

SAINT VINCENT AND THE GRENADINES

BIOSAFETY ACT, 2007

EXPLANATORY NOTE

1. The main purpose of the Biosafety Bill is to make provision for the safe transfer, 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 and animal health, the establishment of a Biosafety Board; and implement the Cartagena Protocol on Biosafety.
2. The Bill contains seven Parts. In the preliminary part of the Bill provision is made for the short title and commencement, interpretation and application in clauses 1-3.
3. Part II of the Bill provides for the establishment of a Biosafety Board. The Biosafety Board is established under clause 4 the Bill. An advisory committee is also established under clause 5 of the Bill to assist the Biosafety Board in performing some of its functions. The functions of the Biosafety Board are identified in clause 6 of the Bill. The other provisions in Part II of the Bill provide for remedial measures, powers of the Biosafety Board, creation of website, immunity, confidentiality, biosafety fund and its administration, annual report and accounts and audit under clauses 7-15 of the Bill.
4. The import of genetically modified organisms is provided for in Part III of the Bill. A restriction is placed on importation without a licence by clause 16 of the Bill. An application for an import licence must be made to the Biosafety Board in accordance with clause 17 of the Bill. The licence must then be gazetted by the Biosafety Board to allow interested persons to provide opposition, if any under clause 18 of the Bill. In reaching a decision with regards to an import licence, the Biosafety Board must follow the advance informed agreement procedure set out in clause 19 of the Bill. After the procedure is followed, the Biosafety Board must either deny or approve the application in accordance with clauses 20 and 21 of the Bill.
5. Part IV of the Bill makes provision for the export of genetically modified organisms. Genetically modified organisms cannot be exported unless a licence is obtained according to clause 22 of the Bill. The application for export must be made in accordance with

clause 23 of the Bill. Any opposition to the licensing for export may be presented under clause 29 of the Bill. The application for export may be denied or approved by virtue of clauses 25 and 26 of the Bill.

6. The movement of genetically modified organisms is provided for in Part V of the Bill. A person cannot move a genetically modified organism within Saint Vincent and the Grenadines unless that person obtains a licence to do so under clause 27 of the Bill. The application can be made in accordance with clause 28 of the Bill. This application can be opposed, denied or approved according to clauses 29-31 of the Bill.
7. In order to enforce the provisions of the Bill, a number of provisions relating to enforcement are contained in Part VI of the Bill. These provisions range from power of entry and search, seizure and notice of seizure, storage, removal etc., forfeiture, confiscation and disposal and compensation. These provisions are made in clauses 32-37 of the Bill.
8. There are miscellaneous provisions in Part VII of the Bill. Therefore, Part VII contains the following provisions in clauses 38-50: precautionary principle, risk assessment, socio-economic considerations, review of decision, risk management, notification of unintentional movement, notification of new information, confidential information, identification and labelling, offences, appeals, amendment of schedule and regulations.

SAINT VINCENT AND THE GRENADINES

BIOSAFETY ACT, 2007

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SCHEDULE

SAINT VINCENT AND THE GRENADINES

ACT NO. OF 2007

BILL FOR

AN ACT to provide for the safe transfer, handling and use of living 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 and animal health; to provide for the establishment of a Biosafety Board; to implement the Cartagena Protocol on Biosafety; and for related matters.

BE IT ENACTED by the Queen’s Most Excellent Majesty, by and with the advice and consent of the House of Assembly of Saint Vincent and the Grenadines and by the authority of the same, as follows:

**PART I
PRELIMINARY**

Short title and commencement

1. This Act may be cited as the Biosafety Act, 2007 and shall come into operation on such day as the Minister may appoint by notice published in the *Gazette*.

Interpretation

2. In this Act, unless the context otherwise requires

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

“biological diversity” means the variability among genetically modified organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part this includes diversity within species, between species and of ecosystems;

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

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

“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;

“domestic use” means the use of a genetically modified organism exclusively for household purposes such as cooking;

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

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

“genetically modified organism” means any biological entity capable of replication or transfer of genetic information, and includes plants, animals, bacteria and all other kinds of micro-organisms, cell cultures (prokaryotic or eukaryotic) created and propagated as such, viruses, 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;

“handling” means the process of packaging and distributing a genetically modified organism;

“intentional introduction into the environment” means any release into the environment, including any production or use that is not contained use of genetically modified organisms or products; this includes releases for: commercial purposes, remediation, research purposes in field experiments, use of genetically modified organisms or products in greenhouses, aquaculture facilities, animal accommodation unless the facility is approved for contained use as part of an approved laboratory or other installation, disposal of waste containing genetically modified organisms or products,

and transport of genetically modified organisms or product;

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

“inspector” means a person appointed under paragraph (3) of subsection (2) of section 4 of this Act to be an inspector for the purposes of this Act;

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

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

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

“modern biotechnology” means the application of:

- (a) in vitro nucleic acid techniques, including recombination deoxyribonucleic acid 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;

“Minister” means the Minister responsible for agriculture;

“packaging” means all products made of any materials of any nature to be used for the containment, protection, handling, delivery and preservation of genetically modified organisms from one place to another;

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

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 and animal health.

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

PART II

ESTABLISHMENT OF THE BIOSAFETY BOARD

Establishment
of the
Biosafety
Board

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

(2) The Biosafety Board shall consist of

- (a) a director appointed in writing by the Minister who shall be the chief executive officer of the Biosafety Board;
- (b) an attorney appointed in writing by the Minister;
- (c) a public accountant appointed in writing by the Minister;
- (d) such consultants having suitable qualifications and experience to provide services to the Biosafety Board, appointed in writing by the Minister; and
- (e) inspectors appointed or designated in writing by the Minister to carry out the duties assigned to inspectors under this Act;
- (f) such other personnel as the Minister considers necessary.

Functions of
the Board

5. The Biosafety Board

- (a) shall receive all applications for licences under this Act;

- (b) shall examine and approve or deny the applications for licences under this Act;
- (c) shall be responsible for monitoring compliance, by a licensee;
- (d) shall be the competent national authority;
- (e) shall be responsible for ensuring the proper administration of this Act.

Advisory
committee

6. (1) The Biosafety Board shall appoint a Biosafety Advisory Committee.

(2) The Advisory Committee shall

- (a) conduct risk assessments -
 - (i) where there is new technology;
 - (ii) to provide a mechanism for determining ways to minimize potential risks;
 - (iii) to adequately assess safety prior to the import or export of a genetically modified organism;
 - (iv) where a genetically modified organism is released intentionally or otherwise and which may cause unintended, unwanted or unacceptable effects;
- (b) review the risk assessments provided in applications;
- (c) to review and determine risk management and risk communication measures;
- (d) to recommend measures, limitations on the duration of applications of measures, reporting mechanisms, remedial measures, monitoring procedures and other appropriate scientifically sound conditions and risk management measures; and

- (e) provide such other expert advice and assistance as the Biosafety Board may require.

(3) The Advisory Committee shall consist of such persons as the Biosafety Board may think fit, bearing in mind the needs of the Committee for the expertise in disciplines relevant to the work of the Committee.

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

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

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

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

Powers of the
Biosafety
Board

- 8. (1) If the Biosafety Board is satisfied that a licensee
 - (a) has knowingly provided false information to the Biosafety Board upon application for license as a licensee;
 - (b) has contravened any provision of this Act;
 - (c) if new information or a review of existing information about the genetically modified organism establishes risk to human or animal health, biological diversity or the environment based on the precautionary principle;
 - (d) has failed to comply with a condition of its licence,

it may take one or more of the actions set out in subsection (2).

(2) The actions that the Biosafety Board may take in pursuance of subsection (1) are as follows:

- (a) revocation of the licence;
- (b) imposition of new or additional conditions upon a licence;
- (c) to require the licensee to take any other action the Biosafety Board considers necessary.

(3) Before ordering any of the actions authorized in subsection (2), the Biosafety Board shall give the opportunity to the licensee to show cause against the action, whether in person or by representation, except where the Biosafety Board determines that it is in the public interest that it shall not give the licensee the opportunity to show cause and a licensee may pursuant to section 48 appeal to the tribunal against any action ordered under subsection (2).

(4) Whenever the Biosafety Board revokes a licence under subsection (2)(a), it shall cause notice of the revocation to be published in the Gazette and in the newspaper or other publication as it may think fit in the circumstances.

Creation of
website

9. (1) The Biosafety Board shall create a biosafety website to assist with the sharing of information on biosafety matters.

(2) The website created pursuant to subsection (1) shall be linked to -

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

(3) The Biosafety Board shall provide to its website and the Biosafety Clearing-House -

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

- (b) summaries of risk assessments;
- (c) final decisions regarding the importation for intentional introduction into the environment of living modified organisms;
- (d) reports concerning national implementation of the Protocol;
- (e) within thirty days of taking a decision under section , a copy of the decision describing the changes to the previous decision and the reasons for the decision; and
- (f) within fifteen days of making a final decision regarding domestic use of a living modified organism that may be subject to export for direct use as food or feed or for processing, provide the information specified in the Annex II of the Protocol concerning the application of that living modified organism;
- (g) within two hundred and seventy days of the date of receipt of an application, the Biosafety Board shall communicate, in writing to the Biosafety Clearing-House its decision under the provision of section 19(7).

Immunity

10. No action shall lie against the director, officers or personnel of the Biosafety Board or any person acting under the direction of the Director for anything done or omitted to be done in good faith and in the administration or discharge of any functions, duties or powers under this Act.

Confidentiality

11. (1) Any person who obtains information in any form as a result of his connection with the Biosafety Board shall not disclose that information to any person except so far as it is required or permitted under this Act or other written law.

(2) Any person who willfully discloses information to any person in contravention of subsection (1) commits an offence and is liable on summary conviction to a fine not exceeding one hundred thousand dollars or to imprisonment for a term not exceeding three years or to both such fine and imprisonment.

Biosafety
Fund

12. (1) There shall be established a fund to be known as the Biosafety Fund ("the Fund").

(2) There shall be paid into the Fund

(a) fees collected under this Act;

(b) any other sums.

(3) The Biosafety Board may authorise payments to be made out of the Fund

(a) for purposes related to public education in relation to genetically modified organisms;

(b) to meet the expenses of the Biosafety Board;

(c) to meet the remuneration and expenses of a consultant appointed under this Act;

(d) to pay compensation awarded under this Act;

(e) to cover costs associated with the administration of the Fund;

(f) for such other purposes as the Biosafety Board may from time to time determine.

Administration
of the Fund

13. (1) The moneys paid into the Fund shall be invested in accordance with the laws of Saint Vincent and the Grenadines, and the income earned from such investments shall be paid into the Fund.

(2) The financial year of the Fund shall end on 31st March in each year.

(3) The Fund shall be subject to the accounting provisions of section 15.

Annual report

14. (1) The Director shall

(a) advise the Minister of the work of the Biosafety Board;

(b) prepare and submit to the Minister on or before the 1st day of April in each year an annual report reviewing the work of the Biosafety Board;

(c) prepare and submit interim reports every three months reviewing the work of the Biosafety Board.

(2) The Minister shall lay or cause to be laid a copy of every annual report on the table of the House of Assembly.

Accounts
and audit

15. (1) The Biosafety Board shall prepare for each financial year an annual budget of revenue and expenditure which shall be submitted to the Minister at least four months prior to the commencement of the financial year.

(2) The accounts of the Biosafety Board for each year shall be audited by the Director of Audit.

(3) As soon as the accounts have been audited the Biosafety Board shall submit a copy to the Minister and a copy of any report made by the Director of Audit.

(4) The Minister shall lay a copy of the audited accounts on the table of the House of Assembly.

PART III

IMPORTS

Restriction on
importation.

16. (1) No person shall import a genetically modified organism for the first time unless a licence is granted under this Act to import.

(2) A person who contravenes this section commits an offence and is liable on summary conviction to a fine not exceeding one hundred thousand dollars or to imprisonment for a term not exceeding two years or to both, and in the case of a continuing offence to a fine not exceeding ten thousand dollars for each day that the offence continues.

Application
for licence

17. (1) A person who is desirous of importing a genetically modified organism for the first time must apply to the Biosafety Board for the grant of a licence.

(2) An application under subsection (1) must

(a) be filed with the Director;

(b) in the case of intentional introduction into the environment, include the information contained in Annex I of the Protocol;

- (c) in the case of domestic use, include the information contained in Annex II of the Protocol;
- (d) in the case of contained use, include the information prescribed in the Regulations;
- (e) be in the prescribed form;
- (f) be accompanied by the fee prescribed in the Regulations.

(3) Upon receipt of an application, the Biosafety Board shall publish the application in the Gazette and at least one newspaper of general circulation.

Opposition to
licensing

18. (1) Any interested person may, within the prescribed period and in the prescribed manner, give notice to the Biosafety Board of opposition to the licensing for the import of the genetically modified organism.

(2) The Biosafety Board shall send a copy of the notice to the applicant, and, within the prescribed period and in the prescribed manner, the applicant shall send to the Biosafety Board a counter-statement of the grounds on which he relies for his application; if he does not do so, he shall be deemed to have abandoned the application.

(3) If the applicant sends a counter-statement, the Biosafety Board shall furnish a copy thereof to the person giving notice of opposition and, after hearing the parties, if either or both wish to be heard, and considering the merits of the case, shall decide whether the living modified organism should be licensed.

Advance
informed
agreement
procedure

19. (1) The Biosafety Board shall, before approving an application for importation apply the advance informed agreement procedure set out in this section.

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

(3) The acknowledgement in subsection (2) shall be in writing and shall include the following particulars

- (a) the date of receipt of the application;
- (b) that the notification, prima facie, contains the information required under section ;

(c) that the applicant must proceed in accordance with this Act.

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

(5) Subject to section , the Biosafety 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 Biosafety Board.

(6) The Biosafety Board shall, within ninety days, inform the applicant, in writing whether the import may proceed

(a) only after the Biosafety Board has given its written consent;

(b) after no less than ninety days without a subsequent written consent;

(7) Within two hundred and seventy days of the date of receipt of the application, the Biosafety Board shall communicate in writing, to the applicant the decision referred to in subsection (6):

(a) approving the import, with or without conditions;

(b) prohibiting the import;

(c) request additional relevant information.

(8) In calculating the time within which the Biosafety Board is to respond, the number of days the Biosafety Board has to wait for additional relevant information shall not be taken into account and the Biosafety Board shall notify the applicant that the period specified in this section is extended by a defined period of time.

(9) A failure by the Biosafety Board to communicate its decision within two hundred and seventy days of the date of receipt of the application shall not imply its consent to the import.

Denial of
application

20. (1) The Biosafety Board may deny an application for a licence to import on any of the following grounds

- (a) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the Biosafety Board;
- (b) 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 and animal health.
- (c) if the genetically modified organism is likely to have an adverse negative effect on social and/or economic situation in the country, especially with regard to the value of biological diversity to indigenous and local communities.

(2) Where the Biosafety Board denies an application in accordance with subsection (1), it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

(3) Whenever the Biosafety Board denies an application under subsection (2), it shall cause notice of the revocation to be published in the Gazette and in the newspaper or other publication as it may think fit in the circumstances.

Approval of application

21. (1) The Biosafety Board may, before approving an application for importation consider all objections and information made available to it.

(2) Where the Biosafety Board approves an application in accordance with section 20, it may issue to the applicant a licence

- (a) including information on how the decisions will apply to subsequent imports of the same genetically modified organism;
- (b) subject to the terms and conditions the Biosafety Board finds necessary; and
- (c) in the prescribed form;
- (d) be accompanied by the fee prescribed in the Regulations.

(4) Where the Biosafety 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.

(5) Whenever the Biosafety Board grants a licence under this section, it shall cause notice of the grant to be published in the Gazette and in the newspaper or other publication as it may think fit in the circumstances.

Categories of
import
licences

20. (1) An import licence granted under this Act shall be in the following categories

- (a) intentional introduction into the environment for the purpose of importing a genetically modified organism for intentional introduction into the environment;
- (b) domestic use for the purpose of importing a genetically modified organism for domestic use;
- (c) contained use for the purpose of importing a genetically modified organism for contained use.

PART IV

EXPORTS

Restriction on
export

22. (1) No person shall export a genetically modified organism unless a licence is granted under this Act to export that genetically modified organism.

(2) A person who contravenes this section commits an offence and is liable on summary conviction to a fine not exceeding one hundred thousand dollars or to imprisonment for a term not exceeding two years or to both, and in the case of a continuing offence to a fine not exceeding ten thousand dollars for each day that the offence continues.

Application
for licence

23. (1) A person who is desirous of exporting a genetically modified organism must apply to the Biosafety Board for the grant of a licence after that person has notified the country of import.

(2) An application under subsection (1) must

- (a) be filed with the Director;

- (b) contain a written advance informed agreement of the competent authority of the country of import;
- (c) be in the prescribed form; and
- (d) be accompanied by the fee prescribed in the Regulations.

(3) Upon receipt of an application, the Biosafety Board shall publish the application in the Gazette and at least one newspaper of general circulation.

Opposition
to licensing

24. (1) Any interested person may, within the prescribed period and in the prescribed manner, give notice to the Biosafety Board of opposition to the licensing of the living modified organism.

(2) The Biosafety Board shall send a copy of the notice to the applicant, and, within the prescribed period and in the prescribed manner, the applicant shall send to the Biosafety Board a counter-statement of the grounds on which he relies for his application; if he does not do so, he shall be deemed to have abandoned the application.

(3) If the applicant sends a counter-statement, the Biosafety Board shall furnish a copy thereof to the person giving notice of opposition and, after hearing the parties, if either or both wish to be heard, and considering the merits of the case, shall decide whether the living modified organism should be licensed.

Denial of
application

25. (1) The Biosafety Board may deny an application for a licence to export a genetically modified organism on any of the following grounds

- (a) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the Board;
- (b) if the living modified organism is likely to have an adverse effect on conservation and sustainable use of biological diversity, taking into account risks to human and animal health;
- (c) if the applicant does not submit a written advance informed agreement from the country of import;

- (d) if the export genetically modified organism is restricted by law.

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

(3) Whenever the Biosafety Board denies an application under subsection (2), it shall cause notice of the revocation to be published in the Gazette and in the newspaper or other publication as it may think fit in the circumstances.

Approval of application

26. (1) If the Biosafety Board is satisfied that the export may proceed, the Biosafety Board may grant the application and issue to the applicant a licence

- (a) subject to the terms and conditions the Biosafety Board finds necessary;
- (b) in the prescribed form;
- (c) be accompanied by the fee prescribed in the Regulations.

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

(3) Whenever the Biosafety Board grants a licence under this section, it shall cause notice of the grant to be published in the Gazette and in the newspaper or other publication as it may think fit in the circumstances.

PART V

CONTROL OF MOVEMENT

Restriction on movement

27. (1) No person shall move a genetically modified organism within Saint Vincent and the Grenadines unless a licence is granted under this Act to move that genetically modified organism.

(2) A person who contravenes this section commits an offence and is liable on summary conviction to a fine not exceeding one hundred thousand dollars or to imprisonment for a term not exceeding two years

or to both, and in the case of a continuing offence to a fine not exceeding ten thousand dollars for each day that the offence continues.

Application
for licence

28. (1) A person who is desirous of moving a genetically modified organism must apply to the Biosafety Board for the grant of a licence.

(3) An application under subsection (1) must

(a) be filed with the Director;

(b) be in the prescribed form;

(c) be accompanied by the fee prescribed in the Regulations.

(3) Upon receipt of an application, the Biosafety Board shall publish the application in the Gazette and at least one newspaper of general circulation.

Opposition to
licensing

29. (1) Any interested person may, within the prescribed period and in the prescribed manner, give notice to the Biosafety Board of opposition to the licensing for the movement of the genetically modified organism.

(2) The Biosafety Board shall send a copy of the notice to the applicant, and, within the prescribed period and in the prescribed manner, the applicant shall send to the Biosafety Board a counter-statement of the grounds on which he relies for his application; if he does not do so, he shall be deemed to have abandoned the application.

(3) If the applicant sends a counter-statement, the Biosafety Board shall furnish a copy thereof to the person giving notice of opposition and, after hearing the parties, if either or both wish to be heard, and considering the merits of the case, shall decide whether the genetically modified organism should be licensed.

Denial of
application

30. (1) The Biosafety Board may deny an application for a licence to move a genetically modified organism on any of the following grounds

(a) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the Biosafety Board;

(b) 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 and animal health.

(2) Where the Biosafety Board denies an application in accordance with subsection (1), it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

(3) Whenever the Biosafety Board denies an application under this section, it shall cause notice of the denial to be published in the Gazette and in the newspaper or other publication as it may think fit in the circumstances.

Approval of application

31. (1) If the Biosafety Board is satisfied that the movement may proceed, the Biosafety Board may grant the application and issue to the applicant a licence

- (a) subject to the terms and conditions the Biosafety Board finds necessary; and
- (b) in the prescribed form;
- (c) be accompanied by the fee prescribed in the Regulations.

(4) Where the Biosafety 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.

(5) Whenever the Biosafety Board grants a licence under this section, it shall cause notice of the grant to be published in the Gazette and in the newspaper or other publication as it may think fit in the circumstances.

PART VI

ENFORCEMENT

32. (1) For the purpose of ensuring compliance with this Act, an inspector may

Power of entry and search

- (a) stop any conveyance, which the inspector believes on reasonable grounds may harbour a genetically modified organism;

- (b) subject to subsections (2) and (3), at a reasonable time, enter and inspect any premises, not being a dwelling house;
- (c) open any container, receptacle or other thing that the inspector believes on reasonable grounds contains any thing in respect of which this Act applies;
- (b) examine any thing in respect of which this Act applies and take samples of it.

(2) An inspector may not enter a dwelling house except with the consent of the occupier or under the authority of a warrant issued by a magistrate.

(3) An inspector may, with a warrant issued by a magistrate, enter and search any premises, where there is reasonable cause to believe that an offence against this Act has taken or is taking place.

(4) An inspector may, in the performance of his duties under this section, be accompanied and assisted by a police officer.

33. (1) In the course of an inspection carried out under this Act, if an inspector believes on reasonable grounds that the provisions of this Act have been or are being contravened, or any genetically modified organism presents a risk, the inspector may seize the genetically modified organism

Seizure and notice of seizure

- (a) by means of or in relation to which he believes on reasonable grounds that the contravention has been or is being committed;
- (b) that he believes on reasonable grounds will afford evidence in respect of the contravention of the provisions of this Act.

(2) An inspector who seizes and detains a genetically modified organism shall, as soon as is practicable, advise the owner of the genetically modified organism of the reason for the seizure and that some or all of the genetically modified organism may be subject within a specified time to any action specified in section 28.

34. An inspector who seizes and detains a genetically modified organism may

Storage, removal etc.

- (a) store, treat, quarantine or dispose of the genetically modified organism at the place where it was seized or move it to any other place for storage, treatment, quarantine or disposition;
- (b) require its owner to store, treat, dispose of, export or move it to any other place.

35. (1) Where a person is convicted of an offence under this Act, the court may, in addition to any penalty imposed, order that any thing used in the perpetration of the offence be forfeited to the Crown and shall be disposed of as the Minister may direct.

Forfeiture

(2) Where the owner of a thing that is seized and detained under this Act consents to the seizure and detention, it is thereby forfeited to the Crown and shall be disposed of as the Minister may direct.

36. (1) An inspector may confiscate and dispose of

Confiscation and disposal

- (a) any genetically modified organism that, after its entry into Saint Vincent and the Grenadines or after treatment, lies unclaimed for a prescribed time;
- (b) any thing that the inspector believes on reasonable grounds is a risk.

(2) An inspector who confiscates a genetically modified organism shall, forthwith, advise the owner of the reason for its confiscation.

37. (1) The Cabinet may, out of money voted for that purpose by Parliament, order compensation to be paid to occupiers or owners of premises in respect of healthy genetically modified organisms destroyed in order to restrict the risk to human and animal health.

Compensation

(2) No compensation is payable to a person who commits an offence under this Act and claims compensation in respect of any premises or thing by means of or in relation to which the offence was committed.

Remedial measures

7. If the Biosafety Board is satisfied that the licensee is engaging in unsafe transfer, handling and use of living 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 and animal health, the Biosafety Board may take one or more of the following actions:

- (a) issue a written warning as is deemed necessary;

- (b) make a written agreement with the licensee providing for a programme of remedial action;
- (c) issue a cease or desist order that requires the licensee to cease or desist from the practice or violations specified in the order; or
- (d) issue any directions it deems necessary to the licensee.

PART VII

MISCELLANEOUS

38. (1) The Biosafety Board in reaching a decision shall take into account the best available scientific evidence or ecological principles, but where little or no scientific evidence is available, the Biosafety Board reach a decision 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 and animal 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.

39. (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.

Risk
assessment

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

(3) The Biosafety 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 Biosafety 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 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 centers 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 Biosafety Board shall, in evaluating the risk assessment report, in addition to the guidelines, also consider and duly determine whether the import of the genetically modified organism or product will

- (a) benefit the country; and
- (a) contribute to, and not undermine, sustainable development.

(8) The Biosafety 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 Biosafety 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 Biosafety 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 consideration

40. The Biosafety 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

41. (1) The Biosafety 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 and animal health, review and change a decision regarding an import or export.

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

(3) An applicant may request the Biosafety Board to review a decision it has made in respect of it 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), the Biosafety Board shall respond in writing to such a request within ninety days and set out the reasons for its decision.

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

Risk
management.

42. (1) The Biosafety 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 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 into account risks to human and animal health, within the country.

(3) The Biosafety Board 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.

Notification
of
unintentional
movement.

43. (1) The Biosafety 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 living 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 and animal health in such countries.

(2) The notification referred to in subsection (1) shall be provided as soon as the Biosafety 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 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 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 and animal 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 and animal health, the Biosafety Board shall immediately consult the affected or potentially affected countries to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Notification
of new
information

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

Confidential
information.

45. (1) The Biosafety 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 Biosafety 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 Biosafety Board shall protect confidential information received under this Act.

(4) The Biosafety 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 Biosafety Board shall respect the confidentiality of commercial and industrial information, including research and

development information as well as information on which the applicant disagree as to its confidentiality.

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

- (a) the name and address of the applicant;
- (b) a general description of the living 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 and animal health; and
- (d) any methods and plans for emergency response.

Identification
and labelling

46. (1) The Biosafety Board shall take necessary measures to require that living modified organisms that 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 and animal health.

(2) A licensee shall ensure that documentation accompanying

- (a) genetically modified organisms that are intended for direct use as food, feed or processing, are clearly labeled to identify that it “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) living modified organisms that are destined for contained use
 - (i) are clearly labeled to identify 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) living modified organisms that are intended for intentional introduction into the environment of the country and any other living modified organism
 - (i) clearly identifies them as living 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; and
 - (iii) contains a declaration that the import or export is in conformity with the requirements of this Act applicable to the licensee.

- Offences
47. (1) A person who
- (a) assaults, resists, threatens, intimidates, or obstructs an inspector exercising lawful powers under this Act;
 - (b) tampers with any samples taken under section (1)(d);
 - (c) fails to comply with an order or direction lawfully made or given under this Act;
 - (d) imports or exports a genetically modified organism in contravention of a licence granted under this Act;
 - (e) knowingly or recklessly provides information which is false for the purpose of obtaining any document under this Act;
 - (f) alters, forges, defaces, or destroys any document issued under this Act;

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

- Appeals
48. (1) An appeal from a decision of the Biosafety Board
- (a) to refuse an application;
 - (b) to revoke a licence; or
 - (c) to apply conditions to the issue of a licence,
- or action of an inspector may be lodged with the Tribunal appointed under subsection (2) within three days of the decision or action in respect of which the appeal is made.
- (2) Cabinet shall appoint a Tribunal to hear the appeal which shall consist of one or more persons but not more than three persons.
- (3) The decision of the Tribunal is subject to further appeal in the High Court.
- Amendment of Schedule
49. The Minister acting on the advice of the Biosafety Board may amend the Schedule.
- Regulations
50. (1) The Minister, acting on the advice and recommendation of the Biosafety Board, may make Regulations generally for the purpose of carrying out or giving effect to the provisions of this Act.
- (2) In particular and without prejudice to the generality of the powers conferred by subsection (1) the Minister may make Regulations in respect of
- (a) the forms to be used for the purposes of this Act;
 - (b) fees applicable under this Act;
 - (c) the promotion and regulation of biotechnology research and development;
 - (d) the evaluation of food safety for foods created by biotechnology;
 - (e) the prohibition or restriction of import or export of a genetically modified organism;
 - (f) the standards for handling, storage, transport, packaging and identification of genetically modified organisms;

- (g) the exemption of genetically modified organisms from the provisions of this Act;
- (h) the regulation of the operation of greenhouses, aquaculture facilities, field experiments, remediation, research and laboratories with respect to genetically modified organisms;
- (i) the standards for disposal of waste;
- (j) quarantine of genetically modified organisms;
- (k) the procedure to be followed when a genetically modified organism is in transit;
- (l) the procedure to be followed for clearance of a genetically modified organism;
- (m) any other matters required by this Act to be prescribed.

Schedule

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 and animal health,

Recognizing that modern biotechnology has great potential for human wellbeing if developed and used with adequate safety measures for the environment and human and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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 and animal 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, and experience with, living modified organisms; and
- (b) Assist Parties to implement the Protocol, taking into account the special needs of developing countries, 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 and animal health; and
- (d) Any methods and plans for emergency response.

Article 22
CAPACITY-BUILDING

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

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacitybuilding shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 23
PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

- (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human and animal 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
RESERVATIONS

No reservations may be made to this Protocol.

Article 39
WITHDRAWAL

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

Article 40
AUTHENTIC TEXTS

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

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

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

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS
UNDER ARTICLES 8, 10 AND 13

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

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

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

Annex III
RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human and animal 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 and animal health;
- (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
- (c) An evaluation of the consequences should these adverse effects be realized;
- (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
- (e) A recommendation as to whether or not the risks are acceptable or

manageable, including, where necessary, identification of strategies to manage these risks; and

- (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

- (a) *Recipient organism or parental organisms.* The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;
- (b) *Donor organism or organisms.* Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
- (c) *Vector.* Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;
- (d) *Insert or inserts and/or characteristics of modification.* Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;
- (e) *Living modified organism.* Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;
- (f) *Detection and identification of the living modified organism.* Suggested detection and identification methods and their specificity, sensitivity and reliability;
- (g) *Information relating to the intended use.* Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and
- (h) *Receiving environment.* Information on the location, geographical, climatic and ecological characteristics, including relevant

information on biological diversity and centres of origin of the likely potential receiving environment.

Passed in the House Assembly this day of 2007.

Clerk of the House of Assembly