;

(c) to make recommendations to the Committee on matters related to biosafety management;

(d) to submit to the Committee at the end of every three months a progress report on the work undertaken by the Sustainable Development and Environment Division related to living modified organisms;

(f) to coordinate the policies and activities of government departments and ministries with respect to living modified organisms;

(e) to review applications to ensure that all required information is present;

(f) to review the biosafety website, the Biosafety Clearing-House and other sources to ensure accuracy of information provided;

(g) to prepare reports concerning national implementation of the Protocol in a timely manner and at such intervals as is agreed by States Parties to the Protocol;

(h) to perform such other functions as may be specified in this Act.

(2) During the absence or disability of the Sustainable Development and Environment Officer or during any vacancy in the office of the Sustainable Development and Environment Officer, the Ministry responsible for Biodiversity and Biosafety shall ensure that the duties and powers of that office are performed by a replacement officer.

**Functions of Public Education Specialist**

8.(1)The functions of the Public Education Specialist are –

(a) to disseminate relevant information on biosafety issues to the general public and target groups relevant to biosafety management in Saint Lucia through the biosafety website and by any other means;

(b) subject to section 95, to raise public awareness and mobilize public participation on biosafety management issues in Saint Lucia;

(c) to inform the public about the means of public access to the national biosafety website and the Biosafety Clearing-House;

(d) to liaise with the Biosafety Clearing-House focal point on matters to be placed on the national biosafety website and the Biosafety Clearing-House;

(e) to liaise with relevant national, regional and international agencies, as appropriate on behalf of Sustainable Development and Environment Division;

(f) to provide relevant information from the Biosafety Clearing House and generally collaborate with other officers for public sensitization and participation on biosafety management issues.

(2) During the absence or disability of the Public Education Specialist or during any vacancy in the office of the Public Education Specialist, the Ministry responsible for Biodiversity and Biosafety shall ensure that the duties and powers of that office are performed by a replacement officer.

**Functions of Information Technology Officer**

9. (1) The functions of the Information Technology Officer are –

(a) to periodically update the biosafety website with relevant information;

(b) compile the mailing list to solicit opinions when applications are received;

(c) collate opinions received from the public.

(2) During the absence or disability of the Information Technology Officer or during any vacancy in the office of the Information Technology Officer, the Ministry responsible for Biodiversity and Biosafety shall ensure that the duties and powers of that office are performed by a replacement officer.

**Inspectors**

10. (1) The functions of Inspectors are –

(a) to verify import and export documentation at the ports for compliance with labeling and documentation requirements under this Act;

(b) to investigate complaints made by members of the public against licensees referred to the Inspector by the Committee;

(c) to monitor the implementation requirements under licences;

(d) to submit to the Committee a final report on all investigations;

(e) to perform such other function as may be specified in this Act.

(2) Inspectors carrying out the functions under this section must be trained and qualified to carry out the functions specified under this Act.

**Establishment of Biosafety Committee**

11. (1) There is hereby established a body to be known as the Biosafety Committee.

 (2) Notwithstanding subsection (1), where a body is established for the coordination of agricultural health and food safety, the Committee may be dissolved and the functions of the Committee may be exercised by that body.

**Constitution of Committee**

12. (1) The Committee shall be appointed by the Minister, on the recommendation of the Chief Sustainable Development and Environment Officer and comprise the following persons –

(a) one public officer from –

(i) the Ministry responsible for Agriculture;

(ii) the Ministry responsible for Sustainable Development;

(iii) the Attorney General’s Chambers;

(iv) the Ministry responsible for Health;

 (v) the Ministry responsible for Pharmacies;

 (vi) the Ministry responsible for Environment health;

(vii) the Ministry responsible for Consumer affairs;

(viii) the National Emergency Management Organization;

(ix) the Department of Customs and Excise;

1. at least four members representing various private sector interests and non-governmental organizations;
2. a representative of the Saint Lucia Solid Waste Management Authority;
3. a representative of the Free Zone Management Authority;

(d) the Sustainable Development and Environment Officer who shall be *ex-officio*, Secretary to the Committee.

(2) The Committee may co-opt any person to attend any particular meeting of the Committee at which it is proposed to deal with a particular matter, for the purpose of assisting or advising the Committee, but persons co-opted do not have the right to vote.

(3) The members of the Committee shall choose a Chairperson and Deputy Chairperson from amongst its members.

(4) The names of the initial members, their title, if any, and every change in membership of the Committee shall be published in the *Gazette*.

**Disqualification**

13. A person is disqualified from being a member of the Committee if that person -

(a) is adjudged by a court to be a bankrupt;

(b) is declared by a court to be mentally incapacitated by reason of unsoundness of mind;

(c) has been convicted of an offence involving dishonesty;

(d) is a member of Parliament.

**Functions of the Committee**

14. (1) The functions of the Committee are -

(a) to review and make **recommendations** on applications, notifications and petitions in consultation with the Sub-Committee in conformity with the requirements of this Act;

(b) to respond to a complaint;

(c) to recommend to the Minister the establishment of administrative mechanisms to ensure the appropriate handling, dissemination and storage of documents and data in connection with the processing of applications and notifications and other matters covered under this Act;

(d) to promote public awareness, education and participation concerning the activities regulated under this Act including through the publication of guidance and other materials that explain and elaborate on the risk assessment, risk management and authorization processes;

(e) to liaise with established regional bodies with regard to regional harmonization within the context of regionalization and the Caribbean Community Single Market and Economy;

(f) to monitor developments in the area of biotechnology and provide advice and recommendations to the Permanent Secretary and the Minister in relation to policy, strategic plans, trade, economic development, environmental management, research and development, science and technology development.

(2) The Committee may in carrying out its functions under this Act consult with and obtain assistance from a Competent National Authority or any other Ministry or Department of Government.

(3) For the purposes of subsection (2), the Committee may enter into a Memorandum of Understanding with any Competent National Authority or any other Ministry or Department of Government.

**Powers of the Committee**

15. (1) For the purposes of the discharge of its functions the Committee has power –

(a) to request any information, documents or things with respect to a complaint, from -

(i) any person making a complaint;

(ii) the person against whom the complaint is made; or

(iii) any other person who, in the opinion of the Committee, may be able to assist;

(b) in the case of a review of a complaint, to request such information, documents or things as it considers necessary to review the complaint.

(2) The Committee may give such guidance to the Sustainable Development and Environment Division as may be necessary to ensure thoroughness in the carrying out of the functions of the Sustainable Development and Environment Division.

**Tenure**

16. (1) A member of the Committee, subject to subsection (2), holds office for three years and may be reappointed.

(2) The appointment of one third of the members of the Committee shall be staggered for the purpose of continuity in accordance with Regulations made under section 101.

**Revocation of appointment**

17. (1) The Minister may at any time, in writing, revoke the appointment of any member of the Committee if, on evidence, the Minister is satisfied that the member is bankrupt or guilty of neglect of duty, misconduct or malfeasance.

 (2) A member of the Committee who is accused of neglect of duty, misconduct or malfeasance is entitled to have the principles of natural justice applied, including -

1. the right to a fair hearing;
2. the right to make representation;
3. notice of the accusation and full particulars;
4. a right to legal representation.

**Alternate member**

18. (1) The Minister may appoint a person to be an alternate member for a specified member of the Committee, other than the Chairperson in a manner that respects the requirements in section 12(1) for the composition of the Committee.

(2) The Minister may at any time, in writing, revoke the appointment of an alternate member in the same way as the revocation for a member may be revoked under section 17.

(3) The alternate member appointed under subsection (1) may act temporarily in the place of that member if that member is absent or incapable of performing the duties of a member.

**Resignation**

19. (1) A member of the Committee shall, by notice in writing to the Minister immediately resign from the membership of the Committee if that member becomes disqualified under section 13.

(2) A member of the Committee may, for any reason other than disqualification under section 13, resign from the membership of the Committee by giving at least three months notice in writing to the Minister of his or her resignation.

**Vacancy**

20. (1) The office of a member of the Committee is vacated –

(a) on the death of the member;

(b) if the member becomes disqualified under section 13;

(c) if the member resigns from membership under section 19;

(d) if the Minister revokes the appointment of that member under section 17; or

(e) if the member fails to attend three consecutive meetings of the Committee without being excused by the Chairperson in writing.

(2) Where a vacancy occurs in the membership of the Committee, the Minister shall appoint a person to fill the vacancy in a manner that respects the requirements in section 12 for the constitution of the Committee.

(3) A member appointed to fill a vacancy shall hold office only for the unexpired portion of the term of the former member.

**Decisions not invalidated**

21. (1) A vacancy in the membership of the Committee does not invalidate a decision of the Committee made at a meeting with the quorum required under section 22.

(2) Where a disqualified member sits at a meeting of the Committee, the Committee may review and amend its decision within two months of that decision being made.

**Meetings of the Committee**

22. (1) The Committee shall meet at such times as may be necessary or expedient for the transaction of business and such meetings shall be held at such places and times and on such days as the Committee determines.

(2) The Chairperson or Deputy Chairperson shall preside at meetings of the Committee and where the Chairperson or Deputy Chairperson is absent from any meeting the members present may elect one of themselves to act as Chairperson for that meeting.

(3) The Chairperson, Deputy Chairperson or elect Chairperson and seven members of the Committee form a quorum.

(4) The Chairperson or Deputy Chairperson of the Committee may at any time call a special meeting of the Committee and shall call a special meeting to be held within seven days of a written request for that purpose addressed to the Chairperson or Deputy Chairperson by any other member of the Committee.

(5) Decisions of the Committee is by a majority of votes and where the voting is equal the Chairperson or Deputy Chairperson has the casting vote.

(6) Subject to this section, the Committee may regulate its own proceedings.

**Declaration of interest and abstention from voting**

23. (1) A member of the Committee who is any way, either directly or indirectly, interested in a matter before the Committee shall declare the nature of his or her interest at the first meeting of the Committee at which it is practicable to do so and shall leave the meeting on the matter coming up for discussion.

(2) A declaration and the departure of a member of the Committee from the meeting in accordance with subsection (1) must be noted in the minutes of the meeting.

(3) A member of the Committee shall not -

(a) vote in respect of a matter before the Committee in which he or she is in any way interested, whether directly or indirectly; or

(b) seek to influence the vote of any other member of the Committee in relation to the matter.

(4) A member of the Committee who fails to comply with subsection (3) is guilty of misconduct and his or her appointment shall be revoked by the Minister under section 17.

**Signing of documents and decisions**

24. All documents made by, and the decisions of the Committee may be signified under the hand of the Chairperson or any member of the Committee authorized by the Chairperson to act in that behalf, or by the Secretary of the Committee.

**Annual report of Committee**

25. (1) In accordance with subsection (2) and not later than three months after the end of each financial year, the Committee shall submit to the Minister an annual report on the work and activities of the Committee for that financial year and the Minister shall not later than one month later lay the same in Parliament.

(2) An annual report under subsection (1) shall be in the prescribed form.

(3) A summary of an annual report under subsection (1) shall be published in the *Gazette* and at least two newspapers in general and at least weekly circulation in Saint Lucia and the entire annual report shall be available to the public on payment of the prescribed fee to the Committee.

 (4) In this section “financial year” means the twelve months ending on 31 March in any year.

**Biosafety Scientific and Technical Advisory Sub-Committee**

26. (1) The Committee shall appoint a Biosafety Scientific and Technical Advisory Sub-Committee with technical competencies for the purposes specified in subsection (2).

(2) The functions of the Sub-Committee are -

1. to conduct risk assessments –
2. when an application is made under this Act;

(ii) where there is new technology;

(iii) to provide a mechanism for determining ways to minimize potential risks;

(iv) to adequately assess safety prior to the import or export of a living modified organism;

(v) where a living modified organism is released intentionally or otherwise and causes unintended, unwanted or unacceptable effects;

(b) where a risk assessment is provided in an application or required under any other law, to review such risk assessment;

(c) to review and determine risk management and risk communication measures;

(d) to recommend to the Committee in relation to an application, measures, limitations on the duration of applications of measures, reporting mechanisms, remedial measures, monitoring procedures and other appropriate scientifically sound conditions and risk management measures; and

(e) to provide such other expert advice and assistance as the Committee may require.

(3) The Sub-Committee consists of the following experts appointed by the Committee from the following fields:

(a) agronomy;

(b) molecular biology;

(c) toxicology;

(d) human health;

(e) environmental science;

(f) socio-economic development; and

1. animal health.

(4) Notwithstanding subsection (3), the Sub-Committee may consist of experts appointed by the Committee who have experience in areas related to the fields specified in subsection (3)(a)-(e).

(5) The Sub-Committee may establish a sub-sub-committee and appoint a chairperson of the sub-sub-committee from the members of the Sub-Committee.

(6) Members of the Sub-Committee and any sub-sub-committee must be drawn from governmental agencies or independent institutions including research institutes and universities and other academic institutions.

(7) Where a member of the Sub-Committee or sub-sub-committee is directly or indirectly interested in a matter before the Sub-Committee or sub-sub-committee, section 22 applies as it applies to members of the Committees.

(8) The Sub-Committee may, with the approval of the Committee, co-opt as members for a stated period, persons including persons from regional or other countries, with expert knowledge or experience required by the Sub-Committee in the discharge of its duties.

(9) The Sub-Committee or a sub-sub-committee established by the Sub-Committee may regulate its own proceedings.

**PART II**

**CATEGORIES OF LICENCES**

**Division 1**

*Contained use licence*

**Contained use licence**

27. (1) A person shall not conduct a contained use activity involving a living modified organismunless that person holds a valid contained use licence.

(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of ten thousand dollars or to imprisonment of two years or to both and the living modified organism being quarantined in accordance with the Quarantine Act, Cap. 11.16.

(3) In order for a person to obtain a contained use licence that person shall, in accordance with subsections (4) and (5), apply to a Competent National Authority for a contained use licence.

(4) An application made under subsection (3) shall be -

(a) addressed to the Secretary of the Committee;

(b) submitted to the Competent National Authority in triplicate;

(c) in the prescribed form;

(d) accompanied with the prescribed application fee.

 (5) An application made under subsection (3) may be made on the biosafety website.

 (6) Upon receipt of an application, the Competent National Authority shall keep one copy of the application and submit two copies of the application to the Sustainable Development and Environment Officer.

 (7) On receiving an application for a contained use licence, the Sustainable Development and Environment Officer shall retain one copy and submit the other copy to the Committee.

(8) The Committee, after consultation with the Sub-Committee, may request in writing that the applicant provide additional information including a risk assessment and risk management plan.

(9) On receiving an application for a contained use licence, the Committee shall -

(a) cause the laboratory, installation or other physical structure to be inspected and reported on by the Ministry responsible for Physical Planning; and

(b) consider the report and any representation made concerning the laboratory, installation or other physical structure by the applicant.

(10) Subject to section 43, where an application is made for a contained use licence under subsection (3), the Committee shall submit a recommendation to the Competent National Authority for the –

(a) grant the contained use licence with conditions where controls or limits are necessary to alleviate damage or risks to human health;

(b) grant the contained use licence without conditions where the living modified organism is not likely to cause damage or risks to human health; or

(c) refuse to grant a contained use licence where it is necessary to protect against damage or risks to human health.

(11) In accordance with a recommendation submitted under subsection (10), the Competent National Authority shall grant with or without conditions or refuse to grant a contained use licence and shall –

(a) immediately notify the applicant of the grant or refusal; and

(b) give reasons in writing for the grant with conditions or refusal to grant a contained use licence.

(12) Where the Competent National Authority grants a contained use licence, the Competent National Authority shall issue a contained use licence in the prescribed form on payment of the prescribed contained use licence fee.

**Safety precautions**

28. A licensee shall ensure that the necessary safety precautions are taken to prevent damage or risks to human health, including measures to limit the detrimental effects of the unintentional introduction of a living modified organism.

**Microbiological practice**

29. A licensee shall ensure that the laboratory, installation or other physical structure is run in accordance with good microbiological practice.

**Records**

30. (1) A licensee shall keep and maintain records of all contained use of living modified organisms.

(2) The records kept under subsection (1) shall be attached to each other while accompanying the living modified organism in transit.

**Division 2**

*Direct use as food, feed or processing licence*

**Direct use as food, feed or processing licence**

31. (1) A person shall not use a living modified organism for direct use as food, feed, or processing unless that person holds a valid direct use as food, feed or processing licence.

(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of ten thousand or to imprisonment for two years or to both, and in addition –

1. the person may be requested to dispose, at his or her own expense, of the living modified organism in question by destruction in accordance with the Waste Management Act, Cap. 6.05 and to the satisfaction of the Competent National Authority; or
2. the living modified organism may be subject to quarantine procedures in accordance with the Quarantine Act, Cap. 11.16.

(3) In order for a person to obtain a direct use as food, feed, or processing licence that person shall, in accordance with subsections (4) and (5), apply to a Competent National Authority for a direct use as food, feed, or processing licence.

(4) An application made under subsection (3) shall -

(a) be addressed to the Secretary of the Committee;

(b) be submitted to the Competent National Authority in triplicate;

(c) be in the prescribed form;

(d) be accompanied by the prescribed application fee.

 (5) An application made under subsection (3) may be made on the biosafety website.

(6) An applicant who intentionally or recklessly obtains a direct use as food, feed or processing licence by fraud, deception or misrepresentation commits an offence and is liable on summary conviction to a fine of five thousand dollars or to imprisonment for a term of one year or to both.

(7) Upon receipt of an application, the Competent National Authority shall retain one copy of the application and submit two copies of the application to the Sustainable Development and Environment Officer.

(8) On receiving an application, the Sustainable Development and Environment Officer shall retain one copy of the application and submit the other copy of the application to the Committee.

a) The Committee, after consultation with the sub-committee, shall request in writing that the applicant provide a risk assessment report

(9) Subject to sections 43 and 95, the Committee shall submit a recommendation to the Competent National Authority for –

(a) the grant of a direct use as food, feed or processing licence with conditions where controls or limits are necessary to alleviate damage or risks to human health;

(b) the grant of a direct use as food, feed or processing licence without conditions where the living modified organism is not likely to cause damage or risks to human health; or

(c) the refusal of a direct use as food, feed or processing licence where it is necessary to protect against damage or risks to human health.

(10) In accordance with a recommendation under subsection (9), the Competent National Authority shall grant with or without conditions or refuse to grant a direct use as food, feed or processing licence and shall –

(a) immediately notify the applicant of the grant or refusal of a direct use as food, feed or processing licence; and

(b) give the reasons in writing for the grant with conditions or refusal to grant a direct use as food, feed or processing licence.

(11) Where the Competent National Authority grants a direct use as food, feed or processing licence, the Competent National Authority shall issue a direct use as food, feed or processing licence in the prescribed form on payment of the prescribed direct use as food, feed or processing licence fee.

**Labelling for direct use as food, feed or processing**

32. (1) A licensee who holds a direct use as food, feed or processing licence shall ensure that -

(a) all products containing living modified organisms above a prescribed limit are labelled or shipments containing more than the prescribed limit of living modified organisms are labelled;

(b) in the case of products consisting of or containing living modified organisms, that the operator receiving the product receives in writing an indication that the product or some ingredients contains or consists of living modified organisms or is produced from living modified organisms and the unique identifier assigned to those living modified organisms, if any;

(c) in the case of products produced from living modified organisms, that the following are transmitted in writing to the operator receiving the product -

(i) an indication of each of the food ingredients which are produced from living modified organisms;

(ii) an indication of each of the feed materials or additives which are produced from living modified organisms;

(d) in the case of products for which no list of ingredients exists, an indication that the product is produced from living modified organisms.

(2) A licensee who holds a direct use as food, feed or processing licence shall retain the information under subsection (1)(b)-(d) for a period of five years from each transaction and be able to identify the person by whom and to whom the products have been made available.

**Labelling for pharmaceuticals**

33. The Committee may make recommendations to the Pharmacy Council or the Bureau of Standards for labelling requirements for pharmaceuticals used for human and animal health.

**Division 3**

*Intentional introduction into the environment licence*

**Intentional introduction into the environment licence**

34. (1) A person shall not intentionally introduce into the environment a living modified organism unless that person holds a valid intentional introduction into the environment licence.

(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of ten thousand dollars or to imprisonment for two years or to both, and in addition –

1. the person may be requested to dispose of the living modified organism in question by destruction, at his or her own expense in accordance with the Waste Management Act and to the satisfaction of the National Competent Authority; or
2. the living modified organism may be subject to quarantine procedures in accordance with the Quarantine Act.

(3) The Minister may prescribe by Order published in the *Gazette* classes of intentional introduction into the environment licences.

(4) In order for a person to obtain an intentional introduction into the environment licence, that person shall, in accordance with subsection (4), apply to the Committee for an intentional introduction into the environment licence.

(5) An application made under subsection (4) shall be -

(a) addressed to the Secretary of the Committee;

(b) submitted to the Competent National Authority in triplicate;

(c) in the prescribed form;

(d) accompanied by the prescribed application fee.

 (6) An application made under subsection (4) may be made on the biosafety website.

(7) A person shall not obtain an intentional introduction into the environment licence by fraud, deception, misrepresentation, misleading or inaccurate information.

(8) A person who contravenes subsection (7) commits an offence and is liable on summary conviction to a fine of ten thousand dollars or to imprisonment for a term of two years or to both.

 (9) Upon receipt of an application, the Competent National Authority shall retain one copy of the application and submit two copies of the application to the Sustainable Development and Environment Officer.

 (10) On receiving an application, the Sustainable Development and Environment Officer shall retain one copy of the application and submit the other copy to the Committee.

 a) The Committee, after consultation with the sub-committee may request in writing that the applicant provide additional information or a risk assessment.

(11) Subject to sections 43 and 95, the Committee shall submit a recommendation to the National Competent Authority for –

(a) the grant of an intentional introduction into the environment licence with conditions where controls or limits are necessary to alleviate damage or risks to human health;

(b) the grant of an intentional introduction into the environment licence without conditions where the living modified organism is not likely to cause damage or risks to human health; or

(c) the refusal of an intentional introduction into the environment licence where it is necessary to protect against damage or risks to human health.

(12) In accordance with a recommendation made under subsection (11), the Competent National Authority shall grant with or without conditions or refuse to grant an intentional introduction into the environment licence and shall –

(a) immediately notify the applicant of the grant or refusal; and

(b) give the reasons in writing for the grant with conditions or refusal to grant an intentional introduction into the environment licence.

(13) Where the Competent National Authority grants an intentional introduction into the environment licence, the Competent National Authority shall issue an intentional introduction into the environment licence in the prescribed form on payment of the prescribed intentional introduction into the environment licence fee.

**Division 4**

***Import licence***

**Import licence**

35. (1) A person shall not import a living modified organism for –

1. contained use; or
2. direct use as food or feed, and processing; or
3. intentional introduction into the environment,

unless that person holds a valid import licence.

(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of ten thousand dollars or to imprisonment for two years or to both, and in addition –

1. the person may be requested to dispose of the living modified organism in question by destruction, at his or her own expense in accordance the Waste Management Act, Cap. 6.05 and to the satisfaction of the Competent National Authority; or
2. the living modified organism may be subject to quarantine procedures in accordance with the Quarantine Act, Cap. 11.16.

(3) In order for a person to obtain an import licence, that person shall, in accordance with subsection (4), apply to the Competent National Authority for an import licence.

(4) An application made under subsection (3) shall be -

(a) addressed to the Secretary of the Committee;

(b) submitted to the Competent National Authority in triplicate;

(c) in the prescribed form;

(d) accompanied by the prescribed application fee.

 **(5) An application made under subsection (3) may be made on the biosafety website.**

(6) A person shall not obtain an import licence by fraud, deception, misrepresentation, misleading or inaccurate information.

(7) A person who contravenes subsection (6) commits an offence and is liable on summary conviction to a fine of ten thousand dollars or to imprisonment for a term of two years or to both.

 (8) Upon receipt of an application, the Competent National Authority shall retain one copy of the application and submit two copies of the application to the Sustainable Development and Environment Officer.

 (9) On receiving an application, the Sustainable Development and Environment Officer shall retain one copy of the application and submit the other copy of the application to the Committee.

(10) The Minister may by Order published in the Gazette specify the classes or subclasses of import licences.

**Make section on contained use, direct use as food, feed or processing and intentional use apply to this section.**

**Advance informed agreement procedure**

36. (1) Where the Committee receives an application for the first import of a living modified organism for-

(a) contained use;

(b) direct use as food, feed or processing; or

(c) intentional introduction into the environment;

the Committee shall follow the advance informed agreement procedure in this section.

(2) Within ninety days of receiving an application, the Sustainable Development and Environment Division shall acknowledge receipt of the application.

(3) The acknowledgement under subsection (2) must be in writing and shall state -

(a) the date of receipt of the application;

(b) that the application contains the information in Annex I of the Protocol;

(c) that the application should proceed according to this Act.

(4) A failure by the Sustainable Development and Environment Division to acknowledge receipt of an application does not imply its consent to an intentional introduction into the environment.

(5) The Committee shall not make a recommendation for the grant of an import licence for intentional introduction into the environment unless the application has been submitted to the Sub-Committee for the conduct of a risk assessment in accordance with section 53.

(6) Within ten days of receipt of the risk assessment report submitted by the Sub-Committee, the Committee shall provide the risk assessment report under section 53to the applicant for comments.

(7) Within thirty days of receipt of the risk assessment report, the applicant shall submit comments, in writing, on the risk assessment to the Committee.

(8) The Committee shall immediately on receipt of the comments provided by the applicant under subsection (7), provide the Sub-Committee with a copy of the comments.

(9) Within two hundred and seventy days of the date of receipt of an application, the Committee shall communicate, in writing, to the applicant and to the Public Education Specialist who shall inform the Biosafety Clearing-House of the -

(a) grant of an import licence, with or without conditions under section 37, including how the grant of the licence will apply to subsequent imports of the same living modified organism;

(b) refusal of the grant of the import licence under section 37;

(c) request for additional information;

(d) extension by a definite period of time of the period specified in this section.

(10) A failure by the Committee to communicate within two hundred and seventy days of the date of receipt of the application under subsection (9) does not imply the consent of the Committee to an intentional introduction into the environment.

(11) Where additional information is requested by the Committee under subsection 9(c) -

(a) the applicant shall be informed of the procedure the Committee will follow in taking further action on the application;

(b) a final written decision under section 37 shall be provided by the Committee to the applicant no later than sixty days following receipt of the additional information.

(12) The Committee may take into account socio-economic considerations on the basis of a Social Impact Assessment conducted in accordance with subsection (13).

(13) The Committee may require that a Social Impact Assessment is carried out in respect of any application for an import licence for intentional introduction into the environment, if the introduction of the living modified organism could significantly affect the social, ethical or religious values of Saint Lucia.

(14) The Committee shall make a final decision under section 37(1) based on the following -

(a) the information submitted in the application under subsection (3)(b) and (9)(c);

(b) the risk assessment report prepared by the Sub-Committee under section 53;

(c) consideration of the written comments of the applicant in consultation with the Sub-Committee;

(d) any relevant comments submitted by the public under section 95.

**Grant or refusal of import licence**

37. (1) Subject to section 43, the Committee shall submit a recommendation to the Competent National Authority for –

(a) the grant of an import licence with conditions where controls or limits are necessary to alleviate damage or risks to human health;

(b) the grant of an import licence without conditions where the living modified organism is not likely to cause damage or risks to human health; or

(c) the refusal of an import licence where it is necessary to protect against damage or risks to human health.

(2) In accordance with a recommendation under subsection (1), the Competent National Authority shall grant with or without conditions or refuse to grant an import licence and shall –

(a) immediately notify an applicant and the Public Education Specialist of the grant or refusal; and

(b) give the reasons in writing for the grant with conditions or refusal of an import licence.

(3) Where the Competent National Authority grants an import licence, the Competent National Authority shall issue an import licence in the prescribed form on payment of the prescribed import licence fee and may state that the import licence will apply to subsequent similar movements to the same licensee.

**Division 5**

*Export licence*

**Export licence**

38. (1) A person shall not export a living modified organism unless that person holds a valid export licence.

(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of ten thousand dollars or to imprisonment for a term of two years or both.

(3) In order for a person to obtain an export licence that person, shall in accordance with subsections (4) and (5), apply to a Competent National Authority for an export licence.

(4) An application made under subsection (3) shall be –

 (a) addressed to the Secretary of the Committee;

 (b) submitted to the Competent National Authority in triplicate;

 (c) in the prescribed form;

 (d) accompanied by the prescribed application fee.

**(5) An application made under subsection (3) may be made on the biosafety website.**

(6) A person shall not make any statement which he or she knows to be false for the purpose of obtaining permission to export under this section.

(7) A person shall not export a living modified organism that is prohibited or restricted in Saint Lucia.

(8) A person who contravenes subsections (6) and (7) commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars or to imprisonment for a term not exceeding two years or to both.

(9) Upon receipt of an application, the Competent National Authority shall keep one copy of the application and submit two copies of the application to the Sustainable Development and Environment Officer.

(10) On receiving an application for an export licence, the Sustainable Development and Environment Officer shall retain one copy and submit the other copy to the Committee.

(11) Subject to sections 43 and 95, where an application is made for an export licence under subsection (3), the Committee shall submit a recommendation to the Competent National Authority for –

(a) the grant of an export licence with conditions where controls or limits are necessary to alleviate damage or risks to human health;

(b) the grant of an export licence without conditions where the living modified organism is not likely to cause damage or risks to human health; or

(c) the refusal of an export licence where it is necessary to protect against damage or risks to human health.

(12) In accordance with a recommendation under subsection (11), the Competent National Authority shall grant with or without conditions or refuse to grant a transit and transshipment licence and shall –

(a) immediately notify the applicant of the grant or refusal; and

(b) give reasons in writing for the grant with conditions or refusal of the export licence.

(13) Where the Competent National Authority grants an export licence, the Competent National Authority shall issue an export licence in the prescribed form on payment of the prescribed export licence fee.

(14) A person who exports a living modified organism which causes harm is responsible for the payment of damages in respect of such harm.

**Division 6**

*Transit and Trans-shipment licence*

**Transit and trans-shipment licence**

39. (1) A person shall not carry or cause to be conveyed in transit or through trans-shipment a living modified organism unless that person holds a valid transit and trans-shipment licence.

 (2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars or to imprisonment for a term not exceeding two years or to both.

 (3) In order for a person to obtain a transit and trans-shipment licence that person shall, in accordance with subsections (4) and (5), apply to a Competent National Authority for a transit and trans-shipment licence.

 (4) An application made under subsection (3) shall be –

 (a) addressed to the Secretary of the Committee;

 (b) submitted to the Competent National Authority in triplicate;

 (c) in the prescribed form;

 (d) accompanied by the prescribed application fee.

 (5) An application made under subsection (3) may be made on the customs automated system in accordance with any law relating to customs.

 (6) Upon receipt of an application, the Competent National Authority shall keep one copy of the application and submit two copies of the application to the Sustainable Development and Environment Officer.

 (7) On receiving an application for a transit and trans-shipment licence, the Sustainable Development and Environment Officer shall retain one copy and submit the other copy to the Committee.

 (8) Subject to sections 43 and 95, the Committee shall submit a recommendation to the Competent National Authority for –

(a) the grant of a transit and trans-shipment licence with conditions where controls or limits are necessary to alleviate damage or risks to human health;

(b) the grant of a transit and trans-shipment licence without conditions where the living modified organism is not likely to cause damage or risks to human health; or

(c) the refusal of a transit and trans-shipment licence where it is necessary to protect against damage or risks to human health.

 (9) In accordance with a recommendation under subsection (8), the Competent National Authority shall grant with or without conditions or refuse to grant a transit and trans-shipment licence and shall –

(a) immediately notify the applicant of the grant or refusal; and

(b) give reasons in writing for the grant with conditions or refusal of the transit and trans-shipment licence.

 (10) Where the Competent National Authority grants a transit and trans-shipment licence, the Competent National Authority shall issue a transit and trans-shipment licence in the prescribed form and on payment of the prescribed transit and trans-shipment licence fee.

**Division 7**

*General*

**Confidentiality**

**40. (1) Information provided in an application must be treated as confidential.**

**(2) The Committee or Sub-Committee, a member of the Committee or member of the Sub-Committee shall at all time preserve and aid in preserving confidentiality.**

**(3) Except for the performance of his or her duties or under legal obligation, a member of the Committee or member of the Sub-Committee shall not communicate any confidential matter to any person or, unless under legal obligation, grant access to any person to any records in their possession, custody or control.**

**(4) In this section “confidential information” does not include -**

**(a) the name and address of the applicant;**

**(b) a general description of the living modified organism;**

**(c) a summary of risk assessments performed on the living modified organism; and**

**(d) any methods and plans for emergency response.**

**Withdrawal of application**

41. An applicant may withdraw his or her application at any time prior to the issuance of a final decision by the Committee without prejudice.

**Cancellation of application**

42. (1) Where the applicant does not furnish the additional information requested by the Committee within thirty days of the request being made, the Committee may give the applicant notice that the application cannot be determined and has been cancelled.

(2) Where the Committee has cancelled an application under subsection (1), the Committee shall return the cancelled application to the applicant.

**Precautionary approach**

**43. (1) The grant of a licence shall be based on the best available scientific evidence or ecological principles.**

**(2) Notwithstanding subsection (1), the Committee may make a recommendation for the grant of a licence in order to avoid or minimize damage or risks to human health where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential damage or risks to human health. (Make this a basis for imposing conditions on the issue of a licence.) Don’t grant licence if there is serious harm or damage.**

**Review of decision**

44. (1) The Committee may, at any time, in light of new scientific information on damage or risks to human health, review and change a decision regarding the grant or refusal of a licence.

(2) Where the Committee changes a decision under subsection (1), the Committee shall, within thirty days, inform any licensee of such decision and shall set out the reasons for its decision.

(3) Any person may request the Committee to review a decision it has made in respect of a licence if that person considers that:

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

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

(4) The Committee shall immediately acknowledge receipt of a request made under subsection (3).

(5) The Committee shall, within ninety days, respond in writing to a request made under subsection (3) and shall set out the reasons for its decision.

(6) The Committee may require a risk assessment for subsequent activities with living modified organisms.

**Validity**

45. A licence issued under this Act is valid for the period specified in the licence.

**Effect of licence**

46. A licence issued under this Act, unless the licence provides otherwise, authorizes the licensee to engage in the activity identified in the licence in relation to the living modified organism identified in the licence.

**Records and furnishing of information**

47. (1)A licensee shall –

(a) keep and maintain records of information regarding the contained use, direct use as food, feed or processing, intentional introduction into the environment, import, export or transit and transshipment of a living modified organism;

(b) supply the Committee, on request, with such information as the Committee considers necessary for it to carry out its functions under this Act or to deal with any emergency situations.

 (2) A licensee who fails to provide the information requested by the Committee under subsection (1)(b) commits an offence and is liable on summary conviction to a fine not exceeding five thousand dollars or to imprisonment for a term of one year or both.

**Placing on the market**

48. (1) A licensee who places a product on the market shall ensure that information is transmitted in writing to the recipient of the product that the product contains or consists of a living modified organism.

(2) A licensee who places a product on the market for use only and directly as food or feed or for processing shall ensure that a declaration in the prescribed form of use and a list of the living modified organism that has been used to constitute the mixture is transmitted in writing to the recipient of the product.

(3) A licensee who places a product on the market shall have in place, for a period of five years from each transaction, systems and standardized procedures to allow the holding of information specified in subsections (1) and (2) and the identification of the sender and recipient to whom the products have been made available.

(4) A licensee who contravenes this section commits an offence and is liable to a fine of ten thousand dollars or imprisonment for two years or to both.

**Documentation for import or export**

49. (1) A licensee who holds an import licence or a person who exports a living modified organism shall ensure that documentation accompanying a living modified organism that is intended for import or export is clearly identified as a living modified organism and shall specify the following -

(a) a brief description of the organisms, including common and scientific name, relevant traits and genetic modification, including transgenic traits and characteristics such as events of transformation or, where available and applicable, a reference to a system of unique identification;

(b) any requirements for safe handling, storage, transport and use of the living modified organisms as provided under applicable existing international requirements, this Act or Regulations made under this Act, or under any agreement entered into by the importer and exporter;

(c) the contact point for further information;

(d) the name and address of the importer and exporter; and

(e) a declaration in the prescribed form that the movement is in conformity with the requirements of the Protocol.

 (2) A licensee who holds an import licence or a person who exports a living modified organism shall ensure that documentation accompanying a living modified organism that is intended for contained use shall be clearly identified as a living modified organism destined for contained use and shall specify the following:

1. a brief description of the organisms, including common and scientific names;
2. the name, address and contact details of the consignee and importer or exporter;
3. any requirements for safe handling, storage, transport and use of the living modified organism under applicable existing international instruments, this Act or Regulations made under this Act or under any agreements entered into by the importer and exporter;
4. where appropriate, further information should include the commercial names of the living modified organism, if available, new or modified traits and genetic modification, including transgenic traits and characteristics such as events of transformation, risk class, specification of use, any unique identification, where available, as a key to accessing information in the Biosafety Clearing House;
5. a declaration in the prescribed form that the movement is in conformity with the requirements of the Protocol.

(3) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of five thousand dollars or imprisonment for a term of one year.

**Suspension or revocation of licence**

50. (1) The Committee may submit a recommendation to the Competent National Authority to suspend or revoke a licence if -

(a) the licensee -

(i) has been convicted of an offence under this Act or the Regulations made under this Act;

(ii) fails to comply with the conditions imposed on the licence;

(b) in the opinion of the Committee, new information or a review of existing information about the living modified organism establishes risks to human health whether or not based on the precautionary approach under section 43.

(2) Where the Committee proposes to suspend or revoke a person’s licence, the Competent National Authority shall give to the licensee notice in writing of the proposal and the Committee’s reasons for the proposal and shall invite the person to show cause why the Committee should not proceed as proposed.

(3) A notice to show cause shall state that within twenty-one days, the licensee may make representations in writing or otherwise and the Committee shall not determine the matter without considering the submissions or representations within that period of twenty-one days.

(4) Where the Competent National Authority suspends or revokes a licence under this section, in accordance with a recommendation of the Committee, the Competent National Authority -

(a) shall give the licensee notice in writing of the revocation and shall give information concerning the right of appeal under section 51;

(b) may, where applicable, order the destruction of any growing organism and the sterilization of the soil in which they are being grown, in whatever way it considers appropriate and in accordance with any applicable law.

(5) Compensation is payable by the licensee for the order for sterilization and destruction of the living modified organism.

**Right of appeal**

51. (1) Where a licence is granted with conditions, refused, suspended or revoked, the applicant or licensee may, within thirty days from receipt of notice of the decision, appeal in writing to the Tribunal, setting out the grounds on which the appeal is made.

(2) Before determining an appeal referred to it under this section, the Tribunal shall give the applicant, licensee, National Competent Authority or Committee the opportunity of appearing before and being heard by it.

**Exemptions**

52. (1) The Minister may, on the recommendation of the Committee, by order published in the Gazette, exempt a living modified organism from the requirements of this Act.

(2) The Committee may make a recommendation under subsection (1) -

(a) where the Committee determines that sufficient experience or information exists to conclude that a living modified organism does not cause damage or risks to human health;

(b) where it is agreed by the meeting of the parties to the Protocol that a living modified organism is not likely to cause damage or risks to human health;

(c) where a petition is made to the Committee and granted by the Committee in accordance with this section; or

(d) where the Committee is satisfied that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms.

(3) A person may, in accordance with subsection (2)(c), make a petition to the Committee to exempt a living modified organism under this Act.

(4) A petition made under subsection (3) shall be –

(a) addressed to the Secretary of the Committee;

(b) submitted to the Competent National Authority in triplicate;

(c) in the prescribed form;

(d) accompanied by the prescribed petition fee.

(5) A petition made under subsection (3) may be made on the biosafety website.

(6) Upon receipt of a petition, the Competent National Authority shall keep one copy of the petition and submit two copies of the petition to the Sustainable Development and Environment Officer.

(7) On receiving a petition, the Sustainable Development and Environment Officer shall retain one copy and submit the other copy to the Committee.

(8) Within ten days of receipt of the petition, the Public Education Specialist shall publish the petition in the *Gazette* and at least two newspapers in general and weekly circulation or any other media in Saint Lucia and the Committee shall transmit the petition to the Sub-Committee for review.

(9) The Committee shall make a recommendation to the Competent National Authority on the petition based on the scientific review conducted by the Sub-Committee and comments submitted by the public.

(10) Within one hundred and twenty days of receipt of the petition by the Committee, the Committee shall submit a recommendation to the Competent National Authority to –

(a) grant the petition with conditions where controls or limits are necessary to alleviate damage or risks to human health; or

(b) grant the petition without conditions where the living modified organism is not likely to cause damage or risks to human health; or

(c) refuse the petition in whole or in part where it is necessary to protect against damage or risks to human health.

(10) In accordance with a recommendation under subsection (9), the Competent National Authority shall grant with or without conditions or refuse to grant a petition and shall –

(a) immediately notify the applicant of the grant or refusal of the petition; and

(b) give reasons in writing for the refusal of the petition.

(11) Where the Competent National Authority grants a petition, the Competent National Authority shall issue a certificate of exemption in the prescribed form on payment of the prescribed fee.

(12) The Committee may submit a recommendation to the Competent National Authority to revoke an exemption if the person exempted fails to comply with any conditions imposed on the exemption.

**PART III**

**RISK ASSESSMENT, RISK MANAGEMENT AND RISK**

**COMMUNICATION**

**Risk assessment**

53. (1) In order to effectively assess all risks posed by the use of a living modified organism, the Sub-Committee may require an applicant to provide the following -

(a) characteristics of the recipient, parental organism and donor organisms;

(b) characteristics of the living modified organism;

(c) safety considerations for human and animal health;

(d) environmental considerations;

(e) socio-economic considerations;

(f) management plan;

(g) monitoring plan;

(h) control of release;

(i) waste treatment;

(j) emergency response plan;

(k) data collection; and

(l) other available scientific evidence,

in order to identify and evaluate the possible damage or risks to human health of a living modified organism.

(2) A risk assessment conducted by an applicant or the Sub-Committee or a review of a risk assessment conducted by the Sub-Committee shall be carried out in accordance with Annex III of the Protocol with the necessary modifications taking into account recognized risk assessment techniques.

(3) Without prejudice to subsection (2), the risk assessment or review of risk assessment shall take into account, the following:

(a) on a case by case basis identify and evaluate the potential damage or risks to human health of a living modified organism;

(b) the precautionary approach;

(c) an identification of the characteristics of the living modified organism including any characteristic of the living modified organism linked to the genetic modification, disease to humans, plants or animals considering allergenic or toxic effects and effects on the dynamics of populations of species in the receiving environment and its use which have potential to cause damage or risks to human health should be compared to those presented by the non-modified parent organism, grown under similar conditions;

(d) an identification of the characteristics which may cause damage or risks to human health by the transfer of inserted genetic material to other organisms, or the same organism whether living modified or not, the spread of the living modified organism in the receiving environment, interactions with other organisms, and changes in management, including where applicable agricultural practices;

(e) an evaluation of the magnitude of the consequences of each potential adverse effect assuming that the adverse effect will occur;

(f) an evaluation of the data for transgene stability and equivalence to non-modified parent lines must be shown by proteomics, transcriptomics and metabolomics;

(g) an estimation of the risk posed to the environment or human health by each identified characteristic of the living modified organism which has the potential to cause damage or risks to human health given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs;

(h) overall risks of the living modified organism taking into account the risk management strategies proposed.

(4) The cost of risk assessment or review of risk assessment is payable by the applicant.

(5) On conclusion of the risk assessment or review of the risk assessment, the Sub-Committee shall provide the Committee with a risk assessment report.

(6) A risk assessment report provided under subsection (5) shall give the recommendation, with justifications, on the grant or refusal of the application and an indication of any measures or actions that need to be taken to ensure the safe use of the living modified organism.

**Risk management**

54. (1) The Committee shall ensure that appropriate mechanisms, measures or strategies are in place to regulate, manage and control risks identified –

(a) during the risk assessment; or

(b) under section 55;

and shall impose such mechanisms, measures or strategies to the extent necessary to prevent damage or risks to human health of a living modified organism.

(2) Without prejudice to the generality of subsection (1), where on the advice of the Committee, the Minister is satisfied that the regulating of the discharge of living modified organisms into an area is necessary to prevent the damage or risks to human health of a living modified organism, the Minister shall by Order published in the *Gazette* declare the area to be a living modified control area or a genetic resource centre.

(3) An Order made under subsection (2) shall specify the boundaries of the living modified organism control area and the living modified organism required to be regulated.

(4) The Committee shall notify the public through the media of the risk management measures taken under this section.

**Risk communication**

55. A licensee who becomes aware of any significant new scientific information indicating that permitted activities may -

(a) adversely affect the conservation and sustainable use of biological diversity, taking into account risks to human health and the environment; or

(b) pose potential risks not previously known or considered;

shall immediately advise the Committee of the new information and newly identified risks and of the measures put in place to ensure the continued safe use of the living modified organism.

**PART V**

**UNINTENTIONAL INTRODUCTION INTO THE ENVIRONMENT AND**

**EMERGENCY MEASURES**

**Unintentional introduction into the environment**

56. (1) Any person who has knowledge of an unintentional introduction into the environment of a living modified organism that is likely to cause damage or risks to human health, shall on knowing of the introduction, immediately notify the Competent National Authority or the Sustainable Development and Environment Division of the occurrence.

(2) A notification under subsection (1) shall include the following -

(a) available relevant information on the estimated quantities and relevant characteristics or traits of the living modified organism;

(b) information on the circumstances and estimated date of the introduction of the living modified organism;

(c) any available information about the possible adverse effect on the conservation and sustainable use of biological diversity or risk to human health and the environment, as well as available information about possible risk management measures;

(d) any other relevant information; and

(e) a point of contact for further information.

(3) The Committee and the Sub-Committee shall consult with the notifier to determine whether any action is necessary to minimize any adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health and the environment.

(4) Where the Committee and the Sub-Committee determine that action is necessary to minimize adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health, the Committee shall exercise the risk management measures under section 54 and the operator shall take the necessary action and is liable for the cost of such action.

(5) Where the Committee knows of an occurrence that leads or may lead to an unintentional introduction into the environment of a living modified organism that is likely to cause damage or risks to human health, in another country, the Committee shall notify -

(a) affected or potentially affected countries or persons;

(b) the Sustainable Development and Environment Division which shall notify the Biosafety Clearing-House established under the Protocol; and

(c) where appropriate relevant international organizations.

**Emergency measures**

57. The Committee shall make recommendations to the National Emergency Management Organization and other Agencies, on appropriate emergency measures in order to minimize any damage or risks to human health.

**PART VI**

**ENFORCEMENT**

**Powers of inspectors**

58. (1) Where an inspector reasonably suspects that there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account risks to human health and the environment, or has to conduct an investigation into a complaint, he or she may -

(a) enter and inspect any premises; and

(b) take with him or her any equipment or material required for the purpose of the inspection;

(c) carry out or cause to be carried out such tests and inspections, and make such recordings, as is necessary;

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

(e) take samples of any organisms, articles or substances found in or on the premises and of the air, water or land in, on, or in the vicinity of, the premises;

(f) in the case of anything found in or on the premises, which appears to him or her to contain or to have contained a living modified organism which has adversely affected or is likely to adversely affect the conservation and sustainable use of biological diversity, taking into account risks to human health and the environment, to cause it, the container or packaging to be dismantled or subjected to any process or test, but not so as to damage or destroy the container or packaging unless it is necessary to do so;

(g) to take possession of a living modified organism and detain it for so long as is necessary for all or any of the following purposes:

(i) to examine it;

(ii) to ensure that it is available for use as evidence in any proceedings for an offence against this Act;

(h) to require the production of, or where the information is recorded in computerised form, the furnishing of extracts from, any records which are required to be kept under this Act or it is necessary for him or her to see for the purposes of any test or inspection under this section and to inspect, and take copies of, or of any entry in, the records;

(i) to require any person to afford him or her such facilities and assistance with respect to any matters or things within that person’s control or in relation to which that person has responsibilities as are necessary to enable the inspector to exercise any of the powers conferred on him or her by this section;

(j) do any other act or thing necessary or convenient to be done to carry out an inspection.

(2) An inspector may only exercise the powers under subsection (1) if the inspector shows proof of identity and the occupier of the premises consents or a warrant is issuedunder section 59.

(3) Any costs incurred by an inspector in exercising the powers under this section shall be paid by the person being inspected.

(4) A person shall not –

(a) assault or obstruct an inspector or fail to give him or her assistance or information that he or she may require in carrying out his or her powers;

(b) knowingly give false information to an inspector or give information that is likely to prevent the inspector from carrying out his or her powers;

(c) by the offer of any inducement, prevent the inspector from carrying out his or her powers.

 (5) A person who contravenes subsection (4) commits an offence and is liable on summary conviction to a fine not exceeding five thousand dollars or to a term of imprisonment not exceeding one year or to both.

**Application for warrant**

59. (1) An inspector may apply to a magistrate for a warrant to enter, search and seize.

(2) A magistrate may issue a warrant for entry, search and seizure, if the magistrate is satisfied by information on oath that such inspection is reasonably necessary.

(3) A warrant issued under this section shall -

(a) describe the place to which the warrant relates;

(b) state the name of the Inspector responsible for executing the warrant;

(c) specify the period for which the warrant remains in force, which must not be more than seven days;

(d) state whether the entry is authorized to be made at any time of the day or night or during specified hours of the day or night;

(e) state the purpose for which the warrant is issued.

(3) In executing a warrant an inspector shall not use force unless accompanied by a police officer and the use of force is specifically authorized in the warrant.

**Forfeiture by consent**

60. Where an inspector has seized any product or thing under section 58 and the owner or the person in lawful possession at the time of seizure consents in writing to the forfeiture of the product or thing, such product or thing is forfeited to the Crown.

**Forfeiture by the Court**

61. (1) Where a person is convicted of an offence against this Act, the court that convicted the person may order the forfeiture to the Crown of anything produced to the court that is shown to relate to the commission of the offence.

(2) The court must not order the forfeiture of anything to the Crown if a person claiming to be the owner or otherwise interested in it applies to be heard by the court unless an opportunity has been given to that person to show cause why the order should not be made.

(3) A thing forfeited to the Crown under this section may be sold or otherwise disposed of as the Competent National Authority, on the advice of the Committee, directs.

**Release of forfeited property**

62. (1) A person whose property has been forfeited to the Crown under section 60 or 61 or a person who has a legal or equitable interest in any such property may apply to the Competent National Authority, within twenty-eight days of the conviction that led to the forfeiture, for the release of the property forfeited.

(2) An application under this section cannot be made by the person convicted of the offence that led to the forfeiture.

(3) After considering an application under this section, the Competent National Authority, on the advice of the Committee, may order the release of the forfeited property on payment to the Crown of an amount the Competent National Authority thinks appropriate, being an amount that does not exceed the amount the property forfeited would, in the estimation of the Committee, be likely to realize if sold by public auction.

(4) In considering whether to order the release of any property, the Competent National Authority must have regard to -

(a) the relationship between the person applying for release of the property and the person convicted of the offence; and

(b) the extent to which the applicant was in a position to foresee that the property would be used in connection with the commission of an offence against this Act when it passed to the possession of the offender.

**Cessation notice and imposition of additional risk management measures**

63. (1) Where the Committee submits a recommendation to the Competent National Authority that there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account risks to human health, on the basis of -

(a) tests conducted and evaluated in a manner consistent with accepted scientific procedures; or

(b) other validated scientific evidence;

the Competent National Authority may issue a notice in the prescribed form for the immediate cessation of any activity covered by the licence and for the immediate imposition of additional risk management measures with respect to such activity.

(2) A notice issued under subsection (1) shall be withdrawn where the Committee submits a recommendation to the Competent National Authority that sufficient information exists to permit the activity to resume or to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of biological diversity, taking into account risks to human health.

(3) A person on whom a cessation notice has been served who carries out, or causes or permits to be carried out any activity prohibited by the order, commits an offence and is liable on summary conviction to a fine not exceeding fifty thousand dollars or imprisonment for a term not exceeding six years or to both.

(4) In accordance with any recommendation submitted by the Committee, the Competent National Authority shall take any steps or measures which appear to it desirable for the purposes of stopping any activity prohibited by the order and may to that end obtain the assistance of a police officer.

**Notice to remedy contravention**

64. (1) Where it appears to the Committee that a person has failed, refused or neglected to comply with the requirements of this Act, the Committee shall submit a recommendation to the Competent National Authority for the service on the person of a notice in the prescribed form to remedy the contravention.

(2) A notice served under subsection (1) shall be in the prescribed form and shall specify the remedy to be employed and the time in which the person must remedy the contravention.

(3) A person who fails to comply with subsection (1) commits an offence and is liable to a fine of two thousand dollars.

**Power to enter and execute remedial works**

65. (1) Where within the period specified in a notice, any steps required by the notice to remedy contravention have not been taken, the Committee may personally or by persons under the Committee’s authority enter on the land and take those steps and may recover any expenses reasonably incurred for those purposes from the person who is contravening this Act.

(2) A person who obstructs or interferes with the exercise of the power vested in the Committee by subsection (1) commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars.

**Payment of compensation**

66. (1) Where it appears to the Committee that loss or damage is caused by the contravention of this Act, the Committee shall submit a recommendation to the Competent National Authority and the Competent National Authority shall by notice require the licensee who caused the loss or damage to pay an amount of compensation for that loss or damage.

(2) A notice in subsection (1) shall be in the prescribed form.

**Injunction**

67. In addition to any other remedy provided by this Act, the Competent National Authority may in any case institute a civil action for an injunction to prevent any person from violating the provisions of this Act, or to enforce any notice to remedy contravention or cessation notice.

**Appeal**

68. Where a notice is issued under section 63, 64, 65 or 66, the person may, within thirty days of receipt of the notice, appeal in writing to the Tribunal, setting out the grounds on which the appeal is made.

**PART VI**

**COMPLAINTS**

**Complaints by public**

69. (1) Any member of the public having a complaint concerning a licensee, whether or not that member of the public is affected by the subject matter of the complaint, may make a complaint in the prescribed form to the Committee through the Sustainable Development and Environment Division.

(2) The person who receives a complaint under subsection (1) shall give a certified copy to the person making the complaint and submit a copy of the complaint to the Committee.

(3) Where the complaint relates to a fatality or alleged criminal conduct a copy of the complaint shall be sent to the Director of Public Prosecutions.

(4) In this section “certified copy” means a copy of the complaint signed by the person receiving the complaint and stamped “certified” with an official stamp.

**Submission of complaint to Inspector**

70. The Committee shall submit the complaint to an inspector through the Sustainable Development and Environment Officer for investigation and resolution in the manner provided in this Act.

**Notification of licensee**

71. Immediately after being notified of a complaint under section 67, the Committee shall, in writing, notify the licensee of the substance of the complaint unless, in the opinion of the Committee to do so might adversely affect or hinder any investigation that is being or may be carried out in respect of the complaint.

**Informal disposition**

72. (1) The Committee shall consider whether a complaint under section 67 can be disposed of informally and, with the consent of the complainant and the licensee concerned, may attempt to so dispose of the complaint.

(2) An answer or statement made, in the course of attempting to dispose of a complaint informally, by the complainant or the licensee shall not be used or receivable in any criminal proceedings.

(3) Where a complaint is disposed of informally the complainant’s agreement to the disposition shall be signified in writing by the complainant and the licensee shall be informed of the disposition.

(4) The provisions of this section do not apply where a complaint relates to a fatality.

**Frivolous complaints**

73. (1) Where the Committee is of the view that the complaint is of a frivolous nature, the person making that complaint shall be informed in writing that no investigation will be undertaken in the matter, or that investigations have been discontinued.

(2) Where a decision is taken not to investigate or to discontinue investigations under subsection (1), the Committee shall, within seven days inform in writing the Inspector, the licensee concerned and the complainant.

**Inspector to investigate complaints**

74. (1) An Inspector shall cause a full investigation to be made into the complaint and on completion of an investigation shall prepare a full report of the investigation together with his or her findings and recommendations.

(2) The report prepared under subsection (1) shall be forwarded to the Committee and the Sustainable Development and Environment Officer, and the recommendations notified to the complainant and the licensee.

**Review of report**

75. (1) The Committee shall review all reports submitted by the inspector under this Act and, unless notice of an application for a review of the findings is served on the Committee under section 76, the Committee may immediately –

(a) refer the matter to the Sub-Committee where the report recommends this course of action;

(b) take such action as the Committee thinks fit; or

(c) refer the matter to the Tribunal.

(2) The Committee shall give notice in writing to the complainant and the licensee of the action taken under subsection (1)(b), giving reasons for such action.

**Application for review**

76. A person who is aggrieved with the findings and recommendations of an inspector may apply in writing to the Committee for a review of the matter by the Committee, within one month of receipt of the outcome of the investigation.

**Inspector to furnish relevant material**

77. (1) On receipt of an application under section 75, the Committee shall notify the inspector in writing and request of the Inspector all material relevant to the particular complaint.

(2) The Inspector shall, upon receiving the request under subsection (1), furnish the Committee with all material relevant to the complaint within twenty -one days.

**Review by Committee**

78. (1) Where, on review, the Committee is satisfied as to the manner of disposition of a complaint, it shall prepare and send a report in writing to that effect to the complainant and the licensee.

(2) Where, the Committee is not satisfied as to the manner of the disposition of a complaint it -

(a) may request the inspector to conduct further investigation into the complaint;

(b) may refer the complaint to the Tribunal for a hearing to inquire into the complaint;

(c) shall inform the complainant of the action taken.

**PART VII**

**TRIBUNAL**

**Establishment of Tribunal**

79. There is hereby established a Tribunal to be known as the Biosafety Tribunal.

**Constitution of Tribunal**

80. (1) The Tribunal shall consist of not less than three or more than five members, appointed by the Chief Justice.

(2) The Chairperson of the Tribunal shall be a legal practitioner of not less than five years standing and the other members shall have training or experience in one or more of the following areas -

(a) agronomy;

(b) molecular biology;

(c) toxicology;

(d) human health; and

(e) environmental science.

(3) The Tribunal may co-opt any person to attend any particular hearing of an appeal at which it is proposed to deal with a particular matter, for the purpose of assisting or advising the Tribunal, but persons co-opted do not have the right to vote.

**Functions**

81. The function of the Tribunal is to hear and determine appeals made by persons against any decision made by the Committee under this Act and complaints.

**Tenure**

82. A member of the Tribunal shall hold office for a period not exceeding three years but shall be eligible for reappointment.

**Temporary members**

83. (1) Where the Chairperson or any member of the Tribunal is absent, unable to perform the functions of their office, dies, resigns or the appointment is revoked, the Committee may appoint another person to act temporarily in place of the Chairperson or that member.

(2) A person appointed under subsection (1) shall be appointed in a manner that respects the requirements in section 80 for the constitution of the Tribunal and shall hold office -

(a) in the case of the absence or inability to perform functions, only for the portion of the term of the absence or inability;

(b) in the case of the death, resignation or revocation of appointment, the unexpired portion of the term of the former member.

**Resignation**

84. (1) Any member of the Tribunal other than the Chairperson, may at any time resign from office by notice in writing addressed to the Chief Justice and transmitted through the Chairperson, and such resignation takes effect as from the date of receipt of that notice by the Chairperson.

 (2) The Chairperson may at any time resign from office by notice in writing addressed to the Chief Justice, and such resignation takes effect as from the date of receipt of that notice by the Chief Justice.

**Revocation of appointment**

85. The Chief Justice may at any time revoke the appointment of any member of the Tribunal, including the Chairperson.

**Publication in the Gazette**

86. The appointment of any member of the Tribunal and the termination of office of any person as a member whether by death, resignation, removal, effluxion of time or otherwise, shall be published in the *Gazette*.

**Secretary of Tribunal**

87. (1) The Chief Justice shall appoint a recording Secretary of the Tribunal who shall have no voting rights.

(2) The Secretary shall keep a written record of all proceedings of the Tribunal, which shall be confirmed by the Chairperson.

**Remuneration**

88. A member of the Tribunal shall be paid such remuneration and allowances, if any, as Cabinet may determine.

**Hearings, deliberations and decisions**

89. (1) The Tribunal shall convene at such time, at such place and on such days as may be necessary or expedient for the discharge of its functions.

(2) The quorum for proceedings of the Tribunal shall comprise a majority of the members but where a member is disqualified from taking part in the proceedings of the Tribunal in respect of any matter, that member shall be disregarded for the purpose of constituting a quorum for hearing, deliberating on and deciding that matter.

(3) The Tribunal shall institute a hearing by sending a notice of the hearing to the complainant and the licensee.

(4) The notice of hearing sent under subsection (3) shall –

(a) specify the purpose of the hearing;

(b) specify the place and time of the hearing; and

(c) be in the prescribed form.

(5) The complainant and the licensee shall attend the hearing and may be represented.

 (6) Where the complainant does not attend the hearing, having had due notice of the time and place of hearing, the Tribunal may dismiss the complaint, unless having received a reasonable excuse for the nonappearance of the complainant the Tribunal thinks it fit to adjourn the matter.

(7) Any other person who -

(a) refuses or neglects without reasonable cause, to attend a hearing in compliance with the requirements of a notice issued under subsection (3); or

(b) departs from a hearing without the authority of the person holding the hearing;

commits an offence and is liable on summary conviction to a fine not exceeding one thousand dollars or to imprisonment not exceeding three months or to both.

(8) The Appeals Tribunal, may call witnesses including persons from regional or other countries, with expert knowledge or experience.

(9) Where an appeal is made to the Appeals Tribunal, the Tribunal shall give its decision within a period of thirty days from the date of receipt of the appeal.

(10) The decisions of the Appeals Tribunal shall be by a majority of votes of those members present and voting and, in addition to an original vote, the Chairperson shall have a second or casting vote in any case in which the voting is equal.

(11) On completion of a hearing, the Tribunal shall prepare and send to the Committee, complainant and the licensee, the decision in writing setting out its findings and recommendations with respect to the complaint.

(12) The appellant shall pay the cost of an appeal.

(13) A member of the Tribunal shall, as soon as is practicable inform the Chairperson of any matter in which he or she has, either directly or indirectly, personally or by his or her relative, partner, business associate or company, any pecuniary or business interest and that member shall take not part, directly or indirectly, in any hearing, deliberation or decision by the Tribunal on that matter.

(14) The decisions of the Tribunal shall be authenticated by the signature of the Chairperson and the Secretary.

(15) Subject to this section, the Tribunal has the power to regulate its own procedure.

**Validity of proceedings**

90. The validity of any proceedings of the Tribunal is not affected by any vacancy in its membership or by any defect in the appointment of any of its members.

**PART VIII**

**BIOSAFETY FUND**

**Biosafety Fund**

91. (1) There is established a fund to be known as the Biosafety Fund.

(2) There shall be paid into the Fund fees collected under this Act.

(3) The … may authorize payment from the Fund for purposes relating to the expenses for the purpose of meeting the objectives of this Act and the administration of the Fund.

**Administration of the Fund**

92. (1) The Fund shall be held and administered by the ...

(2) The **…** shall open and maintain an account with a bank in Saint Lucia, into which all monies payable to the Fund shall be paid.

(3) The **…** may, with the approval of Cabinet, invest monies of the Fund that, at any time are not required to be paid out of the Fund under section 91(3).

1. Income earned from investments made under subsection (3) are part of the Fund.

**Preparation of financial statements**

93. (1) The financial year of the Fund ends on the 31st day of December in each year.

 (2) The **…** shall —

1. keep proper records of the money paid into and out of the Fund and of investments made under section 92(3); and
2. ensure that —
3. money received is properly brought to account,
4. payments are correctly made and properly authorized,
5. adequate control is maintained over the assets of the Fund.

 (3) The financial records kept under subsection (2) must —

1. be sufficient to show and explain all transactions relating to the Fund;
2. enable the financial position of the Fund to be determined with reasonable accuracy at any time; and
3. be sufficient to enable financial statements to be prepared and audited under this section.

(4) Within two months after the end of each financial year, the **…** shall prepare —

1. financial statements containing —
2. a statement of the assets of the Fund at the end of the financial year, and
3. a statement of the money received into the Fund and the payments made out of the Fund during the financial year;
4. such other financial statements for the financial year as may be specified by the . . .; and
5. proper and adequate explanatory notes to the financial statements prepared under paragraphs (a) and (b).

**Audit of financial statements and annual report**

94. (1) The **…** shall cause the financial statements prepared under section 93 to be audited and certified by an auditor to be appointed annually by the Attorney General after consultation with the **…** within three months after the end of the financial year.

 (2) The auditor appointed under subsection (1) may be the Director of Audit or such other suitably qualified person.

(3) The auditor shall prepare a report of his or her audit of the financial statements of the Fund which shall include statements as to whether, in his or her opinion —

1. he or she has obtained all the information and explanations necessaryfor the purposes of the audit; and
2. to the best of his or her information and according to the explanations given to him or her the financial statements give a true and fair view of —
3. the assets of the Fund as at the end of the financial year, and
4. the money received into the Fund and the payments made out of the Fund during the financial year.

(4) Within six months after the end of each financial year, the … shall prepare and submit to the Minister responsible for Finance a copy of the audited financial statements, which shall include the report of the auditor on the financial statements.

(5) The Minister responsible for Finance shall, as soon as reasonably practicable after receipt of the audited financial statements, cause a copy of the audited financial statements, together with the auditor’s report to be laid before Parliament.

**PART IX**

**MISCELLANEOUS**

**Publication**

95. (1) The Public Education Specialist shall -

(a) five days after satisfactory vetting of any application by the Sustainable Development and Environment Officer for a licence made under this Act;

(b) on the Competent National Authority making a decision in respect of an application made under paragraph (a);

(c) within five days of the Committee receiving a petition for the application of exemptions under this Act;

(d) on the Competent National Authority making a decision made in respect of a petition made under paragraph (c);

(e) on receipt by the Tribunal of a notice of an appeal in respect of a decision;

(f) on the Tribunal making of a decision on appeal;

(g) on the Competent National Authority making a decision to suspend, revoke or change its decision on any licence granted in respect of an application;

(h) on the Competent National Authority issuing of a cessation notice, notice to remedy cause of contravention issued in respect of any licence;

(i) on receipt by the Committee of a complaint;

(j) any other matter which may be prescribed by Regulations made under this Act;

publish, in the *Gazette* and at least two newspapers in general and at least weekly circulation or in any other media in Saint Lucia a summary of the application, decision, cancellation or notice.

 (2) An applicant or licensee shall pay any costs related to any publication under subsection (1).

(3) A person may submit comments on an application, decision, cancellation or revocation within fourteen days from the date of the publication.

(4) The comments submitted under subsection (2) shall be submitted by the Public Education Specialist to the Sustainable Development and Environment Officer to be considered by the Committee before any decision is made under this Act.

**Register**

96. (1) The Sustainable Development and Environment Division shall create and keep a register containing particulars of -

(a) any application for a licence made under this Act, including the name and address of the applicant, the date of the application, contact details of the applicant and the living modified organism in relation to which the application is being made;

(b) the date and effect of any decision made in respect of an application made under paragraph (a);

(c) any petitions for the application of exemptions under this Act;

(d) the date and effect of any decision made in respect of a petition made under paragraph (c);

(e) any appeal in respect of such a decision and the decision made on the appeal;

(f) any suspension, revocation or change of decision of any licence granted in respect of any such application;

(g) any cessation notice issued in respect of any licence;

(h) any complaint and the manner in which it was disposed;

(i) any other matter which may be prescribed by Regulations made under this Act.

(2) The register kept by the Sustainable Development and Environment Division under subsection (1) may be kept in an electronic data storage and retrieval system.

(3) A person shall be entitled to access information recorded in the register maintained and kept under subsection (1) and to take copies of such information on payment of the prescribed fee.

**Protection**

97. An action shall not be made against the Committee or any person acting under this Act for anything done or omitted to be done in good faith and in the administration or discharge of any functions, duties or powers under this Act.

**Safety measures**

98. Notwithstanding section 16 of the Free Zone Act, Cap. 15.17 a free zone developer may, or at the request of the Committee shall, prevent any living modified organism which has an adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health from entering the free zone.

**Appeals**

99. An appeal to the High Court may be made from a decision of the Tribunal on a point of law, but not on any matter of fact or on the merits of any decision made by the Committee or the Tribunal.

**Amendment of Schedules**

100. The Minister may, by Order published in the *Gazette*, amend Schedule 1 or Schedule 2.

**Regulations**

101. (1) The Minister may, on the advice of the Committee, make Regulations prescribing all matters required or permitted by this Act to be prescribed or necessary to be prescribed for carrying out or giving effect to this Act.

(2) Without limiting the generality of subsection (1), the Minister may, on the advice of the Committee, make Regulations prescribing -

(a) the form of applications, petitions, notices, notifications, complaints or other documents required under this Act;

(b) fees to be charged under this Act;

(c) the form of a licence required under this Act;

(d) the labelling, traceability, identification, packaging requirements of any living modified organism;

(e) the form of a risk assessment report, risk management plan or emergency response plan required under this Act;

(f) measures for the transport of living modified organisms;

(g) the criteria for a social impact assessment;

(h) information on monitoring, control of release and waste treatment;

(i) procedure at ports of entry or exit;

(j) insurance;

(k) procedure when there is an accident;

(l) food safety guidelines;

(m) monitoring guidelines;

(o) the living modified organisms which are prohibited or restricted from import or export;

(p) biotechnology.

(3) Any regulations made under this section may provide that any person who contravenes or fails to comply with a provision of the Regulations commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars or to imprisonment for a term not exceeding two years or to both.

**SCHEDULE 1**

(Sections 1 and 2)

PART A

|  |  |
| --- | --- |
| **PRODUCT** | **DESCRIPTION OF MODIFICATION** |
| Soyabeans | -Tolerance/resistance to glyphosate (herbicide)-Resistance to Pests (Lepidoptera, fungus, nematodes)-Increased oleic acid content-Tolerance to drought and salt conditions- High stearidonic acid- Low level of fatty acids- Dicamba tolerance |
| Rice | Glufosinate tolerance |
| Maize/Corn | Herbicide(Glyphosate) tolerant, Lepidoptera resistant, Increased / high lysine content, -male sterility, -drought tolerant, -coleopteran resistance,- fertility restoration, Acetolactate synthase inhibitors tolerance- Glufosinate tolerance- Sulfonylurea tolerance |
| Cotton | Resistance to disease, pests (Lepidoptera)and antibiotics (kanamycin), Bromoxynil tolerance- glufosinate tolerance- glyphosate tolerance- sulfonylurea tolerance |
| Papaya | Ringspot virus resistant, delayed ripening |
| Rose | Altered flower colour, kanamycin resistance |
| Canola/Oilseed/ Rapeseed | Herbicide toleranceIncreased oleic acid content, male sterility, fertility restoration, kanamycin resistance, bromoxynil tolerance,  |
| Carnations | Herbicide resistant, coloration |
| Sugar beets | Glyphosate tolerance, glufosinate tolerance, kanamycin resistance,  |
| Phalaenopsis sp. Moth orchid | Virus resistance  |
| Tomato | Reduced pectin degradation, reduced ethylene synthesis, delayed fruit ripening, kanamycin resistance |
| Potato | Kanamycin resistance, Potato leaf roll virus, Potato virus Y resistance, Coleoptera resistance |
| Alf Alfa | Glyphosate tolerance |
| Flax/Linseed | Kanamycin resistance, sulfonylurea tolerance |
|  |  |
| Lentil  | Imidazolinone tolerance |
| Melon  | delayed ripening |
| Squash  | resistance to viral infection |
| sunflower  | imidazolinone tolerance |
| tobacco | herbicide tolerance, reduced nicotine content |
| wheat  | herbicide tolerance |

**PART B**

GM sweetcorn in tins

Oil from GM soy beans;

margarine from GM soy bean oil;

oil from GM rapeseed/canola;

cornflakes from GM corn;

starch from GM corn; products containing GM corn starch

bread with GM soy protein or GM soy flour;

glucose (dextrose), glucose syrup and other ingredients with GM corn starch.

peanut puff snacks

 tacos containing GM corn starch.

**Additives which are produced from GM plants:**

sugar from GM sugar beet;

lecithin from GM soy beans;

vitamin E (tocopherol) from GM soy beans; and

cellulose from GM cotton, used as thickening agents and binder

**Micro-organisms:**

wheat beer with GM yeast;

yeast extract from GM yeast;

Yeast Biomass - S. cerevisiae

yoghurt with GM lactobacilli (lactic acid bacteria);

salami (raw sausages) with GM lactobacilli (lactic acid bacteria);

Bacterial Biomass - B. lactofermentum (additive in Animal feed)

blue cheese with GM moulds; and

Quorn (protein from protazoa) from GM fungi.

**SCHEDULE 2**

(Section 2)

**CARTAGENA PROTOCOL ON BIOSAFETY TO THE**

**CONVENTION ON BIOLOGICAL DIVERSITY**

The Parties to this Protocol,

*Being* Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”,

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

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

consideration, in particular, appropriate procedures for advance informed agreement,

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

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

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

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

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

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

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

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

Have agreed as follows:

Article

**1**

**OBJECTIVE**

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

Article

**2**

**GENERAL PROVISIONS**

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

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

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

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

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

Article

**3**

**USE OF TERMS**

For the purposes of this Protocol:

(a) “Conference of the Parties” means the Conference of the Parties to the Convention;

(b) “Contained use” means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) “Export” means intentional transboundary movement from one Party to another Party;

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

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

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

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

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

(i) “Modern biotechnology” means the application of:

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

b. Fusion of cells beyond the taxonomic family,

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

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

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

Article

**4**

**SCOPE**

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

Article

**5**

**PHARMACEUTICALS**

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

Article

**6**

**TRANSIT AND CONTAINED USE**

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

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

Article

**7**

**APPLICATION OF THE ADVANCE INFORMED**

**AGREEMENT PROCEDURE**

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

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

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

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

Article

**8**

**NOTIFICATION**

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

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

Article

**9**

**ACKNOWLEDGEMENT OF RECEIPT**

**OF NOTIFICATION**

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

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

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

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

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

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

Article

**10**

**DECISION PROCEDURE**

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

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

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

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

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

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

(b) Prohibiting the import;

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

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

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

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

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

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

Article

**11**

**PROCEDURE FOR LIVING MODIFIED ORGANISMS**

**INTENDED FOR DIRECT USE AS FOOD OR FEED,**

**OR FOR PROCESSING**

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the

information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

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

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

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

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

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

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

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

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

Article

**12**

**REVIEW OF DECISIONS**

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

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

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

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

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

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

Article

**13**

**SIMPLIFIED PROCEDURE**

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

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

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

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

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

Article

**14**

**BILATERAL, REGIONAL AND MULTILATERAL**

**AGREEMENTS AND ARRANGEMENTS**

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

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

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

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

Article

**15**

**RISK ASSESSMENT**

1. Risk assessments undertaken under this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article

**16**

**RISK MANAGEMENT**

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article

**17**

**UNINTENTIONAL TRANSBOUNDARY MOVEMENTS**

**AND EMERGENCY MEASURES**

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

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

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

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

Article

**18**

**HANDLING, TRANSPORT, PACKAGING**

**AND IDENTIFICATION**

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

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they “may contain” living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

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

Article

**19**

**COMPETENT NATIONAL AUTHORITIES**

**AND NATIONAL FOCAL POINTS**

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

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

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

Article

**20**

**INFORMATION SHARING AND THE**

**BIOSAFETY CLEARING-HOUSE**

1 . A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

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

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

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

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

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

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

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

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

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

Article

**21**

**CONFIDENTIAL INFORMATION**

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

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

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

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

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

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

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

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

(d) Any methods and plans for emergency response.

Article

**22**

**CAPACITY-BUILDING**

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

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

Article

**23**

**PUBLIC AWARENESS AND PARTICIPATION**

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

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

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

Article

**24**

**NON-PARTIES**

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

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

Article

**25**

**ILLEGAL TRANSBOUNDARY MOVEMENTS**

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

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

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

Article

**26**

**SOCIO-ECONOMIC CONSIDERATIONS**

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

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

Article

**27**

**LIABILITY AND REDRESS**

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

Article

**28**

**FINANCIAL MECHANISM AND RESOURCES**

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties , in particular the least developed and the small island developing States among them, and of the Parties with economies in transition , in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol .

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article

**29**

**CONFERENCE OF THE PARTIES SERVING AS THE**

**MEETING OF THE PARTIES TO THIS PROTOCOL**

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference

of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

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

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

Article

**30**

**SUBSIDIARY BODIES**

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article

**31**

**SECRETARIAT**

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article

**32**

**RELATIONSHIP WITH THE CONVENTION**

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

Article

**33**

**MONITORING AND REPORTING**

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

Article

**34**

**COMPLIANCE**

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

Article

**35**

**ASSESSMENT AND REVIEW**

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

Article

**36**

**SIGNATURE**

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article

**37**

**ENTRY INTO FORCE**

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force under paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

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

Article

**38**

**RESERVATIONS**

No reservations may be made to this Protocol.

Article

**39**

**WITHDRAWAL**

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

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

Article

**40**

**AUTHENTIC TEXTS**

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

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

DONE at Montreal on this twenty-ninth day of January, two thousand.

*Annex I*

**INFORMATION REQUIRED IN NOTIFICATIONS**

**UNDER ARTICLES 8, 10 AND 13**

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

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

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

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

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

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

( m ) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

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

*Annex II*

**INFORMATION REQUIRED CONCERNING LIVING**

**MODIFIED ORGANISMS INTENDED FOR DIRECT**

**USE AS FOOD OR FEED, OR FOR PROCESSING**

**UNDER ARTICLE 11**

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

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

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

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

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

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

*Annex III*

RISK ASSESSMENT

*Objective*

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

*Use of risk assessment*

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

*General principles*

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

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

*Methodology*

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

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

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

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

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

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

*Points to consider*

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

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

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

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

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

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

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

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

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

Passed in the House of Assembly this day of , 2016.

*Speaker of the House of Assembly.*

Passed in the Senate this day of , 2016 .

*President of the Senate.*