Government Gazette

REPUBLIC OF SOUTH AFRICA

Vol. 501 Cape Town 17 April 2007 **No. 29803**

THE PRESIDENCY

No. 347 17 April 2007

It is hereby notified that the President has assented to the following Act, which is hereby published for general information:–

No. 23 of 2006: Genetically Modified Organisms Amendment, 2006

GENERAL EXPLANATORY NOTE:

[ ] Words in bold type in square brackets indicate omissions from existing enactments.

Words underlined with a solid line indicate insertions in existing enactments.

(English text signed by the President.)
(Assented to 11 April 2007.)

ACT

To amend the Genetically Modified Organisms Act, 1997, so as to give effect to the Protocol pertaining to genetically modified organism? to which South Africa is patty; to amend certain definitions and to add new definitions: to amend the composition and remuneration of members of the Committee and Council: to amplify the powers and duties of the Council and the Committee and the functions of the registrar; to clarify the procedure relating to the application for and issuing of permits; to provide for risk assessments and liahiiity determinations: to amend tlie information requirements contemplated in the confidentiality clause; to lay down criteria with regard to offences; to provide for certain procedures during an appeal process; and to provide for matters connected therewith.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:—

Amendment of section 1 of Act 15 of 1997

1. Section I of the Genetically Modified Organisms Acl, 1997 (Act No. I5 of 1997). (hereinafter referred to as the principal Act). is hereby amended—

(a) by the substitution for tlie definition of "accident" of the following definition:
" 'accident' means any—
(i) incident involving an [unintended general] unintentional environmental release of genetically modified organisms [which could] that is likely to have an immediate or delayed adverse impact on the environment or on human or animal health within the Republic, or
(ii) unintentional transboundary movement of genetically modified organisms that is likely to have an immediate or a delayed adverse impact on the environment or on human or animal health;";

(b) by the insertion after the definition of "accident" of the following definition:
" 'activity' means my activity with genetically modified organisms but is not limited to the importation, exportation, transit, development, production, release, distribution, use, storage and application of genetically modified organisms only;";

(c) by the insertion after the definition of "applicant" of lhe following definilioii:
" 'hiosafety' means the level of safety when risk management measures must be taken to avoid potential risk to human and animal health and safety and to the conservation of the environment, as a result of exposure to activities with genetically modified organisms, and 'biological safety' shall have a corresponding meaning;";

(d) by the insertion after the definition of "biosafety" of the following definition:

" **'Biosafety Clearing-House'** means an information-sharing exchange mechanism established under Article 20 of the Protocol;";

(e) by the insertion after the definition of "Committee" of the following definitions:

" **'commodity clearance'** means the authorisation to use a genetically modified organism as a food or feed, or for processing, but excludes the planting of a genetically modified organism as a release into the environment;

'conditional general release' means a release of a genetically modified organism under specific imposed conditions to regulate or monitor the use of that genetically modified organism for a specified period of time;":

(f) by the substitution for the definition of "contained use" of the following definition:

" **'contained use'** means **[any activity in nhich organisms are genetically modified or in which such]** the development, production, cultivation, use, application, storage, movement, destruction or disposal of genetically modified organisms **[are cultured, stored, used, transported, destroyed or disposed of and for which]** within a facility, installation or other physical structure, including a greenhouse, that are controlled by specific measures, including physical barriers or a combination of physical barriers together with chemical or biological barriers or both **[are used to limit]**, that effectively limit contact **[thereof]** of the genetically modified organisms with humans, animals and the external environment and their impact on humans, animals and the external environment;";

(g) by the insertion after the definition of "contained use" of the following definition:

" **'Convention'** means the Convention on Biological Diversity;";

(h) by the insertion after the definition of "environment" of the following definitions:

" **'environmental impact assessment'** means the process used to assess the potential impact of an activity on the environment by collecting, organising, analysing, interpreting and communicating information on such activity;

'extension permit' means a permit issued for activities relating to genetically modified organism; for which a permit had been issued previously;";

(i) by the substitution for the definition of "general release" of the following definition:

"**'general release'** means the **[introduction]** release of a genetically modified **[organisms]** organism into the environment by whatever means, where the **[organisms are]** organism is no longer contained by any system of barriers **[and are no longer under any person's control, so that the organism is likely to survive and be disseminated]**;";

(j) by the insertion after the definition of "prescribed" of the following definition:

" **'Pmtocol'** means the Cartagena Protocol on Biosafety to the Convention. thal has been negotiated and adopted by the Parties to the Convention, acceded to by the Republic on 14 August 2003; A copy of the Protocol is attached for information purposes in the Annexure;";

(k) by the insertion after thedefinition of "regulation" of the following definition:

" **'release'** means release into the environment. and includes a trial release, conditional general release and general release;": and

(l) by the insertion after the definition of "this Act" of the following defnition:

" **'transbsundary movement'** means the movement of a genetically modified organism from the Republic to another country or from another country to the Republic;"

(m) by the substitution for the definition of "user" of the following definition:

" **'user'** means a person who conducts an activity with a genetically modified organism,".

hmendment of section 3 of Act 15 of 1997

2. Section 3 of the principal Act is hereby amended—

(a) by the substitution for subsection (1) of the following subsection:

"(1) There is hereby established a **[council]** juristic person to be known as the Executive Council for Genetically Modified Organisms, which shall consist of not more than **[eight]** 10 members appointed by the Minister.";

(b) by the insertion of the following subsection:

"**(IA)** For each member of the Council referred to in subsection (1), the Minister may appoint an alternate. who may attend and vote at the meeting of the Council on behalf of the member if that member is unable to attend"; and

(c) by the substitution for paragraph *(a)* of subsection (2) of the following paragraph:

"*(a)* shall he one officer of each of tlie following national departments of State, nominated by the relevant department:

(i) The Department of Agriculture;

(ii) the Department of **[Arts, Culture,]** Science and Technology;

(iii) the Department of Environmental **Affairs** and Tourism.

(iv) the Department of Health;

(v) the Department of Labour; **[and]**

(vi) the Department of Trade and Industry;

(vii) the Department of **Arts** and Culture; and

(viii) the Department of Water Affairs and Forestry,

who shall have knowledge of the implications of genetically modified organism? with regard io the sector represented by his or her department, including any existing policies and legislation applicable within that sector."

Substitution of section 4 of Act 15 of 1997

3. The following section is hereby substituted for section **4** of the principal Act:

"**Objectives of Council**

4. The Council shall advise tlie Minister on all aspects concerning **[the development, production, use, application and release of]** activities relating to genetically modified organisms, and **[to]** ensure that **[all activities with regard to the development, production, use, application and release of]** such activities **[genetically modified organisms]** are performed in accordance with **[the provisions of]** this Act.".

Substitution uf section 5 of Act 15 of 1997

4. The following section is hereby substituted for section 5 of the **principal** Act:

"Powers nnd duties of Council

5. (1) The Council shall—

(a) where an applicant applies in the prescrihed manner for a permit to conduct activities in respect of genetically modified organisms determine whether that applicant must, in addition to his or her

application, submit an assessment in accordance with the relevant provisions of the National Environmental Management Act, 1998 (Act No. 107 of 1998), of the impact on the environment and an assessment of the socio-economic considerations of such activities;

(b) in consultation with the Committee, decide whether lo approve an application—

(i) for the use of facilities to conduct activities in respect of genetically modified organisms; or

(ii) to conduct any activity, except an activity for which an extension permit is required;

(c) in considering an application have regard to the following factors

(i) Scientifically based risk assessments: and

(ii) proposed risk management measures;

(d) determine, in the event or—

(i) an intentional change in the use of a facility or an activity for which approval was granted; arid

(ii) being notified by the user of any intended change,

whether that user must re-apply for approval:

(e) evaluate whether the user implemented the prescribed notification procedures in accordance wilh article 8 of the Protocol;

(f) in the event of an accident, determine the manner of notification ani the information to he submitted by a user as required in terms of this Act;

(g) advise the Minister on ways In avoid accidents in the Suture and on measures to minimise any adverse impact on the conservation and sustainable use of biological diversity including risks to human and animal health;

(h) implement appropriate measures regarding the manner of notification that must be given to an affected or potentially affected State, the Biosafety Clearing-House aid, where appropriate. any relevant international organisations. of an unintentional transboundary movement that is likely to have an adverse impact on—

(i) the conservation and the sustainable use of biological diversity; or

(ii) human and animal health,

in such an affected or potentially affected State;

(i) provide an affected or potentially affected State with the prescribed information in the notification referred to in paragraph (h);

(j) consult with an affected or potentially affected State immediately after notifying that State of an unintentional transboundary movement referred to in paragraph (h), to enable that State to Lake lhe necessary actions, including emergency measures:

(k) satisfy itself prior to the Republic entering into a bilateral, regional or multilateral agreement or arrangement. including an agreement or arrangement on contingency plans regarding unintentional transboundary movements, that the level of protection of human and animal health and the environment is not lower than Ihe level of protection provided for in the Prolocol, and shall advise the Minister accordingly;

(l) inform the Minister—

(i) of any approval to conduct an activity contemplated in this Act arid to exercise control over such an activity;

(ii) of any notification received of an unintentional transboundary movement, and any relevant information on such transboundary movement:

(iii) in lhe event of an accident, of the proposed control measures to be implemented to contain that accident; and

(iv) of any other matter with regard tu genetically modified organisms:

(m) make recommendations to the Minister on the appointment of members to the Committee;

(n) where the Couiicil has been informed by the registrar that there is a reasonable suspicion that an activity is conducted contrary to this Act or to a condition contained in a permit issued wider this Acl, determine—

(i) a place or facility whereto a geiietically modified organism used in such a activity or any material or substance used, affected or potentially affected by such activity must be removed; and

(ii) appropriate measures for the disposal or repatriation of any geiietically modified organism used iii such activity or any material or substance used, affected or potentially affected by such activity.

(2) The Council may—

(a) before making a decision regarding an application submitted in terms of this section coiisider the following factors:

(i) Public input.

(ii) the environmental impact assessment; or

(iii) the potential socio-economic impact of such activities;

(b) if the Council is satisfied that the application conforms with the factors in suhsection (1)*(c)* or paragraph *in)*, authorise the registrar, in writing. to issue a permit on such term? and conditions as the Council considers necessary:

(c) in the event of an accident, instruct the registrar to appoint a panel tc enquire into and report on the causes of such accident,

(d) where an applicant applies for an entensioii permit, consult with the Committee on such issues as the Council may consider necessary tc come to a decision,

(e) promote co-operntion hetween the Republic and any other country with regard to research, development and technology transfer in the field of genetic modificalion of organisms and biosafety;

(f) with the consent of the Minister, approve and issue guidelines for activities with genetically mdified organisms and make such guidelines available to the public;

(g) if the Council receives new and relevant scientific or technological evidence about activities conducted in term? of tlus Act, which inay have an impact on the factors referred to in subsection (1)*(c)* or paragraph *(a)*, reconsider any decision taken by it:

(h) co-opt any person knowledgeable in a specific field of science to serve on the Couicil in order to advise the Council on matters where the Couiicil considers it necessary;

(i) invite written comments from any person knowledgeable in a specific field of science on any aspect of genelic modification which falls within the Council's functions.".

Amendment of section 7 of Act 15 of *1997*

5. Section 7 of the principal Act is hereby amended—

(a) by the substitution for subsection (3) of the following subsection:

"**(3)** *(a)* A decision of the Council shall be reached on the basis of consensus by all members of the Council.

(b) In tlie event diat the Council fails to reach consensus on a decision such decision shall he considered as having been refused.";

(b) by the insertion of the following subsection:

"(3A) The Council shall convene a special meeting at such time and place and on such date as determined by the chairperson—

(a) on receipt of a written request by the Minister;

(b) on receipt of a written request signed by at least two members; or

(c) in the even1 of an accident contemplated in section 5(1)*(f)*.", and

(c) by the deletion *of* subsections (5) and (6).

Substitution of section *9* of Act 15 of 1997

6. The following section is hereby substituted for Section 9 of tlie principal Act:

"Functions of registrar

9. (1) The registrar shall, subject to the instructions of and conditions laid down by the Council—

Ia) enamine whether an application conform to the requirements of this Act;

(b) issue a permit or an extension permit in the manner prescribed:

(c) amend or withdraw a permit or an extension permit issued under this Act;

(d) satisfy himself or herself that all users apply ihe appropriale measures to protect the environment and human and animal health during the exercise of any activity with genetically modified organisms; and

(e) attend to any nther matter with regard to biosafety of genetically modified organisms.

(2) The registrar shall—

(a) having regard io section 18, maintain a regisler of—

(i) all the facilities that are used for contained use;

(ii) all the trial release sites; and

(iii) the names and addresses of the persons involved with such contained use or trial release;

(b) arrange for an inspection by an inspector, in the manner contemplated in section **15,** of any activities or facilities where such activities are undertaken:

(c) where the registrar has ascertained or suspects on reasonable grounds thal an activity is conducted contrary to this Act or to a condition contained in a permit or an extension permit issued under this Act require the cessation of any such activity:

(d) submit to *the* Council the application for a permit together with all the prescribed documents and any other documentation the Council may require to make its decision; and

(e) communicate to the Biosaiety Clearing-House tlie information specified in the regulations.

(3) The registrar may, subject to such terms and conditions laid down hy the Council, issue an extension permit for an activity in respect of genetically modified organisms for which a pemiit had been issued previously."

Amendment of section 10 of Act *15* of 1997

7. Section 10 of the principal Act is herehy amended by the suhstitution for paragraph *(b)* of subsection (1) of the following paragraph:

"*(b)* two persons shall he from the public sector **[and]**, of which one person shall have knowledge of ecological matters and genetically modified organisms, and the other- person shall have knowledge of the potential impact of genetically modified organisms on human and animal health."

Amendment uf section 11 of *Act* 15 of 1991

8. Section 11 of the principal Act is hereby amended—

(a) by the substitution in paragraph *(b)* of subsection (1) for the words preceding subparagraph (i) of the following words:

advise:, on request or of its own accord. the Minister. the Council, the registrar, other Ministries and appropriate bodies. on matters concerning the genetic modification oi organisnx and. *inter alia.* advise them—"; and

(h) by the substitution for paragraph *id)* of suhsection (1) of the following paragraph:

"*(d)* co-opt or invite written comments from knowledgeable persons in specific fields of science on any aspect of the genetic modification of organisms which lies within the Committee's brief, to assist the Committee in performing its functions."

Amendment of section 12 of Act 15 of 1997

9. Section 12 of the principal Act is hereby mended by the substitution for subsection (1) of the following subsection:

"(1) To members of the Committee. subcommittee members and the **[member]** members referred to in **[section]** sections 3(2)*(c)*, 5(2)*(h)* and 11*(d)* shall he paid such remuneration as the Minister, with the concurrence of the Minister of Finance, may determine."

Amendment of *section* 15 of Act *15* of 1997

10. Section 15 of the principal Act is hereby amended—

fa) by the *substitution* for paragraphs *(c)* and *(d)* of subsection **(4)** of the following paragraphs:

"*(c)* lo seize any appliance, book, statement **[or]**, document or genetically modified organism and take samples of material or substances which appear to provide proof of a contravention oi any provision of this Act:

(d) to give notice to the owner of any material, substance, genetically modified organism appliance. **hook.** statement or document seized under paragraph *(c)* or to the person who had control over it immediately before any Seizure under **[subparagraph]** paragraph *(c)* to remove the seized items at such person's own cost within a period and to a place specified in such notice;" and

(b) by the addition to subsection (4) of the following paragraph

"*(e)* to dispose of or repatriate any genetically modified organism used or any material or substance used, affected or potentially affected if such activity has an adverse impact on the environment or human and animal health.".

Amendment of section 17 of Act 15 of 1997

11. Section 17 of the principal Act is hereby amended—

in) hy the substitution for suhsection (1) of the following subsection:

"(1) Users shall ensure that appropriate measures are taken to avoid an adverse impact on the environment and human and animal health which may arise from the use of genetically modified organisms.";

(b) by the insertion of the following subsection:

registrar of the damage and in consultation with the registrar investigate, assess and evaluate the damage caused hy the activity on the environment and human and animal health and implement measures including hut not limited to—

(b) minimise, contain or prevent the movement of any genetically modified organisms causing the damage in the event that an activity cannot reasonably be avoided or stopped;

(c) eliminate any source of the damage; or

(d) remedy the effects of the damage caused by the activity."; and

(c) by the substitution for subsection (2) of the following subsection:

"(2) The liability for damage caused by **[the use or release of]** activities relating to a genetically modified organism shall be borne by the user concerned: Provided that when such an organism was in the possession of an inspector as set out in section 15 (4), the user concerned at the time of such **[use or release]** activity shall not be held liable for any damage unless such user foresaw or should have foreseen such damage and could or should have prevented the damage but failed to take reasonable action to prevent such damage.

(3) If a person fails or inadequately implements the measures contemplated in subsection (1A), the Council may take any reasonable measures to remedy the situation.".

Insertion of section 17A in Act 15 of 1997

12. The following section is hereby inserted in the principal Act after section 17:

"Recovery of costs

17A. (1) Subject to subsection (2), the Council may recover all costs incurred as a result of it acting under section 17(3) or section 5(1)(*n*).

(2) The Council may in respect of the recovery of costs under subsection (1), claim proportionally from any other person who benefited from the measures undertaken under section 17(3) or section 5(1)(*n*).

13) The costs claimed under subsections (1) and (2) must be reasonable and may include, without being limited to, labour, administrative and overhead costs.

(4) If more than one person is liable under subsection (2), the Council must, at the request of any of those persons, and after having given the others an opportunity to be heard, apportion the liability, but such apportionment does not relieve any of them of their joint and several liabilities for the full amount of the costs.

(5) Any order referred to in subsections (1) and (2) shall have the effect of civil judgment in a magistrate's court.

(6) Any person affected by an order for costs awarded under this section may lodge an appeal to the appeal board in the manner contemplated in section 19."

Amendment of section 18 of Act 15 of 1997

12. Section 18 of the principal Act is hereby amended—

(a) by the substitution for paragraph (a) of subsection (2) of the following paragraph:

"(a) the general description of the genetically modified organisms, the name and address of the applicant, and the purpose of the contained use or release and the location of use:"; and

(b) by the substitution for paragraph (c) of subsection (2) of the following paragraph:

(c) **[the evaluation of foreseeable impacts, in particular any pathogenic or ecologically disruptive imparts]** the summary of the scientifically based risk assessment of the impact on the environment and human and animal health."

Amendment of section 19 of Act 15 of 1997

13. Section 19 of the principal Act is hereby amended—

(a) by the substitution for paragraphs *(a)* and *(b)* of subsection (2) of the following paragraphs respectively:

"*(a)* An appeal board shall be appointed within 60 days from the date of receipt of the appeal by the registrar, provided that the Minister may, if he or she considers it necessary, extend the period by another 30 days and shall consist of **[the person or]** persons who, in the opinion of the Minister, **[has or]** have expert knowledge of the matter on appeal and who **[is or]** are otherwise suitable to **[decide on the issues of]** make a decision on the appeal concerned.

(b) **[IF an appeal board consisting of more than one person is appointed, the]** The Minister shall designate one of the members of the appeal board as chairperson of that appeal board.":

(b) by the substitution for subsection (4) of the following subsection:

"(4) An appeal board may—

(a) confirm, set aside, substitute or amend the decision or action concerned, which is the subject of the appeal;

(b) refer the relevant matter back to the registrar for reconsideration by the Council; **[or]**

(c) after due consideration of the potential risks and potential benefits related to the matter of appeal, make such other order as it may **[deem]** consider fit in order to minimise a significant negative impact on the environment or human and animal health;

(d) in making a decision—

(i) only follow the prescribed procedures; and

(ii) consider new scientific or technical evidence or any other information that is, in the opinion of the appeal board, directly applicable to the appeal."; and

(c) by the substitution for subsection (6) of the following subsection.

"(6) The full decision of an appeal board, together with the reasons therefor, shall be reduced to writing[,] and **[copies thereof shall be]** furnished to the Minister, the registrar and all parties directly involved in the appeal, and made available to the public, within 30 days after the final decision has been taken **[whereupon]:** Provided that the Minister may take such further action as he or she may **[deem]** consider necessary."

Amendment of section 20 of Act 15 of 1997

14. Section 20 of the principal Act is hereby amended—

(a) by the substitution for paragraphs *(a)* and *(b)* of subsection (1) of the following paragraphs respectively:

"*(a)* regarding the applications for and **[the issue of permits]** the period within which a decision on an application must be taken in terms of this Act.

(b) prescribing the procedure to be followed by an applicant for the purpose of drawing up scientifically based risk assessments, **[and]** environmental impact assessments, socio-economic considerations and risk management measures, for submission to the Council in terms of this Act;"; and

(b) by the insertion in subsection (1) of the following paragraphs after paragraph *(p)*

"*(p*A) regarding the content of the information that a user, in the event of any accident involving genetically modified organisms, is required to supply to the registrar;

*(p*B) regarding the manner and content of the information that must be contained in the notification contemplated in section 5(1)*(h)*;

*(p*C) regarding matters concerning the Biosafety Clearing-House;

Amendment of section 21 of *hct* 15 of 1997

15. Section 21 of the principal Act is herehy *mended* by the substitution in subsection (I) for paragraphs *(a)* and *(c)* of the following paragraphs, respectively:

"*(a)* contravenes or Sails to comply with tlus Act, any condition, restriction, prohibition, reservation or directive imposed or issued in term of this Act:

(c) refuses or fails to furnish information or give an explanation or to reply to the best of his or her **[ability]** knowledge to a question lawfully deinanded from or put to him or her by the registrar, Committee, Council or any inspector In the performance of his or her functions in terms of this Act, or furnishes information, an explanation or a reply to the registrar, Committee. Council or any inspector which is false or misleading, knowing that it is false or misleading; or"

Substitution of long title of Act 15 of 1997

16. The following long title is hereby substituted for the long title of the principal Act:

"**ACT**

To provide for measures *to* promote the responsihle development, production, use and application of genetically modified organisms; to **[ensure that]** provide for an adequate level of protection during all activities involving **[the use of]** genetically modified organisms **[(including importation, production. release and distribution) shall he carried out in such a way as to limit possible harmful consequences tu the environment]** that may have an adverse impact on the conservation and sustainable use ol biological diversity, human and animal health; to give attention to the prevention of accidents and the effective management of waste. to establish common measures for the evaluation and reduction of the potential risks arising out of activities involving the use of genetically nioditied organisms; to lay down the necessary requirements and criteria for scientifically based risk assessments, environmental impact assessments, socio-economic considerations and risk management measures; to establish a **[council]** Council for genetically modified organisms; to ensure that genetically modified organisms are appropriate and do not present a hazard to the environment; and to establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms; and to provide for matters connected therewith."

Short title

17. This Act is called the Genetically Modified Organisms Amendment Act, 2006, arid comes into operation on a date **fixed** by the President by proclamation in the *Gazette*.

ANNEXURE

CARTAGENA PROTOCOL ON BIOSAFETY to the Convention on Biological Diversity

The Parties to this Protocol.

Being Parties to the Convention on Biological Diversity. hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and **4,** and Articles 8*(g)* aid 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 biosaiety. 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 nut 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 laking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safely measures for the environment and human health,

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

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

Recognizing that trade and environinent 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 organism? resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity. **taking** also into account risk to human health, and specifically focusing on transboundary movements.

Article 2

GENERAL PROVISIONS

1. Each Party shell take necessary and appropriate legal, adininistrative 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, laking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States mer their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which Slates have in their exclusive economic zones and their

continental shelves in accordance with international law, and the exercise by ships mid aircraft of all States of navigational rights aiid freedoms as provided *lor 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 thal *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 thal Party's other obligations under international law.

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

Article 3

USE OF TERMS

For the purposes of this Protocol

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility. installation or other physical structure. which Involves living modified organisms thal 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 he imported;

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

(h) "Living organism" means any hiological entity capable of transferring or replicating genetic material. including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means tlie application of:

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

h. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination harriers 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 niodified organism from one Party to another Party, save that Cor the purposes of Articles 17 and 24 transhoundary movement extends to movement between Parties and non-Parties.

Article 4

SCOPE

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

Article 5

PHARMACEUTICALS

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

Article 6

TRANSIT AND CONTAINED USE

1. Notwithslanding 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 thal 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* ine 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 sei standards for contained use within ils jurisdiction, the provisions of this Prolocol with respect to the advance informed agreement procedure shall not apply to the transhoundivy movement of living moditied 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 envirnnment 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 I1 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 transhoundivy 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, laking also into account risks to human health.

Article 8

NOTIFICATION

1 The Party of export shall notify, or require the exporter to ensure notification to, in writing, the *competent* national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall coirtain. 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 informalion 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 iiinety 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 he 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 notitier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of iniport 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 wntinp, to the notilier 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 informalion shall not be taken into account: or

(d) Informing the notiiier that the period specifiedin this paragraph is extended hy a defined mnod 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 hased

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

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from laking a decision, as appropriate, with regard to Uie iinport 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 Parlies 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 he 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 informa-

tion shall contain, at a minimum the information specified in Annex Tl. 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 Clewing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 ahove. 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 decisionon the import of living modifiedorganisms intended for direct use as food or feed. *or* for processing. under its domestic regulatory framework that is consistent with the objective of tlus Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of *my* national laws, regulations and *guidelines* applicable to the import of living modified organisms intended for direct use as food or leed. 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-!–louse that its decision prior to the first import of a living modified organism intended fordirect use as food or feed, or for processing. on which information has been provided wider 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 limeframe, not exceeding two hundred and seventy days.

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

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

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed,or lor 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 informalion on potential adverse effects on the conservetion mid sustainable use of biological *diversity*, taking also into account the risks to human health. review and change a decision regarding an intentional transboundary movement. In such case, the Party shall. within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision. as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notilier 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 notilier considers that:

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

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

3. The Party of iinport 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 suhsequent imports.

Article 13

SIMPLIFIED PROCEDURE

1. A Party of import may. provided that adequate measures arc applied to ensure the safe intentional transboundary movement of living modified orga. isms 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 lo be provided in the notifications referred to in paragraph 1 *(a)* above, shall he the information specified in Annex I.

Article 14

BILATERAL, REGIONAL ANI) MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organism, 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 hetween the parties Lo 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 Clexing-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 he bayed, 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 aid sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are camed 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 aid 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 nsk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and

sustainable use of hiological diversity, taking also into account risks to human health, within the territory of the Party of import.

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

4. Without prejudice to paragraph 2 ahove, 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 organism that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account nsks to human health; and

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

Article 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

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

2. Each Party shalt, 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 liviiig 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, laking also into account risks to human health, as well as available information about possible risk management measures;

id) Any other relevant information; and

(e) **A** point of contact for iurther 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 inniiediately consult the affected or potentially affected States to enable them Io 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 hiological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living. modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, Laking into consideration relevant international rules and standards.

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

(a) Living modilied 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 tlie 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 far this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of his 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 mdified organisms are consigned; and

(c) Living modified organisms thal 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. tlie contact point for further information and, as appropriate, the name and address of the importer aid exporter; and contains a declaration that tlir 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 Pi-otocol 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 Secretanat. Each Party shall also designate one or more competent national authorities, which shall be responsihle for performing the adininistrative functions required by this Protocol and which shall he authorized to act on its behalf wilh respect to those functions. A Party may designate a single entity to fulfil tlie functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of ths 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 Secretanat, with its notification thereof. relevant information on tlie respective responsibilities of those authorities. Where applicable, such information shall, at a minimum specify which competent authority is responsihle for which type of living niodified organism. Each Party shall forthwith notify the Secretanat 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 ahove, and shall also make such informalion 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 tlie clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

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

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

2. The Biosafety Clearing-Iiouse shall serve as a means through which information is made available for the purposes of paragraph I 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 Cleannp-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 ol replicable genetic material obtained through the use of modem 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 or the Parties to this Protocol at its first meeting, and kept under review hereafter.

Article 21

CONFIDENTIAL INFORMATION

1. The Party of import shall permit he 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 he treated as confidential. Justification shali he given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that inlormation identified by the notifier as confidential does not qualify lor such treatment and shall, prior to any disclosure, inform the notifier of its decision, providingreasons 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 inforniation 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 inforination for a commercial purpose, except with h e written consent oi 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 he considered confidential:

(a) The name and address of the notifier.

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

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

(d) Any methods and plans for emergency response.

Article 22

CAPACITY-BUILDING

1. Tne Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in hicsafety. 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 nod small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional aiid national institutions arid organizations and, as appropriale, 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 aiid access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account fur capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation. capabilities and requirements of each Party. include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for hiosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also he 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 hiological diversity. taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate. with other States and inteniational bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living mdified organisms identified in accordance with this Protocol that may he 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 arid 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 hetween Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into hilateral, 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 arid. 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 transhouiidary movements.

2. In tlie 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 Clearin:-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 Prolocol, 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 tlie 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 organism. especially on indigenous and local communities.

Article 27

LIABILITY AND KEDKESS

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 lo the appropriale 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 ihe ongoing processes in international law on these matters, and shall endeavour Lo 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 mechanismestablished in Article 21 of the Convention shall. through the institutional structure entrusted with its operation. be the financial mechanism lor this Protocol.

3. Regarding tlie capacity-building referred to in Article 22 of this Protocol, the Conference of the Parlies serving as the meeting of the Parties to this Protocol, in providing puidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall *take* into account tlie need for financial resources by developing country Parties, in particular tlie least developed and tlie small island developing States among them

4. In the context of paragraph 1 ahove, the Parties shall also lake into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, mid of the Parties with economies in transition, in their efforts to identify and implement their capacity-buildins requirements for the purposes of tlie implementation of this Protocol.

5. The guidance to the financial mechanism of the Convenlion 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 tlie 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 non-governmental, 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 oi any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Prolocol. decisions under the Prolocol shall he 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 he 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 Convenlion shall serve as the secretariat to this Protocol.

2. Article **24,** paragraph 1, of the Convention on the functions of the Secretanat shall apply. *mutatis mutandis.* to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services ior this Protocol shall be met by the Parties hereto. The Conierence 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, tlie 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 he determined by the Conierence of the Parties serving as tlie meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Prolocol 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*. Tnese procedures and mechanisms shall include pmvisions to offer advice or assistance, where appropriale. They shall be separate from and without prejudice to, the dispute settlement procedures aid mechanisms established by Article 27 of the Convenlion.

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 efiectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36

SIGNATURE

This Protocol shall he open for signature at the United Nations Office at Nairobi by Stales 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 dale on which Uiat State or regional economic integration organization deposits its instrument of ratification. acceptance, approval or accession. or on the dale on which the Convention enters into force lor that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 ahove, any instrument deposited hy a regional economic integration organization shall not he counted as additional to those deposited by member Slates 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 tlie 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 tlie 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-nmth 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 charactenstics 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 charactenstics 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 ine parental organisms and a description of the habitats where the organism? 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 handhng, storage, transport and use, including packaging. labelling, documentation, disposal and contingency prwedures, 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 niodified organism? on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

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

General principles

3. Risk assessment should he camed 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 nsk.

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 he considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case. depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective. risk assessment entails. as appropriate. the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment. taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized. takiiig into account the level and kind of exposure of the likely potential receiving environment to tlie 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 tlie level of risk, it may he 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 organisins may persist or proliferate;

(*b*) **Donor organism or organisms** Taxonomic Status and common name, source, and the relevant biological characteristics of the donor organisnx:

(*c*) **Vector.** Characteristics of tlie 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 tlie biological characteristics of :he living modified organism and those of the recipient orpanism 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.