BIOSAFETY ACT

EXPLANATORY MEMORANDUM

PRELIMINARY

Clause 1: Short title

The Minister responsible for 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*.

Clause 2: Interpretation

In clause 2 of the Bill, the definitions of the words used throughout the Bill are provided. Therefore, words such as, "contained use", "genetically modified organism", "intentional introduction into the environment", "modern biotechnology", "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 5-13

Clause 5 of the Bill provides for the establishment of a Biosafety Unit. The functions of the Biosafety Unit are identified in clause 6 of the Bill. Information sharing is dealt with in clause 7. The staff of the Biosafety Unit is provided for in clause 8 of the Bill. The staff consists of a Biosafety Coordinator, a Public Education Specialist, an Administrative

Secretary, inspectors and such other necessary administrative and technical personnel. The functions of these members of staff are stated in clauses 9-13.

Clauses 14-29

A Biosafety Board is established in clause 14 of the Bill. The remaining provisions, therefore, make provision for the constitution of the Board, disqualification from the Board, functions of the Board, tenure, revocation of appointment, alternate members, resignation, vacancy, decisions not invalidated, meetings of the Board, Advisory Committee, declaration of interest and abstention from voting, staff, signing of documents and decisions and remuneration.

Clauses 30-35

The Board will be responsible for receiving and making decisions on applications made pursuant to the Bill and will therefore, receive fees for the services that it will provide. Consequently, provision has to be made for the financial year of the Board, budget and plan of action of the Board to be submitted to the Minister, accounts of the Board and the audit of such accounts, the submission of an auditor's report and annual report. These provisions have been made in clauses 30-35 of the Bill. They will, in addition, ensure transparency in the process.

PART II

MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS

Division 1

Contained use

Clauses 36-40

In clause 36 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 37-39 and consists of safety precautions, good microbiological practice and the keeping of records. Under clause 40, a person may receive authorization for export.

Division 2

Direct use as food, feed or processing

Clauses 41-43

Within clause 41 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 42. The labeling of pharmaceuticals is dealt with in clause 43.

Division 3

Intentional introduction into the environment

Clauses 44-50

Authorisation for intentional introduction into the environment is provided for in clause 44. In clauses 45-48, provision is made for acknowledgement of an application for an intentional introduction into the environment permit, the determination of the application, the issue of an import for intentional introduction into the environment permit, exemptions. Under clause 49 the documentation necessary for import or export for intentional introduction is specified. A person who places products on the market must comply with clause 50.

Division 4

General

Clauses 51-57

By virtue of clauses 51 an applicant may withdraw an application and in clause 52 an application may be cancelled in the circumstances identified. In addition, provision is made for the validity and effect of a licence or permit, the furnishing of information and the revocation of a licence or permit in clauses 53-56. The right of appeal against a decision of the Board is provided for in clause 57.

PART III

RISK ASSESSMENT, RISK MANAGEMENT AND RISK COMMUNICATION

Clauses 58-60 provide for risk assessment, risk management and risk communication.

PART IV

UNINTENTIONAL INTRODUCTION INTO THE ENVIRONMENT AND EMERGENCY MEASURES

In clause 61 provision is made for unintentional introduction into the environment and in clause 62 the determination of emergency measures is provided for.

PART V

COMPLAINTS

Clauses 63-75

A complaint may be made by members of the public under section 63 of the Bill. The complaint will then be submitted to an Inspector in accordance with clause 64 of the Bill. Notification, disposal, frivolous complaints, inspector to investigate complaints and review of the inspector's report are dealt with in clauses 65-69 of the Bill. An application for review may be made under clause 70 of the Bill and the inspector is to furnish relevant material for such review by clause 71 of the Bill. A review by the board must be made in accordance with clause 72 of the Bill and a hearing may be instituted by the Board in accordance with clause 73 of the Bill. Non-attendance of parties and completion of hearing are provided for in clauses 74 and 75 of the Bill respectively.

PART VI

ENFORCEMENT

Part VI of the Bill deals with enforcement. Consequently, clauses 76-87 provides for powers of an inspector, application for warrant, obstruction of inspector, forfeiture, 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, appeal and forfeiture by the court.

PART VII

APPEALS TRIBUNAL

An Appeals Tribunal is established in clause 88 of the Bill and the remaining clauses of Part VII which consists of clauses 89-98 includes provisions for the constitution, tenure, temporary members, resignations and other matters relating to the hearings, deliberations and decisions of the Appeals Tribunal and the validity of their proceedings.

PART VIII

MISCELLANEOUS

In Part VIII of the Bill miscellaneous provisions are provided in clauses 99-105. This Part therefore deals with publication, the register, confidentiality, protection, amendment of schedules, regulations and pending applications.

SCHEDULES

There are five Schedules attached to the Bill. While the Convention on Biological Diversity is in the First Schedule, the Cartagena Protocol is in the Second Schedule. The Third Schedule provides the information required in an application for intentional introduction. Information required for direct use as food, feed or processing is listed in the Fourth Schedule. Finally, in the Fifth Schedule provisions relating to the risk assessment are provided.

Biosafety Act

SAINT LUCIA

No.of 200[ ]

ARRANGEMENT OF SECTIONS

Sections

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PART VIII

MISCELLANEOUS

Biosafety Act

SAINT LUCIA

No.of 200[ ]

A

BILL

ENTITLED

AN ACT to ensure an adequate level of protection in the field of the safe conduct of contained use activity, transfer, handling, and use of genetically modified organisms resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health, to provide a transparent and predictable process for review and decision-making on such genetically modified organisms and related activities 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 -

PART I

PRELIMINARY

Short title and commencement

1. (1) This Act may be cited as the Biosafety Act 200 [ ].

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

Interpretation

2. In this Act -

"Advisory Committee" means the Biosafety Advisory Committee established under section 26;

"Appeals Tribunal" means the Biosafety Appeals Tribunal established under section 88;

"applicant" means a person or country who submits an application or petition pursuant to the provisions of this Act;

"application" means an application made pursuant to this Act;

"application fee" means an application fee to be submitted with an application pursuant to this Act;

"auditor" means a person who is a member of the Institute of Chartered Accountants in Saint Lucia or any other person who is a member of another professional accounting association;

"Biosafety Clearing House" means the information exchange mechanism established under article 20 of the Protocol;

"Biosafety Coordinator" means the Biosafety Coordinator appointed pursuant to section 9;

"Board" means the Biosafety Board established under section 14 as the Competent Authority of Saint Lucia;

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

"Convention" means the Convention on Biological Diversity, the text of which is set out in the First Schedule;

"genetically modified organism" -

(a) means an organism whose genetic material has been modified by the activity of manipulating recombinant deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA) molecules; and

(b) includes –

(i) a living modified organism;
(ii) a product of a genetically modified organism;

(c) does not include organisms arising from techniques that imply the direct introduction into an organism, or hereditary material, when this does not involve the use a recombinant DNA or RNA molecules or genetically modified organisms, modified by processes, such as, in vitro insemination, conjugation, transduction or any other natural process;

"Inspector" means an inspector appointed pursuant to section 12;

"intentional introduction into the environment" –

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

(b) includes the following activities -

(i) the deliberate release of a genetically modified organism for research purposes, such as, field trials;

(ii) the deliberate release of a genetically modified organism for commercial purposes, remedial purposes or such other purposes;

(iii) the use of a genetically modified organism in a greenhouse, aquaculture facility, animal accommodation or other facility, unless the facility in question is approved for contained use as part of an approved laboratory or other installation;

(iv) routine release from contained use;

(v) the disposal of waste containing a genetically modified organism;

(vi) placing on the market of a product consisting of or containing genetically modified organisms;

(vii) transport of a genetically modified organism;

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

"licensee" means a person who is issued a licence under this Act;

"living modified organism" 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;

"Minister" means the Minister responsible for biosafety;

"modern biotechnology" means the application of -

(a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) 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 notification made pursuant to this Act;

"notifier" means a person who makes a notification pursuant to this Act;

"person" includes corporate bodies and unincorporated bodies;

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

"product" means a preparation consisting of, or containing, a genetically modified organism;

"Protocol" means the Cartagena Protocol on Biosafety the text of which is set out in the Second Schedule;

"Public Education Specialist" means the Public Education Specialist appointed pursuant to section 10;

"risk assessment" means the process for dealing with uncertainties and incomplete data in order that decisions may be made in full consideration of potential consequences;

"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 genetically 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 genetically modified organism;

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

"Secretariat" means the Secretariat to the Convention;

"Unit" means the Biosafety Unit established pursuant to section 5 as the national focal point of Saint Lucia.

Application

3. (1) This Act shall apply to -

(a) the contained use, intentional introduction into the environment, and import and export of a genetically modified organism that may have an adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health;

(b) a genetically modified organism that is a pharmaceutical for human use;

(c) a genetically modified organism in transit through but not destined for use in Saint Lucia.

(2) This Act shall not apply to a genetically modified organism that is exempted pursuant to section 48.

The Crown

4. This Act binds the Crown.

PART II

ADMINISTRATION

Establishment of Biosafety Unit

5. There is hereby established a Biosafety Unit under the portfolio of the Minister.

Functions of Unit

6. (1) The Unit established under section 5 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 Biosafety Unit are to -

(a) liaise with the Secretariat;

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

(c) facilitate national, regional and international information sharing in accordance with section 7;

(d) carry out the policies of the Board;

(e) execute decisions made by the Board;

(f) issue permit, licences, certificates and other documents required under this Act;

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

(h) submit the applications, notifications, petitions and complaints referred to in paragraph (g) to the Board for consideration.

Information sharing

7. (1) The Unit shall create a national biosafety website to assist with the sharing of national information on biosafety matters.

(2) The website created pursuant to subsection (1) 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.

(3) The Unit shall provide to the national biosafety website and the Biosafety Clearing-House -

(a) a copy of this Act, including any amendments, decisions made pursuant to this Act or regulations made under this Act, and any other legislation or national guidelines of relevance to the implementation of the Protocol or the management of living modified organisms;

(b) summaries of risk assessments generated pursuant to section 58;

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

(d) reports concerning national implementation of the Protocol;

(e) within thirty days of taking a decision under section 46, a copy of the decision describing the changes to the previous decision and the reasons for the decision.

Staff of the Unit

8. The staff of the Unit comprises -

(a) a Biosafety Coordinator;

(b) a Public Education Specialist;

(c) an Administrative Secretary;

(d) Inspectors;

(e) and such other necessary administrative and technical personnel.

Biosafety Coordinator

9. (1) The Biosafety Coordinator shall be appointed as the Head of the Unit by the Public Service Commission and shall perform the functions specified in subsection (2).

(2) The functions of the Biosafety Coordinator are to –

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

(b) monitor and ensure compliance with this legislation in collaboration with the Board;

(c) liaise with enforcement agencies identified by the Board to collaborate with it and the Unit in enforcing this Act in the execution of their duties;

(d) liaise with the Biosafety Clearing House Task Force;

(e) make recommendations to the Board on matters related to biosafety management;

(f) liaise with the Information Technology Officer on matters to be placed on the national biosafety website and the Biosafety Clearing-House and matters related to unintentional introduction of genetically modified organisms into the environment;

(g) submit to the Board at the end of every three months a progress report on the work undertaken by the Unit;

(h) manage the staff of the unit for timely and effective work output;

(i) check through applications to ensure that all required information is present according to the First and Second Schedules;

(j) check risk assessment reports for scientific soundness;

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

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

Public Education Specialist

10. (1) A Public Education Specialist shall be appointed by the Public Service Commission and shall perform the functions specified in subsection (2).

(2) The functions of the Public Education Specialist are to –

(a) work closely with the Information Technology Officer to disseminate relevant information on biosafety issues to the general public and target groups relevant to biosafety management in Saint Lucia;

(b) raise public awareness and mobilize public participation on biosafety management issues in Saint Lucia;

(c) inform the public about the means of public access to the national biosafety website and the Biosafety Clearing-House in consultation with the Information Technology Officer;

(d) manage effectively the national biosafety website created under section 7, providing regular updates and maintenance;

(e) liaise with relevant national, regional and international agencies, as appropriate on behalf of the Biosafety Coordinator and other members of staff of the Unit;

(f) supply the necessary information as required to the Biosafety Clearing-House;

(g) provide relevant information from the Biosafety Clearing House and generally collaborate with the

Public Education Specialist for public sensitization and participation on biosafety management issues;

(h) perform any other functions as requested by the Biosafety Coordinator.

Administrative Secretary

11. (1) An Administrative Secretary shall be appointed by the Public Service Commission and shall perform the function specified in subsection (2).

(2) The function of the Administrative is to be responsible for the management of the office of the Unit and to perform any other functions as requested by the Biosafety Coordinator.

Inspectors

12. (1) An appropriate number of inspectors, as determined by the Board, shall be appointed by the Public Service Commission and shall perform the functions specified in subsection (2).

(2) The functions of Inspectors are to –

(a) check documentation of exports and imports at the ports for compliance with labeling and documentation requirements under this Act;

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

(c) monitor the implementation requirements under licences;

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

(e) carry out such functions as the Biosafety Coordinator or the Board may assign from time to time;

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

(3) The Board may co-opt persons from the Ministry of Health, the Saint Lucia Bureau of Standards, the Ministry of Agriculture, Forestry and Fisheries and the Solid Waste Management Authority to serve as inspectors under this Act.

(4) The Board shall ensure that the Inspectors appointed pursuant to subsection (1) are at all times properly trained and properly qualified to carry out the functions specified under this Act.

Administrative and technical personnel

13. The Public Service Commission may, on the advice of the Board, appoint such administrative and technical personnel as is deemed necessary.

Establishment of Board

14. There is hereby established a body to be known as the Biosafety Board.

Constitution of Board

15. (1) The Board shall be appointed by the Minister and comprise the following persons –

(a) one public officer from the following Departments of Government –

(i) Agriculture;
(ii) Environment;
(iii) Attorney General's Chambers;
(iv) Health;
(v) Consumer Affairs;
(vi) National Emergency Management Organization;
(vii) Customs and Excise;

(b) at least four members shall be persons representing various private sector interests and non-governmental organizations;

(c) the Biosafety Coordinator appointed pursuant to section 8 who shall be *ex-officio*, Secretary to the Board.

(2) The members of the Board shall choose a Chairperson from amongst its members.

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

Disqualification

16. A person shall be disqualified from being a member of the Board if that person -

(a) is adjudged by a court to be a bankrupt;
(b) is declared by a court to be physically or 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 board

17. (1) The Board established under section 14 shall serve as the competent authority of Saint Lucia and shall perform the functions specified in subsection (2).

(2) The functions of the Board shall be -

(a) to respond to and make decisions on applications, notifications, petitions and complaints in consultation with the Biosafety Advisory Committee in conformity with the requirements of this Act;

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

(c) to monitor and enforce this Act and the Regulations made 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 ensure capacity-building including scientific and technical training in the proper and safe management of biosafety, and in the use of risk assessment and

risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety;

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

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

(3) The Board may in carrying out its functions under this Act consult with the Ministry of Health, the Ministry of Commerce, the National Emergency Management Office, the National Council for Science and Technology Development, the Solid Waste Authority and any other ministry, office or authority.

Powers of the Board

18. (1) For the purposes of the discharge of its functions the Board 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 Board, may be able to assist;

(b) in the case of a review of a complaint to -

(i) request all or any of the parties concerned as well as witnesses to appear before the Board;

(ii) request such information, documents or things as it deems necessary to review the complaint.

(2) The Board may give such guidance to the Unit as may be necessary to ensure thoroughness in the carrying out of the functions of the Unit.

Tenure

19. (1) A member of the Board shall, subject to subsection (2), hold office for three years and may be reappointed.

(2) The appointment of one third of the members of the Board shall be staggered for the purpose of continuity in accordance with Regulations made pursuant to section 104.

Revocation of appointment

20. The Minister may at any time, in writing, revoke the appointment of any member of the Board if, on evidence, the Minister is satisfied that the member is disqualified from being a member of the Board pursuant to section 16, or is guilty of neglect of duty, misconduct or malfeasance.

Alternate member

21. (1) The Minister may appoint a person to be an alternate member for a specified member of the Board, other than the Chairperson.

(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 pursuant to section 20.

(3) The alternate member appointed pursuant to 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

22. (1) A member of the Board shall, by letter to the Minister immediately resign from the membership of the Board if that member becomes disqualified by virtue of section 16.

(2) A member of the Board may, for any reason other than disqualification pursuant to section 16, resign from the membership of the Board by giving at least three months notice in writing to the Minister of his or her resignation.

Vacancy

23. (1) The office of a member of the Board is vacated –

(a) on the death of the member;
(b) if the member becomes disqualified pursuant to section 16;
(c) if the member resigns from membership pursuant to section 22;
(d) if the Minister revokes the appointment of that member pursuant to section 20; or
(e) if the member fails to attend three consecutive meetings of the Board without being excused by the Minister in writing.

(2) If a vacancy occurs in the membership of the Board, the Minister shall appoint a person to fill the vacancy in a manner that respects the requirements in section 15 for the constitution of the Board.

(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

24. (1) A vacancy in the membership of the Board shall not invalidate a decision of the Board made at a meeting with the quorum required pursuant to section 25.

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

Meetings of the Board

25. (1) The Board 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 Board determines.

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

(3) Seven members of the Board shall form a quorum.

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

(5) Decisions of the Board shall be by a majority of votes and where the voting is equal the Chairperson shall have the casting vote.

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

Advisory committee

26. (1) The Board shall appoint a Biosafety Advisory Committee with technical competencies for the purposes specified in subsection (2).

(2) The functions of the Advisory Committee appointed pursuant to subsection (1) are to -

(a) conduct risk assessments -

(i) where there is new technology;

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

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

(iv) where a genetically modified organism is released intentionally or otherwise and which may cause unintended, unwanted or unacceptable effects;

(b) review the risk assessments provided in applications;

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

(d) to recommend 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) provide such other expert advice and assistance as the Board may require.

(3) The Advisory Committee shall consist of the following experts appointed by the Board from the following fields:

(a) agronomy;

(b) molecular biology;

(c) toxicology;

(d) human health; and

(e) environmental science.

(4) The Advisory Committee may establish a subcommittee and appoint a chairperson of the subcommittee from the members of the Advisory Committee.

(5) Members of the Advisory Committee and any subcommittee shall be drawn from governmental agencies or independent institutions including research institutes and universities and other academic institutions.

(6) Where a member of the Advisory Committee or subcommittee is directly or indirectly interested in a matter before the Advisory Committee or subcommittee, section 29 shall apply as it applies to members of the Board.

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

(8) The Advisory Committee or a subcommittee established by the Advisory Committee may regulate its own proceedings.

Declaration of interest and abstention from voting

27. (1) A member of the Board who is any way, either directly or indirectly, interested in a matter before the Board shall declare the nature of his or her interest at the first meeting of the Board 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 Board from the meeting in accordance with subsection (1) shall be noted in the minutes of the meeting.

(3) A member of the Board shall not -

(a) vote in respect of a matter before the Board 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 Board in relation to the matter.

(4) A member of the Board who fails to comply with subsection (3) shall be promptly removed from the Board.

Signing of documents and decisions

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

Remuneration

29. The members of the Board shall be remunerated per meeting attended in accordance with Regulations made pursuant to section 104.

Financial year of Board

30. The financial year of the Board shall be the same as specified for the government under the Finance (Administration) Act.

Budget and plan of action of Board

31. The Board shall not later than three months before the beginning of the next financial year cause to be prepared and shall adopt and submit to the Minister -

(a) a budget with the estimates of its income and expenditure; and

(b) a plan of action;

for the Board in respect of the next financial year.

Accounts of Board

32. The Board shall keep proper records of accounts in accordance with generally accepted international standards and principles and shall prepare and retain financial statements in respect of each financial year.

Audit of Board

33. (1) The Board shall as soon as is practicable after each financial year have its accounts audited annually by an independent auditor appointed by the Board, who shall conduct the audit in accordance with generally accepted international auditing standards and principles.

(2) The Board and staff of the Board shall grant to the auditor appointed pursuant to subsection (1) access to all books, deeds, contracts, accounts, vouchers, or other documents which the auditor may deem necessary and the auditor may require the person holding or accountable for such document to appear, make a signed statement or provide such information in relation to the document as the auditor deems necessary.

(3) A person required to appear, make a signed statement or to provide information under subsection (2) and who fails to comply commits an offence and is on summary conviction liable to a fine not exceeding three thousand dollars or to imprisonment for a term not exceeding six months or to both and to revocation of his or her

appointment as a member or staff of the Board in accordance with this Act.

Auditor's report of Board

34. An independent auditor appointed pursuant to section 33 shall as soon as practicable and not later than two months after the end of each financial year submit copies of the audited financial statement of the Board and a report on the financial statement to the Board.

Annual report of Board

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

(2) An annual report pursuant to subsection (1) shall be in the form prescribed and shall be accompanied by the auditor's report pursuant to section 36.

(3) A summary of an annual report pursuant to 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 Board.

PART III

MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS

Division 1

Contained use

Authorisation for contained use

36. (1) A person shall not conduct a contained use activity involving a genetically modified organism in a laboratory, installation or other physical structure unless that person holds a valid licence for contained use.

(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.

(3) In order for a person to obtain a licence for contained use that person shall, in accordance with subsection (4), apply to the Board for a licence for contained use.

(4) An application made pursuant to subsection (3) shall be -

(a) addressed to the Chairperson of the Board;

(b) submitted to the Unit in quadruple as follows -

(i) three hard copies; and

(ii) one electronic copy;

(c) in the prescribed form and shall include -

(i) the name and contact information for the applicant;

(ii) the location where contained use will be undertaken;

(iii) the nature and identity of the genetically modified organism involved;

(iv) the nature and purpose of the contained use;

(v) a description of the containment measures to be provided and the suitability of those measures for the genetically modified organism;

(vi) a description of any potential risks associated with the contained use to be undertaken; and

(vii) a description of remedial measures to be undertaken in the event of any

unintentional introduction into the environment of the genetically modified organism that may occur as a result of the contained use;

(viii) country of origin;

(ix) place where the genetically modified organism was produced;

(e) accompanied with the prescribed application fee.

(5) The Board in consultation with the Advisory Committee may request in writing that the applicant provide information additional to the information required under subsection (4), including a risk assessment.

(6) On receiving an application for a licence for contained use, the Board shall -

(a) cause the laboratory, installation or other physical structure to be inspected and reported on by an Inspector appointed under section 12; and

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

(7) Where application is made for a licence for contained use pursuant to subsection (3) and the Board has complied with section 99, the Board may grant a licence for contained use with or without conditions or may refuse to grant a licence for contained use.

(8) Where the Board grants a licence for contained use with conditions or refuses to grant a licence for contained use, the Board shall provide the applicant with the reasons for so doing in writing.

(9) Where the Board grants a licence for contained use, the Board shall issue a licence for contained use in the prescribed form on payment of the prescribed licence for contained use fee.

Safety precautions

37. A licensee shall ensure that the necessary safety precautions are taken to prevent adverse effects on health and the environment, including measures to limit the detrimental effects of the unintentional introduction of a genetically modified organism.

Microbiological practice

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

Records

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

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

Authorisation for export

40. (1) A person shall not initially export out of Saint Lucia to a Party of import a genetically modified organism for contained use of the Party of import unless that person holds a valid licence for export for contained use.

(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 or two years or to both.

(3) In order for a person to obtain a licence for export for contained use, that person shall, in accordance with subsection (4), apply to the Board for a licence for export for contained use.

(4) An application made pursuant to subsection (3) shall be -

(a) addressed to the Chairperson of the Board;

(b) submitted to the Unit in quadruple as follows -

(i) three hard copies; and

(ii) one electronic copy;

(c) in the prescribed form and shall include the information specified in the Third Schedule;

(d) accompanied by the prescribed application fee.

(5) A person shall not make any statement which he or she knows to be false for the purpose of obtaining an export for contained use licence under this section.

(6) A person who contravenes subsection (5) commits an offence and is liable on summary conviction to a fine not exceeding five thousand dollars and in default of payment to imprisonment for a term not exceeding one year.

(7) On receipt of an application for a licence for export for contained use pursuant to this section, the Board shall, in accordance with subsection (8), notify the competent authority of the Party of import of the application for export.

(8) The notification pursuant to subsection (7) shall be in writing and shall contain the information contained in the Third Schedule.

(9) If the competent authority of the Party of import authorizes the import and the Board has complied with section 99, the Board shall grant a licence for export for contained use and shall issue a licence for export for contained use in the prescribed form including conditions, if any, on payment of the prescribed licence for export for contained use fee.

Division 2

Direct use as food, feed or processing

Authorisation for direct use as food, feed or processing

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

(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, the person may be requested to dispose, at his or her own expense, of the genetically modified organism in question by destruction.

(3) In order for a person to obtain a permit for direct use as food, feed, or processing that person shall, in accordance with subsection (4), apply to the Board for a permit for direct use as food, feed, or processing.

(4) An application made pursuant to subsection (3) shall be -

(a) addressed to the Chairperson of the Board;

(b) submitted to the Unit in quadruple as follows -

(i) three hard copies; and

(ii) one electronic copy;

(c) in the prescribed form and shall include a risk assessment in accordance with section 58;

(e) accompanied by the prescribed application fee.

(5) The Board may, once it has complied with section 99, grant a permit for direct use as food, feed or processing with or without conditions or may refuse to grant a permit for direct use as food, feed or processing.

(6) Where the Board grants a permit for direct use as food, feed or processing with conditions or refuses to grant a permit for direct use as food, feed or processing, the Board shall provide the applicant with the reasons for so doing in writing.

(7) Where the Board grants a permit for direct use as food, feed or processing, the Board shall issue a permit for direct use as food, feed or processing in the prescribed form on payment of the prescribed permit for direct use as food, feed or processing fee.

Labelling for direct use as food, feed or processing

42. (1) The holder of a permit for direct use as food, feed or processing permit shall ensure that -

(a) all products contaminated by authorized genetically modified organisms above a limit of 1.0% are labeled;

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

(c) in the case of products produced from genetically 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 genetically modified organisms;

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

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

(2) The Minister may, on the advice of the Board, change the limit under subsection (1)(a), by Order published in the *Gazette*.

(3) The holder of a permit for direct use as food, feed or processing shall hold the information under subsection (1)(b)-(d) for a period of five years from each transaction and be able to identify the operator by whom and to whom the products have been made available.

(4) In this section, “unique identifier” means the nine-digit alphabumeric code that is given to each transgenic or genetically

engineered plant that is approved for commercial use, including planting and food or feed use pursuant to the OECD published Guidance for the Designation of a Unique Identifier for Transgenic Plants.

Labelling for pharmaceuticals

43. The Minister may prescribe labelling requirements for pharmeuticals in consultation with the Ministry of Health in Regulations made pursuant to regulation 104.

Division 3

Intentional introduction into the environment

Authorisation for intentional introduction into the environment

44. (1) A person shall not intentionally introduce into the environment a genetically modified organism unless that person holds a valid permit for intentional introduction into the environment.

(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, the person may be requested to dispose, at his or her own expense, of the genetically modified organism in question by destruction.

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

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

(5) An application made pursuant to subsection (1) shall be -

(a) addressed to the Chairperson of the Board;

(b) submitted to the Unit in quadruple as follows -

(i) three hard copies; and

(ii) one electronic copy;

(c) in the prescribed form and shall include -

(i) the information specified in the Third Schedule;

(ii) a risk assessment in conformity with the section 58; and

(iii) any additional information the applicant deems relevant to an assessment of the potential risks or benefits of the requested activity.

(6) A person shall not obtain a permit for intentional introduction into the environment by fraud, deception, misrepresentation, misleading or inaccurate information.

(7) A person who contravenes subsection (5) 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.

(8) The Board may, once it has complied with section 99, grant a permit for intentional introduction into the environment with or without conditions or may refuse to grant a permit for intentional introduction into the environment.

(9) Where the Board grants a permit for intentional introduction into the environment with conditions or refuses to grant a permit for intentional introduction into the environment, the Board shall provide the applicant with the reasons for so doing in writing.

(10) Where the Board grants a permit for intentional introduction into the environment, the Board shall issue a permit for intentional introduction into the environment in the prescribed form on payment of the prescribed permit for intentional introduction into the environment fee.

Acknowledgement of receipt of application

45. (1) Within ninety days of receiving an application, the Board shall, in accordance with subsection (2), acknowledge receipt of the application.

(2) The acknowledgement pursuant to subsection (1) shall be in writing and shall state -

(a) the date of receipt of the application;

(b) that the application, *prima facie*, contains the information referred to in section 48(4);

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

(3) A failure by the Board to acknowledge receipt of an application shall not imply its consent to an intentional introduction into the environment.

Determination of application

46. (1) The Board shall not grant an import for intentional introduction into the environment permit unless the application has been submitted to the Advisory Committee for the conduct of a risk assessment in accordance with section 58.

(2) Within ten days of receipt of the risk assessment report submitted by the Advisory Committee, the Board shall provide the risk assessment report provided pursuant to section 58 to the applicant for comments.

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

(4) The Board shall immediately on receipt of the comments provided by the applicant pursuant to subsection (3), provide the Advisory Committee with a copy of the comments.

(5) Within ninety days, the Board shall, inform the applicant, in writing, whether the intentional introduction into the environment may proceed.

(6) Within two hundred and seventy days of the date of receipt of and application, the Board shall communicate, in writing, to the applicant and to the Unit who shall inform the Biosafety Clearing-House of the decision referred to in subsection (1) -

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

(b) prohibiting the import;

(c) requesting additional relevant information

(d) informing the applicant that the period specified in this section is extended by a defined period of time.

(7) A failure by the Board to communicate its decision within two hundred and seventy days of the date of receipt of the application shall not imply its consent to an intentional introduction into the environment.

(8) Except in a case in which consent is unconditional, a decision under subsection (6), shall set out the reasons on which it is based.

(9) Where additional information is requested by the Board pursuant to subsection (6) -

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

(b) a final written decision as to whether the proposed activities may proceed shall be provided by the Board to the applicant no later than sixty days following receipt of the additional information.

(10) Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity in Saint Lucia, taking into account risks to human health, shall not prevent the Board from taking a decision, as appropriate, with regard to the import of the genetically modified organism in question as referred to in subsection (6), in order to avoid or minimize such potential adverse effects.

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

(12) The Board may require that a Social Impact Assessment shall be carried out in respect of any application for an import for intentional introduction into the environment permit, if the introduction of the genetically modified organism could significantly affect the social, ethical or religious values of Saint Lucia.

(13) The Board shall make a final decision on the application submitted pursuant to section 48 based on the following -

(a) the information submitted in the application made pursuant to this section;

(b) the risk assessment report prepared by the Advisory Committee pursuant to section 58;

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

(d) any relevant comments submitted by the public pursuant to section 106.

Issue of permit for intentional introduction into the environment

47. Where the Board grants an import for intentional introduction into the environment permit, the Board shall issue an import for intentional introduction into the environment permit in the prescribed form including conditions, if any, on payment of the prescribed import for intentional introduction into the environment permit fee.

Exemptions

48. (1) Where -

(a) the Board determines that sufficient experience or information exists to conclude that a genetically modified organism does not pose a significant risk to

the conservation and sustainable use of biological diversity taking into account risks to human health; or

(b) that it is agreed by the parties that a genetically modified organism is not likely to have adverse effects on the conservation and sustainable use of biological diversity and human health;

(c) a petition is made to the Board and approved by the Board in accordance with this section;

the Board may exempt the genetically modified organism from the requirements of section 44.

(2) A person may, in accordance with subsection (3), petition the Board to exempt a genetically modified organism.

(3) A petition made pursuant to subsection (2) shall be in the prescribed form and shall -

(a) contain the following information -

(i) name and address of the applicant;

(ii) name and description of the genetically modified organism for which exemption is sought;

(iii) a comprehensive discussion of the scientific basis for the requested action accompanied by supporting documentation;

(iv) any information known to the applicant that would be unfavourable to the petition; and

(b) be accompanied by the prescribed petition fee.

(4) Within ten days of receipt of the petition, the Board shall publish the petition in the *Gazette* and at least two newspapers in general and weekly circulation in Saint Lucia and transmit the petition to the Advisory Committee for review.

(5) The Board shall make a final decision on the petition based on the scientific review conducted by the Advisory Committee and comments submitted by the public.

(6) Within one hundred and twenty days of receipt of the petition by the Board, the Board shall make a final decision and may either approve or deny the petition in whole or in part.

(7) Where the Board approves the petition, the Board shall issue a certificate of exemption in the prescribed form on payment of the prescribed fee.

Documentation for import or export for intentional introduction into the environment

49. The holder of an import or export for intentional introduction into the environment permit shall ensure that documentation accompanying a genetically modified organism that is intended for intentional introduction into the environment shall be clearly identified as a genetically modified organism and shall specify the following -

(a) the identity and relevant traits or characteristics;

(b) any requirements for safe handling, storage, transport and use;

(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.

Placing on the market

50. (1) A permit holder 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 genetically modified organism.

(2) A permit holder 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 genetically modified organism that has been used to constitute the mixture is transmitted in writing to the recipient of the product.

(3) A permit holder 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.

Division 4

General

Withdrawal of application

51. An applicant may withdraw its application at any time prior to the issuance of a final decision by the Board without prejudice.

Cancellation of application

52. (1) Where the applicant does not furnish the additional information requested by the Board within a reasonable time of the request being made, the Board may give the applicant notice that the application cannot be determined and has been cancelled.

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

Validity

53. A licence or permit issued under this Act shall be valid for the period specified in the licence or permit.

Effect of licence or permit

54. A licence or permit issued pursuant to this Act shall, unless the the licence or permit provides otherwise, authorize only the licensee or permit holder to engage in the activity identified in the licence or permit in relation to the genetically modified organism identified in the licence or permit.

Furnishing of information

55. A licensee or permit holder shall supply the Board, on request, with such information about their activities as is necessary for the Board to carry out its supervisory, monitoring or enforcement tasks under this Act or to deal with any emergency situations.

Revocation of licence or permit

56. (1) The Board may revoke a licence or permit if the licensee or permit holder -

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

(b) fails to comply with the conditions imposed on the licence or permit.

(2) If the Board proposes to cancel a person's licence or permit, the Board shall give to the licensee or permit holder notice in writing of the proposal and the Board's reasons for the proposal and shall invite the person to show cause why the Board should not proceed as proposed.

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

(4) If the Board cancels a licence or permit under this section, the Board shall give the licensee or permit holder notice in writing of the revocation and shall give information concerning the right of appeal under section 57.

Right of appeal

57. (1) Where a licence or permit is granted with conditions, is refused, cancelled or revoked, the person applicant may, within thirty days from receipt of notice of the decision, appeal in writing to the Appeals Tribunal established under section 88, setting out the grounds on which the appeal is made.

(2) Before determining an appeal referred to it under this section, the Appeals Tribunal shall, if the person or the Board so desire, give each of them the opportunity of appearing before and being heard by it.

PART III

RISK ASSESSMENT, RISK MANAGEMENT AND RISK COMMUNICATION

Risk assessment

58. (1) A risk assessment conducted by -

(a) an applicant or the Advisory Committee; or

(b) review of a risk assessment conducted by the Advisory Committee;

shall be carried out in accordance with the Fifth Schedule taking into account recognised risk assessment techniques.

(2) In order to effectively assess all risks posed by the use of a genetically modified organism, the Advisory Committee may require an applicant to provide the following -

(a) characteristics of the vector;

(b) characteristics of the genetically modified organism or product of the genetically 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; and

(k) and other available scientific evidence;

in order to identify and evaluate the possible adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity, taking into account risks to human health.

(3) The cost of risk assessment or review of risk assessment shall be borne by the applicant.

(4) On conclusion of the risk assessment or review of the risk assessment, the Advisory Committee shall provide the Board with a risk assessment report.

(5) A risk assessment report provided pursuant to subsection (4) shall give the opinion, with justifications, on the disposition of the application and indicates any measures or actions that need to be taken to ensure the safe use of the genetically modified organism.

Risk management

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

(a) during the risk assessment process; or

(b) under section 61;

and shall impose such mechanisms, measures or strategies to the extent necessary to prevent adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity, taking into account risks to human health.

(2) Without prejudice to the generality of subsection (1), where on the advice of the Board, the Minister is satisfied that the regulating of the discharge of genetically modified organisms into an area is necessary to prevent the adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity, taking into account risks to human health, the Minister shall by Order published in the *Gazette* declare the area to be a genetically modified control area or a genetic resource centre.

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

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

Risk communication

60. A licensee or permit holder 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; or

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

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

PART IV

UNINTENTIONAL INTRODUCTION INTO THE ENVIRONMENT AND EMERGENCY MEASURES

Unintentional introduction into the environment

61. (1) A licensee or permit holder, who has knowledge of an unintentional introduction into the environment of a genetically modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, shall within twenty four hours of knowing of the introduction, notify the Board 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 genetically modified organism;

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

(c) any available information about the possible adverse effect on the conservation and sustainable use of biological diversity or risk 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.

(2) The Board and the Advisory 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.

(3) Where the Board and the Advisory 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 Board shall exercise the risk management measures under section 59 and the notifier shall take the necessary action and shall be liable for the cost of such action.

(4) Where the Board knows of an occurrence resulting in an introduction that leads or may lead to an unintentional introduction into the environment of a genetically modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, in another country, the Board shall notify -

(a) affected or potentially affected countries;

(b) the Unit who shall notify the Biosafety Clearing-House established under the Protocol; and

(c) where appropriate relevant international organizations.

Emergency measures

62. The Board shall determine, in collaboration with the National Emergency Management Office, appropriate emergency measures 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.

PART V

INVESTIGATION OF COMPLAINTS

Complaints by public

63. (1) Any member of the public having a complaint concerning a licensee or permit holder, 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 Board through the Unit.

(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 Board.

(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

64. The Board shall submit the complaint to an Inspector through the Biosafety Coordinator for investigation and resolution in the manner provided in this Act.

Notification of licensee or permit holder

65. Immediately after being notified of a complaint under section 63, the Board shall, in writing, notify the licensee or permit holder concerned, of the substance of the complaint unless, in the Board's opinion, 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

66. (1) The Board shall consider whether a complaint under section 63 can be disposed of informally and, with the consent of the complainant and the licensee or permit holder 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 or permit holder concerned 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 wiriting by the complainant and the licensee or permit holder concerned shall be informed of the disposition.

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

Frivolous complaints

67. (1) An Inspector shall investigate all complaints in a thorough manner, except that where the Board is of the view that the complaint is of a frivolous nature, the person making that complaint shall be informed 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 Board shall, within seven days accordingly inform the Inspector, the licensee or permit holder concerned and the complainant.

Inspector to investigate complaints

68. (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 its findings and recommendations.

(2) The report shall be forwarded to the Board and the Biosafety Coordinator, and its recommendations notified to the complainant and the licensee or permit holder concerned.

Review of report

69. (1) The Board 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 Board under section 70, the Board may immediately –

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

(b) take such action as the Board thinks fit.

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

Application for review

70. A person who is aggrieved with the disposition of his or her complaint or with the findings and recommendations of the Inspector, may apply in writing to the Board for a review of the matter by the Board, within one month of receipt of the outcome of the investigation.

Inspector to furnish relevant material

71. (1) On receipt of an application under section 70, the Board 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 Board with all material relevant to the complaint within twenty-one days.

Review by Board

72. (1) Where, on review, the Board 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 or permit holder concerned.

(2) Where, the Board 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 institute a hearing to inquire into the complaint;

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

Hearing instituted by Board

73. (1) For the purposes of section 72(2)(b), the Board shall institute a hearing by sending a notice of the hearing to the complainant and the licensee or permit holder concerned.

(2) The notice of hearing shall –

(a) specify the purpose of the hearing;

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

(c) be in the prescribed form.

(3) The complainant and the licensee or permit holder shall attend the hearing.

Non-attendance of parties

74. (1) Where the complainant does not attend the hearing, having had due notice of the time and place of hearing, the Board may dismiss the complaint, unless having received a reasonable excuse for the non-appearance of the complainant the Board thinks it fit to adjourn the matter.

(2) 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 section 73; 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 of one thousand dollars and to imprisonment for one year.

Completion of hearing

75. On completion of a hearing, the Board shall prepare and send to the complainant and the licensee or permit holder, a report setting out its findings and recommendations with respect to the complaint.

PART V
ENFORCEMENT

Powers of inspector

76. (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, 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 may in the circumstances be 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 reasonable 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 genetically modified organism which have adversely affected or is likely to adversely affect the conservation and sustainable use of biological diversity, taking into account risks to human health, to cause it to be dismantled or subjected to any

process or test, but not so as to damage or destroy it unless this is necessary;

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

(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 issued under section 77.

Application for warrant

77. (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 authorised 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 authorised in the warrant.

Obstruction of inspector

78. (1) A person shall not obstruct an inspector acting in the exercise of their power under section 76 or section 77.

(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.

Forfeiture

79. (1) Where an Inspector has seised any product or thing under section 76 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.

(2) If the person is convicted of an offence against this Act, the court that convicted the person may order the forfeiture to the Crown of any thing produced to the court that is shown to relate to the commission of the offence.

(3) The court must not order the forfeiture of any thing 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.

(4) A thing forfeited to the Crown under this section may be sold or otherwise disposed of as the Minister directs on the advice of the Board.

Release of forfeited property

80. (1) A person whose property has been forfeited to the Crown under section 79 or a person who has a legal or equitable interest in any such property may apply to the Minister, 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 Minister may order the release of the forfeited property on payment to the Crown of an amount the Minister thinks appropriate, being an amount that does not exceed the amount the property forfeited would, in the estimation of the Board, be likely to realize if sold by public auction.

(4) In considering whether to order the release of any property, the Minister 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

81. (1) Where the Board determines 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 Board may issue a notice in the prescribed form for the immediate cessation of any activity covered by the licence or permit and for the immediate imposition of additional risk management measures with respect to such activity

(2) A notice issued pursuant to subsection (1) shall be withdrawn once the Board determines 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.

(4) The Board 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 may obtain the assistance of a police officer.

Notice to remedy contravention

82. (1) Where it appears to the Board that a person has failed, refused or neglected to comply with the requirements of this Act, the Board shall immediately serve a notice in the prescribed form to remedy the contravention on the person.

(2) A notice served pursuant to 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

83. (1) If within the period specified in a notice, any steps required by the notice to remedy contravention have not been taken, the Board may personally or by persons under the Board'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 Board by subsection (1) commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars.

Payment of compensation

84. (1) Where it appears to the Board that loss or damage is caused by the contravention of this Act, the Board may by notice require the licensee or permit holder 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 and shall include -

(a) the contravention which caused the loss or damage;

(b) the loss or damage caused; and

(c) the amount of compensation payable.

Injunction

85. In addition to any other remedy provided by this Act, the Board 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

86. Where a notice issued pursuant to section 81, 82 or 83, the person may, within thirty days of receipt of the notice, appeal in writing to the Appeals Tribunal established under section 88, setting out the grounds on which the appeal is made.

Forfeiture by the Court

87. (1) If a person is convicted of an offence against this Act, the court that convicted the person may order the forfeiture to the Crown of any thing produced to the court that is shown to relate to the commission of the offence.

(2) The court must not order the forfeiture of any thing 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 Minister directs.

PART VI

APPEALS TRIBUNAL

Establishment of Appeals Tribunal

88. There is hereby established a body to be known as the Biosafety Appeals Tribunal.

Constitution of Appeals Tribunal

89. (1) The Appeals Tribunal shall consist of not less than three or more than five members, appointed by the Board.

(2) The Chairperson of the Appeals 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.

Tenure

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

Temporary members

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

(2) A person appointed pursuant to subsection (1) shall be appointed in a manner that respects the requirements in section 89 for the constitution of the Appeals 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

92. Any member of the Appeals Tribunal, may at any time resign from office by instrument in writing addressed to the Board and transmitted through the Chairperson, and such resignation shall take effect as from the date of receipt of that instrument by the Board.

Revocation of appointment

93. The Board may at any time revoke the appointment of any member of the Appeals Tribunal, including the Chairperson.

Publication in the Gazette

94. The appointment of any member of the Appeals 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 Appeals Tribunal

95. (1) The Board shall appoint a recording Secretary of the Appeals Tribunal who shall have no voting rights.

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

Remuneration

96. A member of the Appeals Tribunal shall be paid such remuneration and allowances, if any, as the Board may determine.

Hearings, deliberations and decisions

97. (1) The Appeals 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 Appeals Tribunal shall comprise a majority of the members but where a member is disqualified from taking part in the proceedings of the Appeals 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 Appeals Tribunal, may call witnesses including persons from regional or other countries, with expert knowledge or experience.

(4) 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.

(5) 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.

(6) The decision of the Appeals Tribunal referred to it shall be conveyed to the Board and the appellant in writing.

(7) The decision of the Appeals Tribunal on any appeal shall be final.

(8) The appellant shall bear the cost of an appeal.

(9) An appeal to the High Court may be made from a decision of the Appeals Tribunal on a point of law, but not on any matter of fact or on the merits of any decision made by the Board or the Appeals Tribunal.

(10) A member of the Appeals 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 Appeals Tribunal on that matter.

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

(12) Subject to this section, the Appeals Tribunal shall have the power to regulate their own procedure.

Validity of proceedings

98. The validity of any proceedings of the Appeals Tribunal shall not be affected by any vacancy in its membership or by any defect in the appointment of any of its members.

PART VIII

MISCELLANEOUS

Publication

99. (1) The Board shall -

(a) one week after satisfactory vetting of any application for a licence or permit made under this Act;

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

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

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

(e) on receiving notice of appeal in respect of such a decision;

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

(g) on the cancellation or change of decision of any licence or permit granted in respect of an application;

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

(i) on receiving 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 in Saint Lucia a summary of the application, decision, cancellation or notice.

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

Register

100. (1) The Board shall maintain and keep a register containing particulars of -

(a) any application for a licence or permit made under this Act, including the name and address of the applicant, the date of the application and the genetically modified organism in relation to which 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 cancellation or change of decision of any licence or permit granted in respect of any such application;

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

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

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

(2) The register kept by the Board 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 pursuant to subsection (1) and to take copies of such information on payment of the prescribed fee.

Confidentiality

101. (1) An applicant may identify information provided in an application which is to be treated as confidential and shall justify claims of confidentiality if requested to do so.

(2) Where a claim to confidentiality is accepted by the Board, Advisory Committee or subcommittee, a member or employee of the Board or member of the Advisory Committee or subcommittee shall at all times preserve and aid in preserving confidentiality.

(3) Except for the performance of his or her duties or under legal obligation, a member or employee of the Board or member of the Advisory Committee or subcommittee 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 genetically modified organism;

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

(d) any methods and plans for emergency response.

Protection

102. An action shall not be made against the Board 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.

Amendment of Schedules

103. The Minister may, by Order published in the *Gazette*, amend the First Schedule, the Second Schedule or the Third Schedule.

Regulations

104. (1) The Minister may, on the advice of the Board, 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 Board, 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, permit or certification required under this Act;

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

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

(f) measures for the transport of genetically 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.

(3) Any regulations made under this section may provide that any person who contravenes or fails to comply with a provision commits an offence and is liable on summary conviction to a fine of ten thousand or to imprisonment to two years or to both.

Pending applications

105. Where immediately before the coming into operation of this Act an application has been made and the application has not been finally determined, the application shall continue to be dealt with and completed or otherwise determined in all respects in accordance with this Act.

FIRST SCHEDULE

(Section 2)

CONVENTION ON BIOLOGICAL DIVERSITY

Preamble

The Contracting Parties,

Conscious of the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural,recreational and aesthetic values of biological diversity and its components,

Conscious also of the importance of biological diversity for evolution and for maintaining life sustaining systems of the biosphere,

Affirming that the conservation of biological diversity is a common concern of humankind,

Reaffirming that States have sovereign rights over their own biological resources,

Reaffirming also that States are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner,

Concerned that biological diversity is being significantly reduced by certain human activities,

Aware of the general lack of information and knowledge regarding biological diversity and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures,

Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat,

Noting further that the fundamental requirement for the conservation of biological diversity is the in-situ conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings,

Noting further that ex-situ measures, preferably in the country of origin, also have an important role to play,

Recognizing the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components,

Recognizing also the vital role that women play in the conservation and sustainable use of biological diversity and affirming the need for the full participation of women at all levels of policy-making and implementation for biological diversity conservation,

Stressing the importance of, and the need to promote, international, regional and global cooperation among States and intergovernmental organizations and the non-governmental sector for the conservation of biological diversity and the sustainable use of its components,

Acknowledging that the provision of new and additional financial resources and appropriate access to relevant technologies can be expected to make a substantial difference in the world's ability to address the loss of biological diversity,

Acknowledging further that special provision is required to meet the needs of developing countries, including the provision of new and additional financial resources and appropriate access to relevant technologies,

Noting in this regard the special conditions of the least developed countries and small island States,

Acknowledging that substantial investments are required to conserve biological diversity and that there is the expectation of a broad range of environmental, economic and social benefits from those investments,

Recognizing that economic and social development and poverty eradication are the first and overriding priorities of developing countries,

Aware that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential,

Noting that, ultimately, the conservation and sustainable use of biological diversity will strengthen friendly relations among States and contribute to peace for humankind,

Desiring to enhance and complement existing international arrangements for the conservation of biological diversity and sustainable use of its components, and

Determined to conserve and sustainably use biological diversity for the benefit of present and future generations,

Have agreed as follows:

Article 1
Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 2
Use of Terms

For the purposes of this Convention:

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

"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"Country of origin of genetic resources" means the country which possesses those genetic resources in in-situ conditions.

"Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

"Domesticated or cultivated species" means species in which the evolutionary process has been influenced by humans to meet their needs.

"Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

"Ex-situ conservation" means the conservation of components of biological diversity outside their natural habitats.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"Genetic resources" means genetic material of actual or potential value.

"Habitat" means the place or type of site where an organism or population naturally occurs.

"In-situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"In-situ conservation" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"Protected area" means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives.

"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 Convention and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it.

"Sustainable use" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

"Technology" includes biotechnology.

Article 3
Principle

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article 4
Jurisdictional Scope

Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party:

(a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and

(b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

Article 5
Cooperation

Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.

Article 6
General Measures for Conservation and Sustainable Use

Each Contracting Party shall, in accordance with its particular conditions and capabilities:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into

relevant sectoral or cross-sectoral plans, programmes and policies.

Article 7
Identification and Monitoring

Each Contracting Party shall, as far as possible and as appropriate, in particular for the purposes of Articles 8 to 10:

(a) Identify components of biological diversity important for its conservation and sustainable use having regard to the indicative list of categories set down in Annex I;

(b) Monitor, through sampling and other techniques, the components of biological diversity identified pursuant to subparagraph (a) above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use;

(c) Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques; and

(d) Maintain and organize, by any mechanism data, derived from identification and monitoring activities pursuant to subparagraphs (a), (b) and (c) above.

Article 8
In-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate:

(a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;

(b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity;

(c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use;

(d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings;

(e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas;

(f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, inter alia, through the development and implementation of plans or other management strategies;

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

(h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;

(i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components;

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

(k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations;

(l) Where a significant adverse effect on biological diversity has been determined pursuant to Article 7, regulate or manage the relevant processes and categories of activities; and

(m) Cooperate in providing financial and other support for in-situ conservation outlined in subparagraphs (a) to (l) above, particularly to developing countries.

Article 9
Ex-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing in-situ measures:

(a) Adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components;

(b) Establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources;

(c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions;

(d) Regulate and manage collection of biological resources from natural habitats for ex-situ conservation purposes so as not to threaten ecosystems and in-situ populations of species, except where special temporary ex-situ measures are required under subparagraph (c) above; and

(e) Cooperate in providing financial and other support for ex-situ conservation outlined in subparagraphs (a) to (d) above and in the establishment and maintenance of ex-situ conservation facilities in developing countries.

Article 10
Sustainable Use of Components of Biological Diversity

Each Contracting Party shall, as far as possible and as appropriate:

(a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;

(b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;

(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;

(d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and

(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.

Article 11
Incentive Measures

Each Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity.

Article 12
Research and Training

The Contracting Parties, taking into account the special needs of developing countries, shall:

(a) Establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for such education and training for the specific needs of developing countries;

(b) Promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, inter alia, in accordance with decisions of the Conference of the Parties taken in consequence of recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice; and

(c) In keeping with the provisions of Articles 16, 18 and 20, promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.

Article 13
Public Education and Awareness

The Contracting Parties shall:

(a) Promote and encourage understanding of the importance of, and the measures required for, the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in

educational programmes; and

(b) Cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes, with respect to conservation and sustainable use of biological diversity.

Article 14
Impact Assessment and Minimizing Adverse Impacts

1. Each Contracting Party, as far as possible and as appropriate, shall:

(a) Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures;

(b) Introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account;

(c) Promote, on the basis of reciprocity, notification, exchange of information and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other States or areas beyond the limits of national jurisdiction, by encouraging the conclusion of bilateral, regional or multilateral arrangements, as appropriate;

(d) In the case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity within the area under jurisdiction of other States or in areas beyond the limits of national jurisdiction, notify immediately the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage; and

(e) Promote national arrangements for emergency responses to activities or events, whether caused naturally or otherwise, which present a grave and imminent danger to biological diversity and encourage international cooperation to supplement such national efforts and, where appropriate and agreed by the States or regional economic integration organizations concerned, to establish joint contingency plans.

2. The Conference of the Parties shall examine, on the basis of studies

to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

Article 15
Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16
Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention,

undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 17
Exchange of Information

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.

2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

Article 18
Technical and Scientific Cooperation

1. The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.

2. Each Contracting Party shall promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention, inter alia, through the development and implementation of national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building.

3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.

4. The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this Convention. For this purpose, the Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.

5. The Contracting Parties shall, subject to mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.

Article 19
Handling of Biotechnology and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Article 20
Financial Resources

1. Each Contracting Party undertakes to provide, in accordance with its capabilities, financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention, in accordance with its national plans, priorities and programmes.

2. The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions and which costs are agreed between a developing country Party and the institutional structure referred to in Article 21, in accordance with policy, strategy, programme priorities and eligibility criteria and an indicative list of incremental costs established by the Conference of the Parties. Other Parties, including countries undergoing the process of transition to a market economy, may voluntarily assume the obligations of the developed country Parties. For the purpose of this Article, the Conference of the Parties, shall at its first meeting establish a list of developed country Parties and other Parties which voluntarily assume the obligations of the developed country Parties. The Conference of the Parties shall periodically review and if necessary amend the list. Contributions from other countries and sources on a voluntary basis would also be encouraged. The implementation of these commitments shall take into account the need for adequacy, predictability and timely flow of funds and the importance of burden-sharing among the contributing Parties included in the list.

3. The developed country Parties may also provide, and developing country Parties avail themselves of, financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels.

4. The extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities of the developing country Parties.

5. The Parties shall take full account of the specific needs and special situation of least developed countries in their actions with regard to funding and transfer of technology.

6. The Contracting Parties shall also take into consideration the special conditions resulting from the dependence on, distribution and location of, biological diversity within developing country Parties, in particular small island States.

7. Consideration shall also be given to the special situation of developing countries, including those that are most environmentally vulnerable, such as those with arid and semi-arid zones, coastal and mountainous areas.

Article 21
Financial Mechanism

1. There shall be a mechanism for the provision of financial resources to developing country Parties for purposes of this Convention on a grant or concessional basis the essential elements of which are described in this Article. The mechanism shall function under the authority and guidance of, and be accountable to, the Conference of the Parties for purposes of this Convention. The operations of the mechanism shall be carried out by such institutional structure as may be decided upon by the Conference of the Parties at its first meeting. For purposes of this Convention, the Conference of the Parties shall determine the policy, strategy, programme priorities and eligibility criteria relating to the access to and utilization of such resources. The contributions shall be such as to take into account the need for predictability, adequacy and timely flow of funds referred to in Article 20 in accordance with the amount of resources needed to be decided periodically by the Conference of the Parties and the importance of burden-sharing among the contributing Parties included in the list referred to in Article 20, paragraph 2. Voluntary contributions may also be made by the developed country Parties and by other countries and sources. The mechanism shall operate within a democratic and transparent system of governance.

2. Pursuant to the objectives of this Convention, the Conference of the Parties shall at its first meeting determine the policy, strategy and programme priorities, as well as detailed criteria and guidelines for eligibility for access to and utilization of the financial resources including monitoring and evaluation on a regular basis of such utilization. The Conference of the Parties shall decide on the arrangements to give effect to paragraph 1 above after consultation with the institutional structure entrusted with the operation of the financial mechanism.

3. The Conference of the Parties shall review the effectiveness of the mechanism established under this Article, including the criteria and guidelines referred to in paragraph 2 above, not less than two years after the entry into force of this Convention and thereafter on a regular basis. Based on such review, it shall take appropriate action to improve the effectiveness of the mechanism if necessary.

4. The Contracting Parties shall consider strengthening existing financial institutions to provide financial resources for the conservation and sustainable use of biological diversity.

Article 22
Relationship with Other International Conventions

1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

2. Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea.

Article 23
Conference of the Parties

1. A Conference of the Parties is hereby established. The first meeting of the Conference of the Parties shall be convened by the Executive Director of the United Nations Environment Programme not later than one year after the entry into force of this Convention. Thereafter, ordinary meetings of the Conference of the Parties shall be held at regular intervals to be determined by the Conference at its first meeting.

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

3. The Conference of the Parties shall by consensus agree upon and adopt rules of procedure for itself and for any subsidiary body it may establish, as well as financial rules governing the funding of the Secretariat. At each ordinary meeting, it shall adopt a budget for the financial period until the next ordinary meeting.

4. The Conference of the Parties shall keep under review the implementation of this Convention, and, for this purpose, shall:

(a) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 26 and consider such information as well as reports submitted by any subsidiary body;

(b) Review scientific, technical and technological advice on biological diversity provided in accordance with Article 25;

(c) Consider and adopt, as required, protocols in accordance with Article 28;

(d) Consider and adopt, as required, in accordance with Articles 29 and 30, amendments to this Convention and its annexes;

(e) Consider amendments to any protocol, as well as to any annexes thereto, and, if so decided, recommend their adoption to the parties to the protocol concerned;

(f) Consider and adopt, as required, in accordance with Article 30, additional annexes to this Convention;

(g) Establish such subsidiary bodies, particularly to provide scientific and technical advice, as are deemed necessary for the implementation of this Convention;

(h) Contact, through the Secretariat, the executive bodies of conventions dealing with matters covered by this Convention with a view to establishing appropriate forms of cooperation with them; and

(i) Consider and undertake any additional action that may be required for the achievement of the purposes of this Convention in the light of experience gained in its operation.

5. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State not Party to this Convention, may be represented as observers at meetings of the Conference of the Parties. Any other body or agency, whether governmental or non-governmental, qualified in fields relating to conservation and sustainable use of biological diversity, which

has informed the Secretariat of its wish to be represented as an observer at a meeting of the Conference of the Parties, may be admitted unless at least one third of the Parties present object. The admission and participation of observers shall be subject to the rules of procedure adopted by the Conference of the Parties.

Article 24
Secretariat

1. A secretariat is hereby established. Its functions shall be:

(a) To arrange for and service meetings of the Conference of the Parties provided for in Article 23;

(b) To perform the functions assigned to it by any protocol;

(c) To prepare reports on the execution of its functions under this Convention and present them to the Conference of the Parties;

(d) To coordinate with other relevant international bodies and, in particular to enter into such administrative and contractual arrangements as may be required for the effective discharge of its functions; and

(e) To perform such other functions as may be determined by the Conference of the Parties.

2. At its first ordinary meeting, the Conference of the Parties shall designate the secretariat from amongst those existing competent international organizations which have signified their willingness to carry out the secretariat functions under this Convention.

Article 25
Subsidiary Body on Scientific, Technical and Technological Advice

1. A subsidiary body for the provision of scientific, technical and technological advice is hereby established to provide the Conference of the Parties and, as appropriate, its other subsidiary bodies with timely advice relating to the implementation of this Convention. This body shall be open to participation by all Parties and shall be multidisciplinary. It shall comprise government representatives competent in the relevant field of expertise. It shall report regularly to the Conference of the Parties on all aspects of its work.

2. Under the authority of and in accordance with guidelines laid down by the Conference of the Parties, and upon its request, this body shall:

(a) Provide scientific and technical assessments of the status of biological diversity;

(b) Prepare scientific and technical assessments of the effects oftypes of measures taken in accordance with the provisions of this Convention;

(c) Identify innovative, efficient and state-of-the-art technologies and know-how relating to the conservation and sustainable use of biological diversity and advise on the ways and means of promoting development and/or transferring such technologies;

(d) Provide advice on scientific programmes and international cooperation in research and development related to conservation and sustainable use of biological diversity; and

(e) Respond to scientific, technical, technological and methodological questions that the Conference of the Parties and its subsidiary bodies may put to the body.

3. The functions, terms of reference, organization and operation of this body may be further elaborated by the Conference of the Parties.

Article 26
Reports

Each Contracting Party shall, at intervals to be determined by the Conference of the Parties, present to the Conference of the Parties, reports on measures which it has taken for the implementation of the provisions of this Convention and their effectiveness in meeting the objectives of this Convention.

Article 27
Settlement of Disputes

1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation.

2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party.

3. When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory:

(a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II;

(b) Submission of the dispute to the International Court of Justice.

4. If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.

5. The provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned.

Article 28
Adoption of Protocols

1. The Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention.

2. Protocols shall be adopted at a meeting of the Conference of the Parties.

3. The text of any proposed protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such a meeting.

Article 29
Amendment of the Convention or Protocols

1. Amendments to this Convention may be proposed by any Contracting Party. Amendments to any protocol may be proposed by any Party to that protocol.

2. Amendments to this Convention shall be adopted at a meeting of the Conference of the Parties. Amendments to any protocol shall be adopted at a meeting of the Parties to the Protocol in question. The text of any proposed amendment to this Convention or to any protocol, except as may otherwise be provided in such protocol, shall be communicated to the Parties to the instrument in question by the secretariat at least six months before the meeting at which it is proposed for adoption. The secretariat shall also communicate proposed amendments to the signatories to this Convention for information.

3. The Parties shall make every effort to reach agreement on any proposed amendment to this Convention or to any protocol by consensus. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-third majority vote of the Parties to the instrument in question present and voting at the meeting, and shall be submitted by the Depositary to all Parties for ratification, acceptance or approval.

4. Ratification, acceptance or approval of amendments shall be notified to the Depositary in writing. Amendments adopted in accordance with paragraph 3 above shall enter into force among Parties having accepted them on the ninetieth day after the deposit of instruments of ratification, acceptance or approval by at least two thirds of the Contracting Parties to this Convention or of the Parties to the protocol concerned, except as may otherwise be provided in such protocol. Thereafter the amendments shall enter into force for any other Party on the ninetieth day after that Party deposits its instrument of ratification, acceptance or approval of the amendments.

5. For the purposes of this Article, "Parties present and voting" means Parties present and casting an affirmative or negative vote.

Article 30
Adoption and Amendment of Annexes

1. The annexes to this Convention or to any protocol shall form an integral part of the Convention or of such protocol, as the case may be, and, unless expressly provided otherwise, a reference to this Convention or its protocols constitutes at the same time a reference to any annexes thereto. Such annexes shall be restricted to procedural, scientific, technical and administrative matters.

2. Except as may be otherwise provided in any protocol with respect to its annexes, the following procedure shall apply to the proposal, adoption and entry into force of additional annexes to this Convention or of annexes to any protocol:

(a) Annexes to this Convention or to any protocol shall be proposed and adopted according to the procedure laid down in Article 29;

(b) Any Party that is unable to approve an additional annex to this Convention or an annex to any protocol to which it is Party shall so notify the Depositary, in writing, within one year from the date of the communication of the adoption by the Depositary. The Depositary shall without delay notify all Parties of any such notification received. A Party may at any time withdraw a previous declaration of objection and the annexes shall thereupon enter into force for that Party subject to subparagraph (c) below;

(c) On the expiry of one year from the date of the communication of the adoption by the Depositary, the annex shall enter into force for all Parties to this Convention or to any protocol concerned which have not submitted a notification in accordance with the provisions of subparagraph (b) above.

3. The proposal, adoption and entry into force of amendments to annexes to this Convention or to any protocol shall be subject to the same procedure as for the proposal, adoption and entry into force of annexes to the Convention or annexes to any protocol.

4. If an additional annex or an amendment to an annex is related to an amendment to this Convention or to any protocol, the additional annex or amendment shall not enter into force until such time as the amendment to the Convention or to the protocol concerned enters into force.

Article 31
Right to Vote

1. Except as provided for in paragraph 2 below, each Contracting Party to this Convention or to any protocol shall have one vote.

2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their member States which are Contracting Parties to this Convention or the relevant protocol. Such organizations shall not exercise their right to vote if their member States exercise theirs, and vice versa.

Article 32
Relationship between this Convention and Its Protocols

1. A State or a regional economic integration organization may not become a Party to a protocol unless it is, or becomes at the same time, a Contracting Party to this Convention.

2. Decisions under any protocol shall be taken only by the Parties to the protocol concerned. Any Contracting Party that has not ratified, accepted or approved a protocol may participate as an observer in any meeting of the parties to that protocol.

Article 33
Signature

This Convention shall be open for signature at Rio de Janeiro by all States and any regional economic integration organization from 5 June 1992 until 14 June 1992, and at the United Nations Headquarters in New York from 15 June 1992 to 4 June 1993.

Article 34
Ratification, Acceptance or Approval

1. This Convention and any protocol shall be subject to ratification, acceptance or approval by States and by regional economic integration

organizations. Instruments of ratification, acceptance or approval shall be deposited with the Depositary.

2. Any organization referred to in paragraph 1 above which becomes a Contracting Party to this Convention or any protocol without any of its member States being a Contracting Party shall be bound by all the obligations under the Convention or the protocol, as the case may be. In the case of such organizations, one or more of whose member States is a Contracting Party to this Convention or relevant protocol, the organization and its member States shall decide on their respective responsibilities for the performance of their obligations under the Convention or protocol, as the case may be. In such cases, the organization and the member States shall not be entitled to exercise rights under the Convention or relevant protocol concurrently.

3. In their instruments of ratification, acceptance or approval, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

Article 35
Accession

1. This Convention and any protocol shall be open for accession by States and by regional economic integration organizations from the date on which the Convention or the protocol concerned is closed for signature. The instruments of accession shall be deposited with the Depositary.

2. In their instruments of accession, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

3. The provisions of Article 34, paragraph 2, shall apply to regional economic integration organizations which accede to this Convention or any protocol.

Article 36
Entry Into Force

1. This Convention shall enter into force on the ninetieth day after the date of deposit of the thirtieth instrument of ratification, acceptance, approval or accession.

2. Any protocol shall enter into force on the ninetieth day after the date of deposit of the number of instruments of ratification, acceptance, approval or accession, specified in that protocol, has been deposited.

3. For each Contracting Party which ratifies, accepts or approves this Convention or accedes thereto after the deposit of the thirtieth instrument of ratification, acceptance, approval or accession, it shall enter into force on the ninetieth day after the date of deposit by such Contracting Party of its instrument of ratification, acceptance, approval or accession.

4. Any protocol, except as otherwise provided in such protocol, shall enter into force for a Contracting Party that ratifies, accepts or approves that protocol or accedes thereto after its entry into force pursuant to paragraph 2 above, on the ninetieth day after the date on which that Contracting Party deposits its instrument of ratification, acceptance, approval or accession, or on the date on which this Convention enters into force for that Contracting Party, whichever shall be the later.

5. 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 37
Reservations

No reservations may be made to this Convention.

Article 38
Withdrawals

1. At any time after two years from the date on which this Convention has entered into force for a Contracting Party, that Contracting Party may withdraw from the Convention 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.

3. Any Contracting Party which withdraws from this Convention shall be considered as also having withdrawn from any protocol to which it is party.

Article 39
Financial Interim Arrangements

Provided that it has been fully restructured in accordance with the requirements of Article 21, the Global Environment Facility of the United Nations Development Programme, the United Nations Environment Programme and the International Bank for Reconstruction and Development shall be the institutional structure referred to in Article 21 on an interim basis, for the period between the entry into force of this Convention and the first meeting of

the Conference of the Parties or until the Conference of the Parties decides which institutional structure will be designated in accordance with Article 21.

Article 40
Secretariat Interim Arrangements

The secretariat to be provided by the Executive Director of the United Nations Environment Programme shall be the secretariat referred to in Article 24, paragraph 2, on an interim basis for the period between the entry into force of this Convention and the first meeting of the Conference of the Parties.

Article 41
Depositary

The Secretary-General of the United Nations shall assume the functions of Depositary of this Convention and any protocols.

Article 42
Authentic Texts

The original of this Convention, 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 Convention.

Done at Rio de Janeiro on this fifth day of June, one thousand nine hundred and ninety-two.

Annex I

IDENTIFICATION AND MONITORING

1. Ecosystems and habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social, economic, cultural or scientific importance; or, which are representative, unique or associated with key evolutionary or other biological processes;

2. Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance; or importance for research into the conservation and sustainable use of biological diversity, such as indicator species; and

3. Described genomes and genes of social, scientific or economic importance.

Annex II

Part 1

ARBITRATION

Article 1

The claimant party shall notify the secretariat that the parties are referring a dispute to arbitration pursuant to Article 27. The notification shall state the subject-matter of arbitration and include, in particular, the articles of the Convention or the protocol, the interpretation or application of which are at issue. If the parties do not agree on the subject matter of the dispute before the President of the tribunal is designated, the arbitral tribunal shall determine the subject matter. The secretariat shall forward the information thus received to all Contracting Parties to this Convention or to the protocol concerned.

Article 2

1. In disputes between two parties, the arbitral tribunal shall consist of three members. Each of the parties to the dispute shall appoint an arbitrator and the two arbitrators so appointed shall designate by common agreement the third arbitrator who shall be the President of the tribunal. The latter shall not be a national of one of the parties to the dispute, nor have his or her usual place of residence in the territory of one of these parties, nor be employed by any of them, nor have dealt with the case in any other capacity.

2. In disputes between more than two parties, parties in the same interest shall appoint one arbitrator jointly by agreement.

3. Any vacancy shall be filled in the manner prescribed for the initial appointment.

Article 3

1. If the President of the arbitral tribunal has not been designated within two months of the appointment of the second arbitrator, the Secretary-General of the United Nations shall, at the request of a party, designate the President within a further two-month period.

2. If one of the parties to the dispute does not appoint an arbitrator within two months of receipt of the request, the other party may inform the Secretary-General who shall make the designation within a further two-month period.

Article 4

The arbitral tribunal shall render its decisions in accordance with the provisions of this Convention, any protocols concerned, and international law.

Article 5

Unless the parties to the dispute otherwise agree, the arbitral tribunal shall determine its own rules of procedure.

Article 6

The arbitral tribunal may, at the request of one of the parties, recommend essential interim measures of protection.

Article 7

The parties to the dispute shall facilitate the work of the arbitral tribunal and, in particular, using all means at their disposal, shall:

(a) Provide it with all relevant documents, information and facilities; and

(b) Enable it, when necessary, to call witnesses or experts and receive their evidence.

Article 8

The parties and the arbitrators are under an obligation to protect the confidentiality of any information they receive in confidence during the proceedings of the arbitral tribunal.

Article 9

Unless the arbitral tribunal determines otherwise because of the particular circumstances of the case, the costs of the tribunal shall be borne by the parties to the dispute in equal shares. The tribunal shall keep a record of all its costs, and shall furnish a final statement thereof to the parties.

Article 10

Any Contracting Party that has an interest of a legal nature in the subject-matter of the dispute which may be affected by the decision in the case, may intervene in the proceedings with the consent of the tribunal.

Article 11

The tribunal may hear and determine counterclaims arising directly out of the subject-matter of the dispute.

Article 12

Decisions both on procedure and substance of the arbitral tribunal shall be taken by a majority vote of its members.

Article 13

If one of the parties to the dispute does not appear before the arbitral tribunal or fails to defend its case, the other party may request the tribunal to continue the proceedings and to make its award. Absence of a party or a failure of a party to defend its case shall not constitute a bar to the proceedings. Before rendering its final decision, the arbitral tribunal must satisfy itself that the claim is well founded in fact and law.

Article 14

The tribunal shall render its final decision within five months of the date on which it is fully constituted unless it finds it necessary to extend the time-limit for a period which should not exceed five more months.

Article 15

The final decision of the arbitral tribunal shall be confined to the subject-matter of the dispute and shall state the reasons on which it is based. It shall contain the names of the members who have participated and the date of the final decision. Any member of the tribunal may attach a separate or dissenting opinion to the final decision.

Article 16

The award shall be binding on the parties to the dispute. It shall be without appeal unless the parties to the dispute have agreed in advance to an appellate procedure.

Article 17

Any controversy which may arise between the parties to the dispute as regards the interpretation or manner of implementation of the final decision may be submitted by either party for decision to the arbitral tribunal which rendered it.

Part 2

CONCILIATION

Article 1

A conciliation commission shall be created upon the request of one of the parties to the dispute. The commission shall, unless the parties otherwise agree, be composed of five members, two appointed by each Party concerned and a President chosen jointly by those members.

Article 2

In disputes between more than two parties, parties in the same interest shall appoint their members of the commission jointly by agreement. Where two or more parties have separate interests or there is a disagreement as to whether they are of the same interest, they shall appoint their members separately.

Article 3

If any appointments by the parties are not made within two months of the date of the request to create a conciliation commission, the Secretary- General of the United Nations shall, if asked to do so by the party that made the request, make those appointments within a further two-month period.

Article 4

If a President of the conciliation commission has not been chosen within two months of the last of the members of the commission being appointed, the Secretary-General of the United Nations shall, if asked to do so by a party, designate a President within a further two-month period.

Article 5

The conciliation commission shall take its decisions by majority vote of its members. It shall, unless the parties to the dispute otherwise agree, determine its own procedure. It shall render a proposal for resolution of the dispute, which the parties shall consider in good faith.

Article 6

A disagreement as to whether the conciliation commission has competence shall be decided by the commission.

SECOND SCHEDULE

(Section 2)

CARTAGENA PROCOTOL 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 ORGANISMSINTENDED FOR DIRECT USE AS FOOD OR FEED,OR FOR PROCESSING

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

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

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

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

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

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

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

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

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

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

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

Article 12

REVIEW OF DECISIONS

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

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

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

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

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

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

Article 13
SIMPLIFIED PROCEDURE

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

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

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

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

Article 14
BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

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

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

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

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

of its decision.

Article 15

RISK ASSESSMENT

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

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

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

Article 16
RISK MANAGEMENT

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

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

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

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that iscommensurate 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 cl e a ri n g - house mechanism under A rt i cle 18, p a ragraph 3, of the Conve n t i o n , in order to:

(a) Facilitate the exchange of scientific, technical , envi ronmental 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 Pa rt i e s , in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

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

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

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

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

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

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

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

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

Article 21
CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part

of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

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

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

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

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

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

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

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

(d) Any methods and plans for emergency response.

Article 22
CAPACITY-BUILDING

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

regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacitybuilding 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 avail able 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 pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

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

Article 38
RESERVATIONS

No reservations may be made to this Protocol.

Article 39

WITHDRAWAL

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

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

Article 40
AUTHENTIC TEXTS

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

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

DONE at Montreal on this twenty-ninth day of January, two thousand.

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) V*ector*. 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.

THIRD SCHEDULE

(Sections 42, 48 and 53)

INFORMATION REQUIRED

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the genetically modified organism, as well as the domestic classification, if any, of the biosafety level of the genetically modified organism in the State of export.

(d) Intended date or dates of the import or export, 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 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 genetically modified organism.

(i) Intended use of the genetically modified organism, namely, processed materials that are of genetically modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the genetically modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with section 62.

(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 genetically 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 genetically modified organism is banned in the State of export, the reason for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the genetically modified organism to be transferred.

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

FOURTH SCHEDULE

(Section 44)

INFORMATION REQUIRED CONCERNING GENETICALLY MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

(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 genetically modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the genetically modified organism.

(e) Any unique identification of the genetically 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 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 related to biosafety.

(i) Approved uses of the genetically modified organism.

(j) A risk assessment report in accordance with the Third Schedule.

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

FIFTH SCHEDULE

(Section 62)

RISK ASSESSMENT

Objective

1. The objective of risk assessment and review of risk assessment is -

(a) to identify and evaluate the potential adverse effects of genetically 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;

(b) on a case by case basis identify and evaluate the potential adverse effects of a genetically modified on human health and the environment which the contained use, handling, import or export, intentional introduction or placing on the market of a genetically modified organism may have.

Use of risk assessment

2. Risk assessment and review of risk assessment is used to make informed decisions regarding genetically modified organisms.

General principles

3. Risk assessment and review of a risk assessment should be carried out -

(a) in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations;

(b) in accordance with the precautionary principle.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpretated as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with genetically modified organisms or products of genetically modified organisms, namely, processed materials that are of

genetically modified organisms 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 and a review of the 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 genetically modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment or review 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 or review of risk assessment entails, as appropriate, the following steps -

(a) an identification of -

(i) any novel genotypic and phenotypic characteristics associated with the genetically modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(ii) characteristics of the genetically modified organisms including any characteristic of the genetically 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 adverse effects should be compared to those presented by the non-modified parent organism, grown under similar conditions;

(iii) characteristics which may cause adverse effects by the transfer of inserted genetic material to other organisms, or the same organism whether genetically modified or not, the spread of the genetically modified organism in the receiving environment, interactions with other organisms, and changes in management, including where applicable agricultural practices;

(b) an evaluation of -

(i) 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 genetically modified organism;

(ii) the magnitude of the consequences of each potential adverse effect assuming that the adverse effect will occur;

(iii) the consequences should these adverse effects be realized;

(iv) the data for transgene stability and equivalence to non-modified parent lines must be shown by protemics, transcriptomics and metabolomics;

(c) an estimation of the -

(i) overall risk posed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

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

(d) a recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks to prevent

or minimize adverse effects of genetically modified organisms or products of genetically modified organisms on human, animal health, the environment, physical and social and biological diversity;

(e) an overall risk of the genetically modified organism taking into account the risk management strategies proposed;

(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 or monitoring the genetically modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment or review of 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*. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organism;

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

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

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

(f) *Detection and identification of the genetically 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 genetically 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 ,2005.

Speaker of the House of Assembly.

Passed in the Senate this day of , 2005.

President of the Senate.