



ST. CHRISTOPHER AND NEVIS

CHAPTER 9.30 **BIOSAFETY ACT**

Revised Edition
showing the law as at 31 December 2017

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The Regional Law Revision Centre Inc.,
P.O. Box 1626, 5 Mar Building,
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West Indies.

Available for purchase from—

Attorney General's Chambers,
Government Headquarters, P.O. Box 164,
Church Street, Basseterre, St. Kitts,
West Indies

Tel: (869) 465-2521

Ext. 1013

Tel: (869) 465-2127

Fax: (869) 465-5040

Email: attorneygeneral@gov.kn

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CHAPTER 9.30

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CHAPTER 9.30

BIOSAFETY ACT

AN ACT TO PROVIDE FOR THE MOVEMENT, TRANSIT, HANDLING AND USE OF GENETICALLY MODIFIED ORGANISMS RESULTING FROM MODERN BIOTECHNOLOGY THAT MAY HAVE ADVERSE EFFECTS ON CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY, TAKING ALSO INTO ACCOUNT RISKS TO HUMAN HEALTH; TO PROVIDE FOR THE ESTABLISHMENT OF A BIOSAFETY BOARD; TO IMPLEMENT THE CARTAGENA PROTOCOL ON BIOSAFETY; AND TO PROVIDE FOR RELATED OR INCIDENTAL MATTERS.

PART I

PRELIMINARY MATTERS

Short title.

1. This Act may be cited as the Biosafety Act.

Interpretation.

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

“advanced informed agreement procedure” means the procedure whereby consent is obtained before any activity is undertaken based upon full disclosure of all relevant matters in accordance with section 53;

“analyst” means a person appointed under section 18 of this Act to be an analyst for the purposes of this Act;

“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 a part of, including diversity within species, between species and of ecosystems;

“Biosafety Clearing-House” means the Biosafety Clearing-House established under article 20 of the Protocol;

“Board” means the Biosafety Board established under section 4 of this Act;

“cell technology” means any technique for the production of living cells with new combinations of genetic material by the fusion of two or more cells;

“Chairperson” means the Chairperson of the Board;

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

“Court” means the High Court;

“domestic use” includes placing on the market for direct use as food, feed or processing;

“ecosystem” means a dynamic complex of plant, animal and micro-organism communities and their non-living systems interacting as a functional unit;

“gene technology” means techniques that involve the isolation, characterization, modification and introduction of deoxyribonucleic acid into cells or viruses;

“genetically modified organism” means any biological entity including plants, animals, bacteria and all other kinds of micro-organisms, cell cultures (prokaryotic or eukaryotic) created and propagated as such, virus, and plasmids and other kinds of vectors, in which the genetic material has been altered in a way that does not occur naturally, by means of cell or gene technology;

“inspector” means a person appointed under section 18 of this Act to be an inspector for the purposes of this Act;

“intentional introduction into the environment” includes—

- (a) any production or use that is not contained use;
- (b) releases for—
 - (i) commercial purposes;
 - (ii) remediation;
 - (iii) research purposes in field experiments;
 - (iv) use of genetically modified organisms in greenhouses, aquaculture facilities, animal accommodation unless the facility is approved for contained use as part of an approved laboratory or other installation;
 - (v) disposal of waste containing genetically modified organisms,

but does not include genetically modified organisms intended for direct use as food, feed or processing;

“label” means any legend, word, mark, symbol, or design applied to, included in, belonging to, or accompanying any genetically modified organism or a package thereof;

“Minister” means the Minister responsible for biosafety;

“placing on the market” means supplying or making available to third parties;

“product” means any material derived by processing or otherwise from any genetically modified organism;

“Protocol” means the Cartagena Protocol on Biosafety the text of which is set out in the First Schedule to this Act;

“risk assessment” means the evaluation of the direct and indirect risks to human and animal health, the environment, biological diversity and to the socioeconomic conditions and ethical values of the country or its populace, which may be posed by the import, contained use, intentional introduction into the environment or domestic use and includes the evaluation of secondary and long-term effects;

“Scientific Advisory Committee” means the Scientific Advisory Committee appointed under section 23;

“socio-economic impact” means the direct or indirect effects to the economy, social or cultural practices, livelihoods, indigenous knowledge systems, or

indigenous technologies as a result of the intentional introduction into the environment, domestic use, contained use or import of the genetically modified organism or product.

Application.

3. (1) This Act applies to the movement, transit, handling and use of all genetically modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

(2) Notwithstanding subsection (1), this Act does not apply to the import or export of genetically modified organisms which are pharmaceuticals for humans.

(3) This Act binds the Crown.

PART II

ESTABLISHMENT OF THE BOARD, ITS POWERS AND FUNCTIONS

Establishment of the Board.

4. (1) There is established a Board to be known as the Biosafety Board, which shall consist of not more than twelve members appointed by the Minister upon such terms and conditions as may be prescribed.

(2) Persons to be appointed as members of the Board under this section shall be appointed from such interest groups on the islands of Saint Christopher and Nevis as the Minister may deem fit, which interest groups shall include the following, that is to say—

- (a) health services;
- (b) agricultural services;
- (c) environment;
- (d) trade and custom services;
- (e) non-governmental organizations;
- (f) consumer groups.

(3) The Minister shall appoint one of the members to be the Chairperson of the Board and another to be the Secretary to the Board.

(4) The Minister may appoint a person to act temporarily in the place of a member of the Board who is absent or is unable to carry out the functions of his office.

Tenure of Members of the Board.

5. (1) Subject to the provisions of subsections (2) and (3) of this section, a member of the Board shall, unless he vacates office earlier, hold office for a period of three years, except that such a member shall be eligible for re-appointment.

(2) A member who is appointed to fill a vacancy that is created by the death, resignation, or removal from office for a justifiable cause shall hold office only for the unexpired period of the former member, except that such member may be eligible for re-appointment.

(3) A member whose period of appointment expires in accordance with the provisions of subsection (1) of this section shall continue to hold office until his successor is appointed.

Functions of the Board.

6. The Board shall carry out the following functions—
- (a) act as Saint Christopher and Nevis' competent authority for biosafety;
 - (b) determine any application submitted to it for licences;
 - (c) grant or cancel any licence in accordance with the provisions of this Act;
 - (d) advise the Minister on matters relevant to the making of regulations under this Act;
 - (e) monitor the implementation of the regulations made under this Act;
 - (f) review any decision made in accordance with the provisions of this Act;
 - (g) make available any information to, and receive comments from the public in accordance with the provisions of this Act;
 - (h) establish mechanisms to facilitate the collection, storage and dissemination of data on local conditions, such as agronomic, epidemiological, logistic and environmental data;
 - (i) establish mechanisms for exchange of information with other countries, particularly those in the region;
 - (j) furnish such information, reports, and returns as the Minister may require.

Meetings of the Board.

7. The provisions of the Second Schedule to this Act shall have effect in relation to the meetings and other matters of the Board as specified in that Schedule.

Policy Directions to the Board.

8. The Minister may, give to the Board directions of a general nature as to the policy to be followed in the exercise or discharge of its functions, and the Board shall give effect to those directions.

Resignations from the Board.

9. (1) The Chairperson may, at any time, in writing, resign his or her office and the resignation shall be addressed to the Minister.

(2) A member of the Board, other than the Chairperson, may, at any time, in writing, resign from office and the resignation shall be addressed to the Chairperson.

Termination of Appointment of Board Members.

10. The Minister may, after consultation with Cabinet, terminate the appointment of a member of the Board who—

- (a) becomes of unsound mind;
- (b) becomes incapable of carrying out his or her duties;

- (c) becomes bankrupt or compounds with or suspends payment to his or her creditors;
- (d) is sentenced to a term of imprisonment that exceeds six months;
- (e) is convicted of an offence involving dishonesty;
- (f) is found guilty of misconduct in relation to his or her duties;
- (g) is absent, without the permission of the Minister or the Board, from three consecutive meetings of the Board; or
- (h) fails to carry out any duties or functions conferred or imposed on him or her under this Act.

Disclosure of Interest.

11. (1) A member of the Board whose interest is likely to be affected, directly or indirectly, by the decision of the Board on any matter or is likely to evoke an allegation of bias, shall disclose the nature of his or her interest at the first meeting of the Board at which he or she is present after the relevant facts have come to his or her knowledge.

(2) A disclosure made under subsection (1) of this section shall be recorded in the minutes of the Board and after the disclosure the member making the disclosure shall, unless the Board otherwise directs, leave the meeting.

(3) Where a member referred to in subsection (2) of this section is allowed by the Board to stay in the meeting, the member shall not take part in the deliberations on the matter by the Board nor shall the member vote on the matter.

National Database.

12. (1) The Board shall create a national database to assist with the sharing of national information on biosafety matters.

(2) The national database created under subsection (1) of this section shall be linked to—

- (a) regional biosafety databases for collaboration on matters related to risk assessment and risk management; and
- (b) the Biosafety Clearing-House;

(3) The Board shall provide to the Biosafety Clearing-House the following information—

- (a) a copy of this Act, including any amendments or decisions made in accordance with the provisions of this Act or the regulations made under this Act, and any other laws or national guidelines of relevance to the implementation of the Protocol or the management of genetically modified organisms;
- (b) a copy of any risk assessment conducted under this Act or the regulations made under this Act;
- (c) within two hundred and seventy days of the date of receipt of an application for importation for intentional introduction into the environment, its decision concerning that application and reasons for arriving at that decision;
- (d) reports on the national implementation of the Protocol;

- (e) within fifteen days of making a decision under section 30, a copy of the decision describing the changes to the previous decision and the reasons for the decision.

Funds of the Board.

13. The funds of the Board shall consist of—
- (a) annual grants appropriated by the National Assembly;
 - (b) fees charged under the provisions of this Act for applications and licences;
 - (c) donations and grants from international organisations and other agencies; and
 - (d) loans.

Borrowing powers of the Board.

14. The Board may, with the approval of the Minister, and subject to the regulations made under this Act, by way of loans, raise such sums of money as it considers expedient for the purpose of discharging its functions under this Act.

Keeping of Accounts of the Board.

15. The Board shall keep proper books of accounts which shall be kept in such manner and form as the Minister responsible for Finance may direct.

Audit.

16. The books of accounts and accounts of the Board shall be audited annually.

Report.

17. The Board shall make an annual report to the Minister detailing the activities carried out by the Board during the year in question and such report shall contain a financial statement certified by the auditor.

PART III**STAFF OF THE BOARD, THEIR FUNCTIONS AND POWERS****Appointment of Inspectors, Analysts and other Officers.**

18. (1) For the purpose of enabling the Board to carry out its functions under this Act, the Board shall appoint such officers as may be necessary.

(2) In appointing the officers referred to in subsection (1) the Board may, with the approval of the Minister, appoint on the island of Saint Christopher and on the island of Nevis such persons from outside the public service, who are suitably qualified to be inspectors, analysts, public relations specialists and any other staff of the Board.

Engagement of Consultants.

19. (1) The Minister may, whenever he considers it necessary or on the recommendation of the Board, cause to be secured the services of a consultant.

(2) A consultant referred to in this section shall only be engaged for the purpose of advising the Minister or the Board on any matter arising under this Act or the regulations made under this Act.

Duties and Powers of Inspectors.

20. (1) An inspector appointed under subsection (1) of section 18 of this Act shall perform the following functions, that is to say—

- (a) inspect any vehicle, land or premises in accordance with the provisions of this Act; and
- (b) make such examination, inspection, investigation, and inquiries as may be necessary to ascertain whether the provisions of this Act and the regulations made under this Act are being complied with;
- (c) enforce identification, labelling and packaging provisions in this Act.

(2) An Inspector may, for the purpose of discharging his or her duties under this Act—

- (a) enter, at any reasonable time, any vehicle in which—
 - (i) a genetically modified organism is about to be, is being, or has been transported; or
 - (ii) he has reasonable cause to believe that a breach of this Act or the regulations is about to be, is being or has been committed;
- (b) enter, at any reasonable time, any land or premises on which—
 - (i) a genetically modified organism is about to be, is being, or has been used or packaged;
 - (ii) is being, has been, or is about to be used for a purpose connected with the use or packaging of a genetically modified organism;
- (c) require the production of, or seize, inspect and examine, and copy records, or other documents kept for the purpose of or required to be kept by the regulations;
- (d) require any person whom he finds in a vehicle, on land or premises, as the case may be, to give such information as it is in his power to give as to who is occupier thereof or the employer of workers employed to work thereon;
- (e) examine, either alone or in the presence of any other person as the inspector thinks fit, with respect to the observance of the provisions of this Act or the regulations, any person whom—
 - (i) he or she finds in such vehicle or on such land or premises as mentioned in subsection (1) of this section; or
 - (ii) he or she has reasonable cause to believe to be, or to have been within the preceding two months, employed thereon,

and to require any such person to be questioned and to sign a declaration of the truth of the matters respecting which he or she is questioned; so, however, that no person shall be required under this

provision to answer any question or to give evidence tending to incriminate himself;

- (f) open and examine any package that on reasonable grounds he or she believes to contain a genetically modified organism;
- (g) seize and detain for such time as may be necessary any article by means of which, or in relation to which he or she reasonably believes any provision of this Act or the regulations made under this Act has been contravened;
- (h) if the Inspector reasonably believes that any provisions of this Act or the regulations made under this Act has been contravened—
 - (i) take, without payment, samples of any article being used or transported, and submit them to the analyst for analysis or examination;
 - (ii) take, without payment, but with the approval of the Comptroller of Customs samples of any article imported into the country but not delivered to the importer, out of the charge of customs, and submit them to an analyst appointed under this Act for analysis or examination.

(3) Subject to subsection (4) of this section, an inspector shall, for the purpose of exercising the powers conferred upon him or her by subsection (2) of this section, first obtain a search warrant issued by the Magistrate.

(4) Where circumstances are such that a genetically modified organism may be removed from the vehicle, land or premises before the inspector obtains the search warrant pursuant to subsection (3), the inspector may enter the vehicle, land or premises without the warrant, in which case he or she shall produce his or her identification card to the owner, occupier, or person in charge of the vehicle, land or premises, as the case may be.

(5) The inspector may, if he or she deems it necessary, be accompanied by a member of the police force, a public health inspector, or any person who possesses expert knowledge in the use or effects of any genetically modified organism for the purposes of discharging his functions under this Act.

Functions of Analyst.

21. An analyst shall be responsible for analysing or examining any sample submitted to him for analysis or examination in accordance with the provisions of this Act or regulations made under this Act.

Functions of Public Relations Specialist.

22. A public relations specialist appointed under subsection (1) of section 18 of this Act shall perform the following functions, that is to say—

- (a) disseminate relevant information on biosafety issues to the general public and target groups;
- (b) raise public awareness and mobilize public participation on biosafety management issues;
- (c) inform the public about the means of public access to the national database and the Biosafety Clearing-House;
- (d) perform any other functions as the Board may think fit.

Scientific Advisory Committee.

23. (1) The Board may establish a Scientific Advisory Committee to assist in the performance of its functions.

(2) Persons to be appointed as members of the Scientific Advisory Committee under this section shall be suitably qualified and shall be appointed from such disciplines as the Board may deem fit, which disciplines may include the following—

- (a) ecology;
- (b) molecular genetics;
- (c) population genetics;
- (d) microbial physiology;
- (e) pathology;
- (f) entomology;
- (g) atmospheric physics;
- (h) veterinary science;
- (i) laboratory applications;
- (j) industrial processes;
- (k) food safety;
- (l) social sciences, such as, sociology and anthropology;
- (m) economics;
- (n) land use planning.

(3) The Scientific Advisory Committee may co-opt—

- (a) consultants, experts and advisors from national, regional or international organisations;
- (b) personnel from other Ministries; or
- (c) persons, whether or not they are connected with the Board,

as it thinks fit, to be members of the Scientific Advisory Committee.

(4) A member of the Scientific Advisory Committee whose interest is likely to be affected, directly or indirectly, by the decision of the Scientific Advisory Committee on any matter or is likely to evoke an allegation of bias, shall disclose the nature of his or her interest at the first meeting of the Scientific Advisory Committee at which he or she is present after the relevant facts have come to his or her knowledge.

(5) A disclosure made under subsection (4) of this section shall be recorded in the minutes of the Scientific Advisory Committee and after the disclosure the member making the disclosure shall, unless the Scientific Advisory Committee otherwise directs, leave the meeting.

(6) Where a member referred to in subsection (5) of this section is allowed by the Scientific Advisory Committee to stay in the meeting, the member shall not take part in the deliberations on the matter by the Scientific Advisory Committee nor shall the member vote on the matter.

(7) Subject to this section, the Scientific Advisory Committee may regulate its own procedure.

PART IV

CONTROL OF GENETICALLY MODIFIED ORGANISMS

Restrictions on intentional introduction into the Environment.

24. No person shall—

- (a) transport a genetically modified organism unless that genetically modified organism is registered in accordance with the provisions or the regulations made under this Act;
- (b) intentionally introduce into the environment a genetically modified organism without a licence issued in that respect in accordance with the provisions of this Act or regulations made under this Act;
- (c) manufacture a genetically modified organism for domestic use without a licence issued in that respect in accordance with the provisions of this Act or regulations made under this Act;
- (d) operate any facility, installation or other physical structure for contained use without a licence issued in that respect in accordance with the provisions of this Act or regulations made under this Act;
- (e) import a genetically modified organism for intentional introduction into the environment or domestic use without a licence issued in that respect in accordance with the provisions of this Act or regulations made under this Act;
- (f) export a genetically modified organism without a licence issued in that respect in accordance with the provisions of this Act or the regulations made under this Act.

PART V

REGISTRATION AND LICENSING OF GENETICALLY MODIFIED ORGANISMS

*Registration of genetically modified organism product***Application for registration of genetically modified organism product.**

25. (1) A person who wishes to register a genetically modified organism product as required by this Act shall apply to the Board to have the genetically modified organism product registered by the Board, and the application shall be in such form and shall contain such particulars or samples as may be prescribed by regulations made under this Act.

(2) The application referred to in subsection (1) of this section shall be accompanied by the prescribed fee in respect of the grant of registration, which fee shall be paid to the Accountant General.

(3) The Board shall, upon receipt of the application, cause to be published in at least two newspapers on the island of Saint Christopher and on the island of Nevis for two consecutive weeks, a notice containing the scientific and common name, and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

Objection to Registration.

26. (1) A person may object to the registration of a genetically modified organism product on any ground that may be prescribed by regulations made under this Act.

(2) Any objection to the registration of a genetically modified organism product shall be lodged with the Board within twenty-one days of the publication of the notice referred to in subsection (3) of section 25 of this Act.

Consideration of Application.

27. The Board shall, before approving an application for registration of a genetically modified organism product, consider all objections and information made available to it, and the Board may, where it is satisfied that the use of the genetically modified organism is justified, approve the application.

Refusal of Application.

28. (1) The Board may refuse to approve an application for registration of a genetically modified organism product on any of the following grounds—

- (a) if the application is not accompanied by all the particulars or samples required to be submitted along with the application;
- (b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the Board;
- (c) if the genetically modified organism may have adverse effects on conservation and sustainable use of biological diversity, taking into account risks to human health.

(2) Where the Board refuses to approve an application in accordance with the provisions of subsection (1) of this section, it shall as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Registration of Genetically Modified Organism Product.

29. (1) Where the Board approves registration of a genetically modified organism product the Board shall assign a registration number for use in connection with the genetically modified organism product and shall enter the particulars of the certificate in a Register of Genetically Modified Organisms Products which shall be open to inspection by the public on payment of the prescribed fee.

(2) Upon registration of the genetically modified organism product, the applicant shall be issued an appropriate certificate of registration upon payment of the prescribed fee, and the certificate shall contain such contents as may be prescribed by the regulations made under this Act.

(3) The registration of a genetically modified organism product shall be subject to such conditions as the Board considers necessary and the Board may, in accordance with the provisions of the regulations made in that behalf, amend such conditions.

(4) Where the Board registers a genetically modified organism product in accordance with the provisions of this section, the Board shall, by notice published in the *Gazette* and at least one newspaper on the island of Saint Christopher and one on the island of Nevis, inform the public of the registration of the genetically modified organism product.

Cancellation of Registration.

30. (1) The Board may, at any time, cancel the registration certificate issued under the provisions of subsection (2) of section 29 on any of the following grounds—

- (a) upon a breach of a condition on which the registration certificate was granted;
- (b) where the holder of the registration certificate contravenes any provision of this Act or the regulations made under this Act;
- (c) where, after the issue of the registration certificate, it comes to the knowledge of the Board that information which was submitted in support of the application for registration of the genetically modified organism misled or created an erroneous impression on the Board by reason of being false or deceptive;
- (d) for any other justifiable reason the Board may think proper to do so for the purpose of protecting conservation and promoting the sustainable use of biological diversity, taking into account risks to human health.

(2) Where the Board cancels a registration certificate in accordance with the provisions of this section, the Board shall, within seven days, by notice published in the *Gazette* and at least one newspaper on the island of Saint Christopher and one on the island of Nevis for two consecutive weeks, inform the public of the cancellation of the certificate, and the registration of the genetically modified organism.

Custody of Rejected Genetically Modified Organisms.

31. Where the Board refuses to approve an application for registration of a genetically modified organism product or where the Board cancels the registration of a genetically modified organism product, as the case may be, the applicant or the holder of the registration certificate shall collect all the packages of the genetically modified organism product and deposit the same in such place as the Board may direct, and the genetically modified organism product shall be kept there until the Board decides on the manner of its disposal.

*Licensing for intentional introduction into the environment***Application for Intentional Introduction into the Environment.**

32. (1) A person who wishes to apply for a licence for intentional introduction into the environment as required by this Act shall apply to the Board, and the application shall be in such form and shall include the following information, that is to say—

- (a) the name, address and contact details of the applicant;
- (b) the name and identity of the genetically modified organism or product;
- (c) the taxonomic status, common name, point of collection or acquisition, and characteristics of the recipient organism or parental organisms related to biosafety;
- (d) 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;

- (e) taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism related to biosafety;
- (f) description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the genetically modified organism;
- (g) intended use of the genetically modified organism or product, 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;
- (h) a risk assessment report consistent with section 63 of this Act;
- (i) suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate;
- (j) a declaration in the prescribed form that the information in paragraphs (a)-(i) is factually correct.

(2) The application referred to in subsection (1) of this section shall be accompanied by the prescribed fee in respect of the grant of licence, which fee shall be paid to the Accountant General.

(3) The Board shall, upon receipt of the application, cause to be published in at least one newspaper on the island of Saint Christopher and one on the island of Nevis, for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

Objection to Licensing.

33. (1) A person may object to the licensing of a genetically modified organism for intentional introduction into the environment on any ground that may be prescribed by regulations made under this Act.

(2) Any objection to the licensing of a genetically modified organism for intentional introduction into the environment shall be lodged with the Board within twenty-one days of the publication of the notice referred to in subsection (3) of section 32 of this Act.

Consideration of Application.

34. The Board, before approving an application for a licence for intentional introduction into the environment—

- (a) shall, consider all objections and information made available to it;
- (b) may, request additional information from the applicant.

Refusal to Approve Application.

35. (1) The Board may refuse to approve an application for licensing of a genetically modified organism for intentional introduction into the environment on any of the following grounds, that is to say—

- (a) if the application is not accompanied by all the information required to be submitted along with the application;

- (b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the Board;
- (c) if the use of the genetically modified organism is likely to produce adverse effects on conservation and sustainable use on biological diversity, taking into account risks to human health.

(2) Where the Board refuses to approve an application in accordance with the provisions of subsection (1) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of Licence for intentional Introduction into the Environment.

36. (1) Where the Board is satisfied that there is firm and sufficient evidence that the genetically modified organism poses no risk to human and animal health, the environment and biological diversity, the Board may grant the licence.

(2) Upon the grant of the licence for intentional introduction into the environment the applicant shall be issued an appropriate licence on payment of the prescribed licence fee and the licence shall contain such contents as may be prescribed by the regulations made under this Act.

(3) The licence for intentional introduction into the environment shall be subject to the following conditions—

- (a) that the licensee carry out monitoring and evaluation of risks;
- (b) that the licensee takes out a policy of insurance against liability to pay compensation for damages;
- (c) such other conditions as the Board considers necessary for the protection of conservation and sustainable use of biological diversity, taking into account risks to human health.

(4) The Board may impose new conditions if, in the opinion of the Board, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle in accordance with section 25 of this Act.

(5) Where the Board grants a licence in accordance with the provisions of this section, the Board shall enter the particulars of the licence in the Register of Licences which shall be open to inspection by the public on payment of the prescribed fee.

(6) Where the Board grants a licence in accordance with the provisions of this section, the Board shall, by notice published in the *Gazette* and at least one newspaper on the island of Saint Christopher and one on the island of Nevis for two consecutive weeks, inform the public of the grant of the licence.

Cancellation of Licence.

37. (1) The Board may, at any time, cancel the licence issued under the provisions of subsection (2) of section 36 on any of the following grounds, that is to say—

- (a) upon a breach of a condition to which the licence was granted;
- (b) where the licensee contravenes any provision of this Act or the regulations made under this Act;
- (c) where, after the issue of the licence, it comes to the knowledge of the Board that information which was submitted in support of the

application for the grant of a licence for intentional introduction into the environment, misled or created an erroneous impression on the Board by reason of being false or deceptive;

- (d) if, in the opinion of the Board, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle in accordance with section 62 of this Act;
- (e) for any other justifiable reason the Board may think proper to do so by reason of protecting conservation and sustainable use of biological diversity, taking into account the risks to human health.

(2) Where the Board cancels a licence in accordance with the provisions of this section, the Board shall, within seven days, by notice published in the *Gazette* and at least one newspaper on the island of Saint Christopher and one on the island of Nevis, inform the public of the cancellation of the licence.

(3) Where the Board cancels a licence in accordance with the provisions of this section, the Board may, order the destruction of any growing organisms and the sterilization of the soil in which they are being grown, in whatever way it deems appropriate.

(4) No compensation shall be payable as a consequence of the cancellation of a licence or an order for sterilization.

Licensing for domestic use

Application for Domestic Use.

38. (1) A person who wishes to apply for a licence for domestic use as required by this Act or regulations made under this Act shall apply to the Board, and the application shall be in such prescribed form and shall include the following information—

- (a) the name and contact details of the applicant for a decision for domestic use;
- (b) name and identity of the genetically modified organism or product;
- (c) description of the gene modification, the technique used, and the resulting characteristics of the genetically modified organism;
- (d) any unique identification of the genetically modified organism or product;
- (e) taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organisms 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 names, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;

- (h) intended uses of the genetically modified organism or product;
- (i) a risk assessment report consistent with the provisions of section 63 of this Act;
- (j) suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(2) The application referred to in subsection (1) of this section shall be accompanied by the prescribed fee in respect of the grant of licence, which fee shall be paid to the Accountant General.

(3) The Board shall, upon receipt of the application, cause to be published in at least one newspaper on the island of Saint Christopher and one on the island of Nevis for two consecutive weeks, a notice containing the common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

Objection to Licensing for Domestic Use.

39. (1) A person may object to the licensing of a genetically modified organism for domestic use on any ground that may be prescribed by regulations made under this Act.

(2) Any objection to the licensing of a genetically modified organism for domestic use shall be lodged with the Board within twenty-one days of the publication of the notice referred to in subsection (3) of section 38 of this Act.

Consideration of Application.

40. The Board, before approving an application for a licence for domestic use—

- (a) shall consider all objections and information made available to it;
- (b) may, request additional information from the applicant.

Refusal to Approval Application.

41. (1) The Board may refuse to approve an application for licensing of a genetically modified organism for domestic use on any of the following grounds, that is to say—

- (a) if the application is not accompanied by all the information required to be submitted along with the application;
- (b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the Board;
- (c) if the use of the genetically modified organism is likely to produce adverse effects on the conservation of biological diversity or sustainable use of biological organisms, taking into account risks to human health.

(2) Where the Board refuses to approve an application in accordance with the provisions of subsection (1) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of Licence for Domestic Use.

42. (1) Where the Board is satisfied that there is firm and sufficient evidence that the genetically modified organism poses no risk to human and animal health, the environment and biological diversity, the Board may grant the licence.

(2) Upon the grant of the licence for domestic use the applicant shall be issued an appropriate licence upon payment of the prescribed fee and the licence shall contain such contents as may be prescribed by the regulations made under this Act.

(3) The licence for domestic use may be subject to—

- (a) the condition that the licensee take out a policy of insurance against liability to pay compensation for damages; or
- (b) such other conditions as the Board considers necessary for the protection of the conservation of biological diversity or sustainable use of biological organisms, taking into account risks to human health.

(4) Where the Board grants a licence in accordance with the provisions of this section, the Board shall enter the particulars of the licence in the Register of Licences which shall be open to inspection by the public on payment of the prescribed fee.

Cancellation of licence.

43. (1) The Board may, at any time, cancel the licence issued under the provisions of subsection (2) of section 42 of this Act on any of the following grounds, that is to say—

- (a) upon a breach of a condition to which the licence was granted;
- (b) where the licensee contravenes any provision of this Act or the regulations made under this Act;
- (c) where, after the issue of the licence, it comes to the knowledge of the Board that information which was submitted in support of the application for the grant of a licence for domestic use misled or created an erroneous impression on the Board by reason of being false or deceptive;
- (d) if, in the opinion of the Board, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle in accordance with section 63 of this Act;
- (e) for any other justifiable reason the Board may think proper to do so by reason of protecting conservation and sustainable use of biological diversity, taking into account the risks to human health.

(2) Where the Board cancels a licence in accordance with the provisions of this section, the Board shall, within seven days, by notice published in the *Gazette* and at least two newspapers on the island of Saint Christopher and on the island of Nevis for two consecutive weeks, inform the public of the cancellation of the licence.

(3) No compensation shall be payable as a consequence of the cancellation of a licence.

*Licensing for contained use***Application for use of licensing facility.**

44. (1) A person who wishes to use any facility, installation or other physical structure for contained use shall apply, in the prescribed form, to the Board to have the premises licensed by the Board in accordance with the provisions of this Act or regulations made under this Act.

(2) An application referred to in subsection (1) of this section shall be accompanied by the prescribed fee, which fee shall be payable to the Accountant General.

(3) The Board shall, upon receipt of the application, cause to be published in at least one newspaper on the island of Saint Christopher and one on the island of Nevis for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

Objection to licensing.

45. (1) A person may object to the licensing of a facility, installation or other physical structure for contained use on any ground that may be prescribed by regulations made under this Act.

(2) Any objection to the licensing of a facility, installation or other physical structure for contained use shall be lodged with the Board within twenty-one days of the publication of the notice referred to in subsection (3) of section 44 of this Act.

Inspection of facility.

46. Where an application is made to the Board as required by section 42 of this Act, the Board shall arrange for an inspection of the facility, installation or other physical structure by an inspector, analyst or a member of the Board, as the case maybe, who shall prepare a report and submit it to the Board as early as possible.

Consideration of application.

47. The Board shall, upon receipt of the report submitted to it pursuant to the provisions of section 46 of this Act, consider the application, and in so doing shall take into account the construction, facilities and the staff that is used or is to be used in the facility, installation or other physical structure.

Grant of licence.

48. (1) Where, upon consideration of the application referred to in section 47, the Board is satisfied that the requirements of this Act and any regulations made under this Act are complied with, the Board may grant a licence to the applicant on such terms and conditions as the Board may deem fit, and the licence may be issued on payment of the prescribed fee and shall be in the prescribed form.

(2) Where the Board grants a licence in accordance with the provisions of this section, the Board shall enter the particulars of the licence in the Register of Licences which shall be open to inspection by the public on payment of the prescribed fee.

(3) Where the Board is of the opinion that the facility, installation or other physical structure, facilities or staffing of the applicant need to be altered or modified in order to comply with the provisions of this Act or regulations made under this Act,

the Board shall, by notice in writing, require the applicant to make the necessary alterations or modifications before a licence is granted.

Variation or Cancellation of licence.

49. (1) The Board may, where a licensee to whom a licence has been granted under this Part is convicted of an offence under this Act or the regulations made under this Act, or contravenes any condition attached to the licence, vary or cancel the licence.

(2) Notice of variation or cancellation shall be sent to the licensee or person in charge of the facility, installation or other physical structure to which the licence relates, and the variation or cancellation shall have effect upon receipt of the notice.

(3) Where the Board varies or cancels a licence in accordance with the provisions of this section, the Board shall, within seven days, by notice published in the *Gazette* and at least two newspapers on the island of Saint Christopher and on the island of Nevis, inform the public of the variation or cancellation of the licence.

Publication of list of facilities.

50. The Board shall publish in the *Gazette*, as necessary, a list of facilities, installations or other physical structures that are licensed for contained use and shall do likewise in the case of any facility, installation or other physical structure in respect of which any licence is varied or cancelled.

Licensing for Imports

Application for import.

51. (1) A person who wishes to apply for a licence for the import of a genetically modified organism as required by this Act shall apply to the Board, and the application shall be in a prescribed form and shall include the following information, that is to say—

- (a) in the case of a genetically modified organism imported for intentional introduction into the environment, the information in Annex I of the Protocol;
- (b) in the case of a genetically modified organism imported for domestic use, the information in Annex II of the Protocol.

(2) The application referred to in subsection (1) of this section shall be accompanied by the prescribed fee in respect of the grant of licence, which fee shall be paid to the Accountant General.

(3) The Board shall, upon receipt of the application, cause to be published in at least one newspaper on the island of Saint Christopher and one on the island of Nevis for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

Objection to licensing.

52. (1) A person may object to the licensing of a genetically modified organism for import.

(2) Any objection to the licensing of a genetically modified organism for import shall be lodged with the Board within twenty-one days of the publication of the notice referred to in subsection (3) of section 51.

Decision procedure for importation for intentional introduction into the environment.

53. (1) The Board shall, before approving an application for the import for intentional introduction into the environment, apply the advance informed agreement procedure in accordance with Article 7 of the Protocol.

(2) The Board shall within ninety days of receipt of an application submitted to it pursuant to section 51 of this Act, acknowledge receipt of the application.

(3) The acknowledgement referred to in subsection (2) of this section shall be in writing in the prescribed form and shall include the following information, that is to say—

- (a) the date of receipt of the application;
- (b) whether the application, *prima facie* contains the information referred to in section 51;
- (c) that the import is to proceed in accordance with the provisions of this Act.

(4) A failure by the Board to acknowledge receipt of an application for import for intentional introduction into the environment does not imply its consent to the import.

(5) Subject to the provisions of section 63 of this Act, the Board shall consider the application, and in so doing shall take into account a risk assessment report submitted by the applicant or undertaken by the Board.

(6) Within two hundred and seventy days of the date of receipt of the application, the Board shall communicate, in writing, to the applicant and to the Biosafety-Clearing House its decision as follows—

- (a) approving the import for intentional introduction into the environment;
- (b) prohibiting the import;
- (c) requesting additional relevant information; or
- (d) informing the applicant that the period specified in this subsection is extended by a defined period of time.

(7) In calculating the time within which the Board is to respond in paragraph (c) of subsection (6) of this section, the number of days the Board has to wait for additional relevant information shall not be taken into account.

(8) The Board may refuse to approve an application for a licence to import for intentional introduction into the environment on any of the following grounds, that is to say—

- (a) if the application is not accompanied by all the information required to be submitted along with the application;
- (b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the Board;

- (c) if the genetically modified organism is likely to have an adverse effect on conservation and sustainable use of biological diversity, taking into account risks to human health.

(9) Where the Board refuses to approve an application in accordance with the provisions of subsection (8) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

(10) Where the Board refuses to approve an application in accordance with the provisions of this section, the Board shall, by notice published in the *Gazette* and at least one newspaper on the island of Saint Christopher and one on the island of Nevis for two consecutive weeks, inform the public of the refusal of the licence.

Decision procedure for imports for domestic use.

54. (1) The Board, before approving an application for a licence for import for domestic use—

- (a) shall, consider all objections and information made available to it;
- (b) may, request additional information from the authority referred to in paragraph (b) of Annex I of the Protocol.

(2) The Board may refuse to approve an application for a licence for import for domestic use on any of the following grounds, that is to say—

- (a) if the application is not accompanied by all the information required to be submitted along with the application;
- (b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the Board;
- (c) if the use of the genetically modified organism is likely to produce adverse effects on conservation and sustainable use on biological diversity, taking into account risks to human health.

(3) Where the Board refuses to approve an application in accordance with the provisions of subsection (2) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of licence for import.

55. (1) Where the Board approves an import or a licence for importation in accordance with section 53 or section 54 of this Act and it is satisfied that there is firm and sufficient evidence that the genetically modified organism to be imported poses no risk to human and animal health, the environment and biological diversity, the Board may grant the licence subject to the provisions of subsection (2) of this section.

(2) The licence granted under this section—

- (a) shall be issued upon payment of the prescribed fee;
- (b) may include information on how the decisions will apply to subsequent imports of the same genetically modified organism;
- (c) shall be subject to the condition that—
 - (i) the applicant shall carry out monitoring and evaluation of risks after the genetically modified organism has been imported for intentional introduction into the environment;

- (ii) the applicant take out a policy of insurance against liability to pay compensation for damages;
- (iii) or such other condition as the Board may consider necessary; and
- (iv) shall be in the prescribed form.

(3) Where the Board grants a licence subject to conditions it shall, as soon as practicable inform the applicant of its decision and the reasons for the decision.

(4) A licence may be subjected to new conditions, if in the opinion of the Board, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle.

(5) Where the Board grants a licence in accordance with the provisions of this section, the Board shall, by notice published in the *Gazette* and at least two newspapers on the island of Saint Christopher and on the island of Nevis, inform the public of the grant of the licence.

(6) Where the Board grants a licence in accordance with the provisions of this section, the Board shall enter the particulars of the licence in the Register of Licences which shall be open to inspection by the public on payment of the prescribed fee.

Cancellation of licence.

56. (1) The Board may, at any time, cancel a licence issued under the provisions of section 55 of this Act on any of the following grounds, that is to say—

- (a) upon a breach of a condition on which the licence was granted;
- (b) where the licensee contravenes any provision of this Act or the regulations made under this Act;
- (c) if, in the opinion of the Board, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle;
- (d) for any other justifiable reason the Board may think proper to do so by reason of protecting the conservation and sustainable use of biological diversity, taking into account the risks to human health.

(2) Where the Board cancels a licence in accordance with the provisions of this section, the Board shall, by notice published in the *Gazette* and at least two newspapers on the island of Saint Christopher and one on the island of Nevis for two consecutive weeks, inform the public of the cancellation of the licence.

Licensing for export

Application for export.

57. (1) A person who wishes to apply for a licence for the export of a genetically modified organism as required by this Act shall apply to the Board, and the application shall be in such form and shall contain such particulars as may be prescribed.

(2) The application referred to in subsection (1) of this section shall be accompanied by the prescribed fee in respect of the grant of licence, which fee shall be paid to the Accountant General.

(3) The Board shall, upon receipt of the application—

- (a) cause to be published in at least one newspaper on the island of Saint Christopher and one on the island of Nevis for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application;
- (b) notify, or require the applicant to notify the competent national authority of the country of import.

(4) The notification referred to in paragraph (b) of subsection (3) of this section shall be in writing and shall include the following information, that is to say—

- (a) the name, address and contact details of the applicant;
- (b) the 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;
- (c) the intended date of the export, if known;
- (d) the taxonomic status, common name, point of collection or acquisition, and characteristics of the recipient organisms or parental organisms related to biosafety;
- (e) 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;
- (f) taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism related to biosafety;
- (g) description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the genetically modified organism;
- (h) intended use of the genetically modified organism or products thereof, 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;
- (i) quantity or volume of the genetically modified organism to be exported;
- (j) a previous and existing risk assessment report consistent with the provisions of this Act;
- (k) suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate;
- (l) regulatory status of the genetically modified organism within the country of export and if the genetically modified organism is banned in the country of import, the reason for the ban;
- (m) purpose for and result of any application by the applicant to other countries regarding the genetically modified organism to be exported;

- (n) a declaration that the information submitted under paragraphs (a) to (m) is factually correct.

Objection to licensing.

58. (1) A person may object to the licensing of a genetically modified organism for export.

(2) Any objection to the licensing of a genetically modified organism for export shall be lodged with the Board within twenty-one days of the publication of the notice referred to in subsection (3) of section 57 of this Act.

Consideration of application.

59. The Board shall, before approving an application for export, consider all objections and information made available to it, and the Board may, where it is satisfied that there is an advance informed agreement with the competent authority of the country of import, approve the application.

Refusal to approve application.

60. (1) The Board may refuse to approve an application for a licence to export on any of the following grounds, that is to say—

- (a) if the application is not accompanied by all the information required to be submitted along with it;
- (b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the Board;
- (c) if the genetically modified organism or product is likely to have an adverse effect on conservation and sustainable use of biological diversity, taking into account risks to human health;
- (d) if the genetically modified organism or product is banned by the laws of the country of import.

(2) Where the Board refuses to approve an application in accordance with the provisions of subsection (1) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of licence for export.

61. (1) Where the Board is satisfied that the export may proceed, the Board may grant the licence subject to the provisions of subsection (2) of this section.

(2) The licence granted under this section—

- (a) shall be issued upon payment of the prescribed fee;
- (b) may be subject to such conditions as the Board may consider necessary; and
- (c) shall be in the prescribed form.

(3) Where the Board grants a licence subject to conditions it shall, as soon as practicable inform the applicant of its decision and the reasons for the decision.

*General***Precautionary principle.**

62. (1) Approval of an application by the Board under this Part shall be based on the best available scientific evidence or ecological principles, but where little or no scientific evidence is available, the Board may approve an application based on the precautionary principle.

(2) In this section “precautionary principle” means the principle that where there is lack of scientific certainty due to insufficient relevant adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity, taking into account risks to human health, does not prevent the taking of a decision, as appropriate, with regard to the genetically modified organism or product in question, in order to minimize such potential adverse effects.

Risk assessment.

63. (1) An applicant shall carry out, or cause to be carried out, an assessment of the impacts and risks posed by the genetically modified organism or product to human and animal health, the environment and biological diversity based on the guidelines in Annex III of the Protocol.

(2) A report in respect of the assessment shall be prepared and submitted by the applicant to the Board in accordance with the provisions of this Act.

(3) The Board shall make an evaluation of the risk assessment report submitted by an applicant.

(4) The evaluation of the risk assessment report referred to in subsection (1) of this section shall be done on a case-by-case basis and in accordance with the guidelines set out in Annex III of the Protocol.

(5) The Board may, at the completion of the evaluation of the risk assessment report, conduct, or cause to be conducted, an assessment of risks.

(6) Without prejudice to the guidelines set out in Annex III of the Protocol, the risk assessment and the evaluation of the risk assessment report shall take into account, the following—

- (a) all relevant scientific evidence and experience;
- (b) the general characteristics of both the genetically modified organism or product and the parent organism, the vector used, the genetic modification and the novel trait, including the marker trait and other sequences even when not exposed;
- (c) the native environment or host range of the recipient organism and donor organism;
- (d) the intended use of the genetically modified organism or product and the nature of the receiving or surrounding environment;
- (e) potential impacts of the genetically modified organism or product, on the environment, including long-term, direct and indirect ecological impacts, particularly on centres of origin and areas with high genetic diversity of taxa related to the genetically modified organism or product;

- (f) effects, long-term and direct or indirect, of the genetically modified organism or product on human, plant and animal health;
- (g) conformity with ethical and cultural values and norms;
- (h) details of risk assessments completed elsewhere.

(7) The Board shall, in evaluating the risk assessment report, in addition to the guidelines, also consider and duly determine whether the intentional introduction into the environment, domestic use, contained use or import of the genetically modified organism or product will—

- (a) benefit the country; and
- (b) contribute to sustainable development.

(8) The Board shall also consider the efficacy of sustainable alternatives to the introduction of the genetically modified organism or product as well as safer alternative technologies.

(9) The Board shall, upon completion of the evaluation, produce a report which shall include the following—

- (a) the decision;
- (b) the grounds for the decision;
- (c) the matters considered and determined by the Board in subsections (7) and (8) of this section.

(10) The Board may require the applicant to bear all, or any part of the costs for evaluating the risk assessment report or carrying out the risk assessment.

Socio-economic considerations.

64. The Board may, in reaching a decision under this Act, take into account socio-economic considerations arising from the impact of genetically 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.

Review of decision.

65. (1) The Board may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health, review and change a decision regarding an import or export.

(2) Where the Board reviews and changes a decision pursuant to subsection (1) of this section, the Board shall, within thirty days, inform any applicant that had previously notified the import or export of the genetically modified organism referred to in such decision, as well as, the Biosafety Clearing-House, and shall set out the reasons for its decision.

(3) An applicant may request the Board to review a decision it has made where the applicant considers that—

- (a) a change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based;
- (b) additional relevant scientific or technical information has become available.

(4) Where a request is made pursuant to subsection (3) of this section, the Board shall respond in writing to such a request within ninety days and set out the reasons for its decision.

(5) The Board may, at its discretion, require a risk assessment for subsequent imports.

Risk management.

66. (1) The Board shall establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment associated with the use, handling and import or export of genetically modified organisms.

(2) Without prejudice to the generality of subsection (1) of this section, the Board may take the following measures—

- (a) subject any genetically modified organism to a period of observation commensurate with its life-cycle or generation time, at the cost of the original applicant, before it is put to its intended use, provided that this does not result in continuous trials in the field or contained use;
- (b) restrict or prohibit the import, intentional introduction into the environment, contained use or domestic use;
- (c) order the cessation of any activity that is being undertaken in violation of any of the provisions of this Act or any decisions made under this Act;
- (d) order the cessation of any activity that is shown to cause risks to human or animal health, biological diversity or the environment;
- (e) subject to subsection (3), require a licensee to take such measures as may be necessary to prevent or limit any harm or damage to human or animal health, biological diversity or the environment, or to restore the environment to its previous state as far as feasible;
- (f) in case of imminent and serious danger to human or animal health, biological diversity or the environment, and where immediate intervention is required, the Board shall take such measures as are necessary without prior notice, and all costs and expenses shall be borne by, or be recoverable from, the licensee;
- (g) require the applicant to submit reports periodically in respect of monitoring and evaluation of risks carried out after the grant of a licence under the provisions of this Act;
- (h) prohibit the import, intentional introduction into the environment or placing on the market of the genetically modified organism if the Board is satisfied that it contains characteristics or specific traits which pose risks to human, animal or plant health, the environment, or biological diversity.

(3) If no action is taken within a reasonable time after notification by the licensee under paragraph (3) of subsection (2) of this section, the Board may undertake the necessary measures and all costs and expenses shall be borne by, or be recoverable from the licensee.

(4) Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the genetically modified organism on the

conservation and sustainable use of biological diversity, taking into account risks to human health, within the country.

(5) The Board shall endeavour to ensure that any genetically modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

Notification of unintentional movement.

67. (1) The Board shall take appropriate measures to notify affected or potentially affected countries, 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 movement 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 such countries.

(2) The notification referred to in subsection (1) of this section shall be provided as soon as the Board knows of the situation and shall include the following information, that is to say—

- (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 release, and on the use of the genetically modified organism in the originating country;
- (c) any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking 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.

(3) In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, the Board shall immediately consult the affected or potentially affected countries to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

(4) The Board shall ensure that, where necessary, before any intentional introduction into the environment or contained use, an emergency plan is prepared for the protection of human and animal health, biological diversity and the environment in the event of an accident and the appropriate emergency and other services are informed of this plan in writing.

Notification of new information.

68. A licensee shall immediately notify the Board of new information that becomes available on the possible risks to human or animal health, biological diversity or the environment.

Confidential information.

69. (1) The Board shall permit the applicant to identify information submitted under this Act that is to be treated as confidential and justification shall be given in such cases upon request.

(2) The Board shall consult the applicant if it decides that information identified by the applicant as confidential, does not qualify for such treatment and shall, prior to any disclosure, inform the applicant 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) The Board shall protect confidential information received under this Act.

(4) The Board shall not use such information for a commercial purpose, except with the written consent of the applicant.

(5) Where an applicant withdraws or has withdrawn an application, the Board shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the applicant disagrees as to its confidentiality.

(6) Without prejudice to subsection (5) of this section, the following information shall not be considered confidential—

- (a) the name and address of the applicant;
- (b) a general description of the genetically modified organism;
- (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.

Handling, transport, packaging and identification.

70. (1) The Board shall take necessary measures to require that genetically modified organisms that are subject to import or export are handled, packaged and transported under conditions of safety, in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

(2) A licensee or a holder of a certificate shall ensure that documentation accompanying—

- (a) genetically modified organisms that are intended for direct use as food, feed or processing, clearly identifies that they “may contain” genetically modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information;
- (b) genetically modified organisms that are destined for contained use—
 - (i) clearly identifies them as genetically modified organisms; and
 - (ii) 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 genetically modified organisms are consigned; and

- (c) genetically modified organisms that are intended for intentional introduction into the environment of the country and any other genetically modified organism—
 - (i) clearly identifies them as genetically modified organisms;
 - (ii) specifies the identity and relevant traits 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 licensee or holder of the certificate; and
 - (iii) contains a declaration that the import or export is in conformity with the requirements of this Act applicable to the licensee or a holder of a certificate.

Right of redress against licensee.

71. (1) A person shall have a right of redress against a licensee where that licensee fails to comply with the provisions of this Act or regulations made under this Act and the person suffers harm, injury or loss, including personal injury, damage to property, financial loss and damage to the environment or to biological diversity.

(2) In addition to the right of redress set out in subsection (1) of this section, a person may have a right of redress for harm or damage caused to the economy, social or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies, including disruption or damage to production systems, agricultural systems, reduction in yields, and damage to the economy of an area or community.

Remedies against licensee.

72. (1) Where a person has a right of redress under section 71(1) of this Act, the person may exercise the remedies specified in this section.

(2) Where the failure can be remedied, the person may require the licensee to remedy the failure within a reasonable time.

(3) Where the licensee who is required to remedy a failure, refuses or neglects to do so, or does not succeed in doing so within a reasonable time, the person may inform the Board who may have the failure remedied and recover from the licensee all reasonable costs incurred in having the failure remedied.

(4) Subject to subsection (5) of this section, where the harm caused is harm to the environment or to biological diversity, redress shall include the cost of reinstatement, rehabilitation or clean-up measures actually incurred or to be incurred and, where applicable, the costs of preventive measures and any loss or damage caused by the taking of the preventive measures.

(5) The licensee responsible may be required to carry out the reinstatement or rehabilitation at his or her own cost and to the satisfaction of the Board.

PART VI

COMPLAINTS

Submission of complaints.

73. (1) A person who is aggrieved by conduct engaged in by a licensee which contravenes the provisions of this Act may, upon payment of the prescribed fee, submit a complaint to the Board.

(2) A complaint made under this section shall be in writing, and if made orally shall be reduced in writing, and be addressed to the Chairperson of the Board.

(3) Subject to section 83, where a complainant is dissatisfied with the decision of the Board, he or she may apply to the Tribunal for further consideration of his or her complaint, on payment of a prescribed fee.

(4) This section does not affect the right of any person to enforce in the High Court a complaint referred to in this section except that the person shall not institute proceedings in both the Tribunal and the Court in respect of the same complaint.

Determination of action to be taken.

74. (1) Upon receipt of a complaint the Board shall determine the action to be taken on the complaint and may require the complainant to submit such additional information as the Board may require.

(2) The Board may refuse to take action in relation to a complaint, on any of the following grounds, that is to say—

- (a) that the complaint is trivial, frivolous or vexatious or not made in good faith;
- (b) where the complainant does not have a sufficient interest in the complaint;
- (c) where the complainant fails or refuses to submit further particulars requested by the Chairperson;
- (d) if the conduct complained of, in the opinion of the Board, does not constitute conduct which is in contravention of any provision of this Act;
- (e) where the complaint should more appropriately be dealt with by a court in the exercise of its criminal jurisdiction.

(3) Where the Board refuses to take action under subsection (2) of this section, a licensee may, either refer the matter to the Tribunal or apply to the High Court for the determination of the matter.

Written undertakings.

75. Where the Board is of the opinion that a licensee is engaged in conduct that does not necessitate the instituting of any proceedings under this Act the Board may demand a written undertaking from the licensee to the effect that the licensee shall desist from that kind of conduct, and the written undertaking shall be enforceable in a court of law.

Institution of criminal or civil proceedings.

76. (1) The Board may, on its own initiative or upon a request of any person, institute criminal or civil proceedings in respect of any contravention or breach of the provisions of this Act.

(2) Nothing in this section shall be deemed to limit the private right of action available to an individual to enforce his rights under the provisions of this Act.

PART VII**ESTABLISHMENT OF TRIBUNAL, ITS POWERS AND FUNCTIONS****Establishment of Tribunal.**

77. (1) There is established a Tribunal to be known as the Biosafety Claims Tribunal.

(2) The Tribunal shall consist of five members appointed by the Governor-General, acting in accordance with the recommendation of the Judicial and Legal Services Commission, upon such terms and conditions as may be specified in their instrument of appointment.

(3) No person shall qualify for appointment as a member of the Tribunal unless that person has qualifications or experience in law, economics, science or technology, except that the person appointed as Chairperson shall be legally qualified.

(4) The Governor-General, acting in accordance with the recommendation of the Judicial and Legal Services Commission, shall, in accordance with the provisions of subsection (3), appoint a Chairperson of the Tribunal from among members of the Tribunal.

(5) Where a member of the Tribunal is temporarily absent or is temporarily incapacitated such that the member is not able to discharge his or her duty, the Governor-General, acting in accordance with the recommendation of the Judicial and Legal Services Commission, may, by notice published in the *Gazette*, appoint a suitable person to act in the member's place.

(6) The Minister shall publish in the *Gazette*, notice of a person appointed as a member of the Tribunal.

Duration of office.

78. A member of the Tribunal shall hold office for a period not exceeding three years, except that the member shall be eligible for re-appointment.

Resignation of a member of the Tribunal.

79. (1) A member of the Tribunal may, at any time, and in writing, resign from the Tribunal and the member's resignation shall be addressed to the Governor-General.

(2) The Minister shall publish in the *Gazette*, notice of every resignation of a member of the Tribunal.

Termination of membership of a member of the Tribunal.

- 80.** (1) The office of a member of the Tribunal shall become vacant if—
- (a) the member dies;
 - (b) the member's term of office expires;
 - (c) the member resigns in accordance with section 79;
 - (d) the member is convicted of an indictable offence; or
 - (e) the member is removed from office in accordance with the provisions of subsection (2).
- (2) The Governor-General, acting in accordance with the recommendation of the Judicial and Legal Services Commission, may remove a member from the Tribunal if the Governor-General is satisfied that the member—
- (a) is permanently incapable of performing his or her duties;
 - (b) has engaged in dishonourable conduct;
 - (c) is incompetent;
 - (d) has neglected his duty; or
 - (e) is bankrupt.
- (3) A member of the Tribunal shall not be removed from office except as provided by this section.
- (4) The Minister shall publish in the *Gazette*, notice of every member whose office falls vacant in accordance with the provisions of this section.

Remuneration.

- 81.** (1) The Minister of Finance may direct that sums of money shall be paid by way of remuneration—
- (a) to a member of the Tribunal; and
 - (b) to a person appointed to assist the Tribunal.
- (2) The Minister may also direct payment of any other expenses, consequent upon the discharge of the functions of the Tribunal.
- (3) Any payment directed to be made under this section shall be made out of moneys voted for the purpose by Parliament.

Jurisdiction of the Tribunal.

- 82.** (1) The jurisdiction of the Tribunal shall be to—
- (a) determine complaints made to it in accordance with this Act; and
 - (b) make awards and other decisions in accordance with the powers conferred on it by this Act.
- (2) The Tribunal shall not have jurisdiction to hear and determine any criminal matter that arises out of the contravention of any provision of this Act.

Board to exhaust efforts for redress.

83. The Tribunal shall not hear and determine a complaint unless it is satisfied that the Board has made all reasonable efforts to obtain redress for the complainant and has failed to obtain such redress.

Sitting of the Tribunal.

84. (1) The Tribunal shall meet on such occasions as may be expedient for the hearing and determination of disputes, and at such places and times as the Tribunal may determine.

(2) The Tribunal shall, for the purpose of exercising its jurisdiction, normally consist of a Chairperson and two other members.

(3) The Minister of Justice and Legal Affairs shall, by regulations, prescribe the procedure to be followed by the Tribunal in hearing and determining disputes referred to it.

(4) There shall be appointed a Registrar of the Tribunal who shall be a public officer.

Appeals.

85. A person who is dissatisfied with the decision of the Tribunal may appeal against the decision to the High Court within fourteen days from the day the decision is made, and the appeal so made shall be on a question or point of law only.

PART VIII

MISCELLANEOUS PROVISIONS

Detention of seized articles.

86. (1) An inspector may, after seizing any article in accordance with the provisions of this Act, order that the article be kept and secured in the building or place where it is seized or being kept and secured in another place as he or she may deem fit.

(2) An inspector shall, after seizing any articles in accordance with the provisions of this Act, give written notice to the owner of the article or to a person in whose possession the article was at the time of seizure, in which notice he shall state the grounds upon which the article was seized and, where appropriate, state what had to be done for the purpose of complying with the provisions of this Act and the regulations made under this Act.

Disposal of seized articles.

87. (1) Subject to the provisions of subsection (3) of this section, an inspector shall release any article seized by him when the relevant provision of this Act and the regulations made under this Act have been complied with.

(2) Subject to the provisions of subsection (3) of this section, where the owner of an article or person in whose possession the article was at the time of the seizure, consents, in writing, to the destruction of the article, the article shall be forfeited to

the Crown, and shall be disposed of as the Minister may, on the advice of the Board, direct or as may be prescribed by regulations made under this Act.

(3) Where proceedings are instituted pursuant to the provisions of this Act any article that is seized under this article shall not be released or destroyed before the proceedings are concluded.

Offences.

88. (1) A person who—

- (a) contravenes any condition attached to a licence granted to him in respect of a genetically modified organism;
- (b) resists, obstructs, intimidates, or assaults an inspector in the execution of his duties under this Act;
- (c) by any form of inducement, attempts to prevent or prevents an inspector from carrying out his duties under this Act;
- (d) fails to comply with any requirement imposed by an inspector pursuant to the provisions of this Act;
- (e) conceals or prevents any person from appearing or being examined by an inspector;
- (f) recklessly or knowingly makes a false or misleading statement, orally or in writing, to an inspector;
- (g) fails to keep any record which he is required to keep by regulations made under this Act;
- (h) willfully makes a false entry in a register, record, return, or other document kept or furnished in pursuance of regulations made under this Act, or willfully makes use of such false entry;
- (i) removes, alters or interferes in any way with an article seized under the provisions of this Act without the authority of an inspector,

commits an offence.

(2) A person who commits any of the offences specified in subsection (1) of this section shall be liable—

- (a) on summary conviction, to a fine not exceeding five thousand dollars or to imprisonment for a period not exceeding one year or both;
- (b) on conviction upon indictment, to a fine not exceeding twenty-five thousand dollars or to imprisonment for a period not exceeding three years or both.

(3) The Courts may, in addition to the punishment imposed by subsection (2) of this section, disqualify a person convicted of an offence under this section from obtaining a licence in respect of any activity relating to genetically modified organisms.

(4) No proceedings by way of indictment for an offence committed under this Act shall be commenced without the written approval of the Director of Public Prosecutions.

Offences by Corporations.

89. Where an offence is committed by a body corporate, a person who at the time of the commission of the offence was a director, manager, secretary, or other officer of the body corporate, shall be deemed to have committed the offence, unless they prove that the offence was committed without their consent or connivance and that they exercised such due diligence as they ought to have exercised having regard to the nature of their duties to prevent the commission of the offence.

Inspector may Prosecute.

90. An inspector may prosecute any offence committed under this Act or the regulations made under this Act in any court of competent jurisdiction.

Time-limit on prosecution.

91. An offence committed under this Act or the regulations made under this Act shall be prosecuted within a period of twelve months from the date the prosecution becomes aware of the offence.

Evidence etc.

92. (1) Notwithstanding any provision of any other enactment and subject to the provisions of this section, in any proceedings relating to an offence committed under this Act or the regulations made under this Act—

- (a) a certificate issued by an analyst in which it is stated that he or she analysed or examined an article or a sample submitted to him or her by an inspector, and in which certificate he or she states the results of his or her analysis or examination;
- (b) a certificate issued by the Board pursuant to the provisions of this Act;
- (c) a licence granted by the Board under the provisions of this Act,

shall be admissible in evidence, and any statement in such certificate or licence, as the case may be, shall be *prima facie* evidence of such statement.

(2) No certificate referred to in subsection (1) of this section shall be received in evidence unless the prosecution has, prior to the trial, given the accused person fourteen days notice of the intention of the prosecution to produce the certificate or a certified copy of the certificate, as the case may be.

(3) The Court may, upon request, cause the part of any sample retained, as prescribed by regulations for future comparison, to be analysed by another analyst who did not issue the certificate which is before the Court, as the case may be.

Modification of article.

93. Where a person is found guilty of an offence under this Act or the regulations made under this Act in respect of any article, the Court may, before convicting the accused person, give the accused person an opportunity to modify the article and bring it in conformity with the provisions of this Act and the regulations, within such a period as the court may specify.

Forfeiture.

94. Where a person is convicted of an offence under this Act or the regulations made under this Act in respect of an article, the Court may order that—

- (a) such article; or
- (b) any similar article which belongs to or is in possession of the accused person, which article the Court reasonably believes to be kept in contravention of this Act or regulations made under this Act,

be forfeited to the Crown.

Application of Protocol.

95. (1) The Protocol set out in the First Schedule shall have the force of law in Saint Christopher and Nevis.

(2) The Minister may, by Order, on the recommendation of the Board, amend the First Schedule to this Act.

Regulations.

96. The Minister may, after consulting the Board, make regulations generally for giving effect to the provisions of this Act, and without prejudice to the generality of the foregoing he or she may, in particular, make regulations prescribing—

- (a) forms for the purposes of this Act and the regulations made under this Act;
- (b) fees for the purposes of this Act and the regulations made under this Act;
- (c) standards for the following—
 - (i) use of genetically modified organisms;
 - (ii) disposal of waste containing genetically modified organisms;
 - (iii) handling of genetically modified organisms;
 - (iv) identification of genetically modified organisms; and
 - (v) transporting of genetically modified organisms;
- (d) contents of an emergency plan;
- (e) requirement for the safe handling and disposal of genetically modified organisms;
- (f) evaluation of foods containing genetically modified organisms using modern biotechnology;
- (g) the procedure for the quarantine of any genetically modified organism in any place;
- (h) the genetically modified organisms which are restricted or prohibited;
- (i) restricting or prohibiting genetically modified organisms from any area for the conservation and sustainable development of that area;
- (j) anything required to be prescribed under this Act.

Transitional provisions.

97. (1) After the date of the entry into force of this Act, any person engaged in an activity regulated under the provisions of this Act, shall submit an application for approval of the activity in accordance with the provisions of this Act.

(2) The application referred to in subsection (1) of this section shall be submitted to the Board within two months of the coming into force of this Act.

(3) If the application has been made within the time period specified in subsection (2) of this section, the activity in respect of which the application is made may continue until a decision is made by the Board under this Act.

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

FIRST SCHEDULE*(Section 2)***CARTAGENA PROTOCOL TO THE CONVENTION ON BIOLOGICAL
DIVERSITY**

The Parties to this Protocol,

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

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention, *Recalling* also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

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

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

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

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

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

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

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

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

Have agreed as follows:

ARTICLE 1

OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology

that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

ARTICLE 2

GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.
2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.
3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.
4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.
5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

ARTICLE 3

USE OF TERMS

For the purposes of this Protocol:

- (a) "Conference of the Parties" means the Conference of the Parties to the Convention;
- (b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;
- (c) "Export" means intentional transboundary movement from one Party to another Party;
- (d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

- (e) “Import” means intentional transboundary movement into one Party from another Party;
- (f) “Importer” means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;
- (g) “Living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
- (h) “Living organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;
- (i) “Modern biotechnology” means the application of:
 - a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
 - b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;
- (j) “Regional economic integration organization” means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;
- (k) “Transboundary movement” means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

ARTICLE 4

SCOPE

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

ARTICLE 5

PHARMACEUTICALS

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

ARTICLE 6

TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.
2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

ARTICLE 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.
2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.
3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.
4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

ARTICLE 8

NOTIFICATION

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

ARTICLE 9

ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.
2. The acknowledgement shall state:
 - (a) The date of receipt of the notification;
 - (b) Whether the notification, prima facie, contains the information referred to in Article 8;
 - (c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.
3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.
4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

ARTICLE 10

DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.
2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:
 - (a) Only after the Party of import has given its written consent; or
 - (b) After no less than ninety days without a subsequent written consent.
3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing- House the decision referred to in paragraph 2 (a) above:
 - (a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;
 - (b) Prohibiting the import;
 - (c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or
 - (d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.
4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.
5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.
7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

ARTICLE 11

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

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.
2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.
3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.
4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.
5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.
6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:
 - (a) A risk assessment undertaken in accordance with Annex III; and
 - (b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.
7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism

intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.
9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

ARTICLE 12

REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.
2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:
 - (a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or
 - (b) Additional relevant scientific or technical information has become available.
3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.
4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

ARTICLE 13

SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:
 - (a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

- (b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure. Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.
2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

ARTICLE 14

BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.
2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.
3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.
4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

ARTICLE 15

RISK ASSESSMENT

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

ARTICLE 16

RISK MANAGEMENT

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

ARTICLE 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.
2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.
3. Any notification arising from paragraph 1 above, should include:
 - (a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

- (b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;
 - (c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;
 - (d) Any other relevant information; and
 - (e) A point of contact for further information.
4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

ARTICLE 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.
2. Each Party shall take measures to require that documentation accompanying:
 - (a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they “may contain” living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;
 - (b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and
 - (c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

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

ARTICLE 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.
2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.
3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

ARTICLE 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:
 - (a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and
 - (b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.
2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.
3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

- (a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;
 - (b) Any bilateral, regional and multilateral agreements and arrangements;
 - (c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;
 - (d) Its final decisions regarding the importation or release of living modified organisms; and
 - (e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.
4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

ARTICLE 21

CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.
2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.
3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.
4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.
5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.
6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

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

ARTICLE 22

CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.
2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

ARTICLE 23

PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:
 - (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
 - (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.
2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

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

ARTICLE 24

NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.
2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

ARTICLE 25

ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.
2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.
3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

ARTICLE 26

SOCIO-ECONOMIC CONSIDERATIONS

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

PRESERVATIONS

No reservations may be made to this protocol.

ARTICLE 39

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

ARTICLE 40

AUTHENTIC TEXTS

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

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

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

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

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

*Annex II*INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS
INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING
UNDER ARTICLE 11

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

Annex III

RISK ASSESSMENT

Objective

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

Use of risk assessment

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

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.
4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non- modified recipients or parental organisms in the likely potential receiving environment.
6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.
8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:
 - (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
 - (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
 - (c) An evaluation of the consequences should these adverse effects be realized;
 - (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
 - (e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
 - (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:
 - (a) *Recipient organism or parental organisms.* The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;
 - (b) *Donor organism or organisms.* Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
 - (c) *Vector.* Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

- (d) *Insert or inserts and/or characteristics of modification.* Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;
- (e) *Living modified organism.* Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;
- (f) *Detection and identification of the living modified organism.* Suggested detection and identification methods and their specificity, sensitivity and reliability;
- (g) *Information relating to the intended use.* Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and
- (h) *Receiving environment.* Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

SECOND SCHEDULE

(Section 7)

MEETINGS AND OTHER MATTERS OF THE BOARD

1. The Board shall meet at such times as may be necessary for the transaction of business, and the meetings shall be held at such place and times and days as the Board may determine.
2. Meetings of the Board shall be called by the Chairperson of the Board, and the Chairperson may, at any time, call a special meeting of the Board and shall call a special meeting of the Board within fourteen days of receipt of a request for that purpose addressed to him in writing and signed by at least three members of the Board.
3. The Chairperson shall preside at all meetings of the Board, and in his absence the members present and forming a quorum shall elect from amongst their number a member of the Board to act as Chairperson for that meeting.
4. Decisions of the Board shall be by majority votes of members present and voting, and in case of equality of votes the Chairperson or acting Chairperson shall have a casting vote.
5. The quorum of the Board shall be half the number of members of the Board.
6. The Board may invite any person to attend any of its meetings where the Board considers it necessary to do so, but that person shall not vote on any matter before the Board.
7. (1) Minutes of each meeting of the Board shall be recorded and kept by the Secretary of the Board.
(2) A certified copy of the minutes of each meeting of the Board shall be forwarded to the Minister within fourteen days after the meeting at which they were confirmed.

8. Subject to this Schedule, the Board may regulate its own procedure, and may delegate to any member of the Board power to carry out on behalf of the Board such duties as the Board may determine.
 9. All documents made by the Board, and all decisions of the Board shall be signified under the hand of the Chairperson, a member of the Board authorized to act on behalf of the Board, or the Secretary to the Board.
 10. The Minister may grant leave to any member of the Board, and may appoint another person to act in place of the member granted leave.
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