GENETICALLY MODIFIED ORGANISMS ACT
NO. 15 OF 1997

Assented to: 20 May 1997 Date of commencement: 1 December 1999

ACT

To provide for measures to promote the responsible development, production, use and application of genetically modified organisms; to provide for an adequate level of protection during all activities involving genetically modified organisms that may have an adverse impact on the conservation and sustainable use of 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 modified 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 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.

[Long Title amended by s. 16 of Act No. 23 of 2006]

INDEX

1. Definitions
2. Application of Act
3. Executive Council of Genetically Modified Organisms
4. Objectives of Council
5. Powers and duties of Council
6. Vacancies in Council
7. Meetings of Council
8. Appointment of registrar
9. Functions of registrar
10. Advisory Committee
11. Functions of Committee
12. Funding
13. Conflict of interest
14. Prohibition of activities concerning genetically modified organisms
15. Inspectors
16. Routine inspections by inspectors
17. Determination of risks and liability
18. Confidentiality
19. Appeals
20. Regulations
21. Offences and penalties
22. Delegation of powers
23. Short title and commencement

1. Definitions

In this Act, unless the context otherwise indicates-

accident means any—

(i) incident involving an unintentional environmental release of genetically modified organisms that is likely to have an immediate or delayed adverse impact on the environment or on human or animal health with 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;

[Definition of accident amended by s. 1(a) of Act No. 23 of 2006]

activity means any 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;

[Definition of activity inserted by s. 1(b) of Act No. 23 of 2006]

appeal board means an appeal board appointed in terms of section 19;

applicant means any person in control of facilities and activities involving genetic modification of organisms and includes "user";

biosafety means the level of safety when risk management measures must be taken t6o 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;

[Definition of biosafety inserted by s. 1(c) of Act No. 23 of 2006]

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

[Definition of Biosafety Clearing-House inserted by s. 1(d) of Act No. 23 of 2006]

Committee means the Advisory Committee established by section 10;

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;

[Definitions of commodity clearance and conditional general release inserted by s. 1(e) of Act No. 23 of 2006]

contained use means the development, production, cultivation, use, application, storage, movement, destruction or disposal of genetically modified organisms 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, that effectively limit contact of the genetically modified organisms with humans, animals and the external environment and their impact on humans, animals and the external environment;

[Definition of contained amended by s. 1(f) of Act No. 23 of 2006]

Convention means the Convention on Biological Diversity;

[Definition of Convention inserted by s. 1(g) of Act No. 23 of 2006]

control means to examine, regulate, manage or direct any activity within a person's jurisdiction;

Council means the Executive Council for Genetically Modified Organisms established by section 3;

department means the Department of Agriculture;

Director-General means the Director-General: Department of Agriculture;

environment means the aggregate of surrounding objects, conditions and influences that influence the life and habits of man or any other organism or collection of organisms;

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 organisms for which a permit had been issued previously;

[Definitions of environmental impact assessment and extension permit inserted by s. 1(h) of Act No. 23 of 2006]

general release means the release of a genetically modified organism into the environment by whatever means, where the organism is no longer contained by any system of barriers;

[Definition of general release amended by s. 1(i) of Act No. 23 of 2006]

gene therapy means a technique for delivering functional genes (to replace aberrant ones) into living cells by means of a genetically modified vector or by physical means in order to genetically alter the living cell;

genetically modified organism means an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and "genetic modification" shall have a corresponding meaning;

hazard means an intrinsic biological, chemical or physical characteristic of a genetically modified organism which could lead to an adverse impact on the environment;

inspector means any person appointed as an inspector in terms of section 15;

Minister means the Minister for Agriculture;

monitoring means the maintaining of regular surveillance over, the checking of, the warning about or the recording of a situation or process;

notification means the presentation to the Council of documents containing the information required by the Council;

officer means an officer as defined in section 1 (1) of the Public Service Act, 1994 (Proclamation No. 103 of 1994), read with section 1 of the Public Service Amendment Act, 1996 (Act No. 13 of 1996);

organism means a biological entity, cellular or non-cellular, capable of metabolism, replication, reproduction or of transferring genetic material and includes a micro-organism;

permit means a permit referred to in section 5(a) and includes a written authority;

prescribed means prescribed by regulation;

Protocol means the Cartagena Protocol on Biosafety to the Convention, that 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;

[Definition of Protocol inserted by s. 1(j) of Act No. 23 of 2006]

registrar means the person appointed under section 8;

regulation means a regulation made under this Act;

release means release into the environment, and includes a trial release, conditional general release and general release;

[Definition of release inserted by s. 1(k) of Act No. 23 of 2006]

risk means the probability of causing or incurring a loss or damage or an adverse impact or a misfortune;

this Act includes the regulations;

transboundary movement means the movement of a genetically modified organism from the Republic to another country or from another country to the Republic;

[Definition of transboundary movement inserted by s. 1(l) of Act No. 23 of 2006]

trial release means the deliberate release of genetically modified organisms into the environment in the open under conditions where the degree of dissemination of the genetically modified organisms is limited by chemical or physical barriers or by built-in barriers which prevent the survival of such organisms in the environment;

user means a person who conducts an activity with a genetically modified organism;

[Definition of user amended by s. 1(m) of Act No. 23 of 2006]

waste means any matter, whether gaseous, liquid or solid or any combination thereof, which is, in the opinion of the person in whose possession or under whose control it is, an undesirable or superfluous by-product, emission, residue or remainder of any process or activity in connection with genetically modified organisms.

2. **Application of Act**

(1) This Act shall apply to-

(a) the genetic modification of organisms;

(b) the development, production, release, use and application of genetically modified organisms (including viruses and bacteriophages); and

(c) the use of gene therapy.

(2) This Act shall not apply to techniques-

(a) involving human gene therapy;

(b) in which recombinant DNA molecules or genetically modified organisms are, not employed-

(i) in *in vitro* fertilisation in humans and animals;
(ii) in conjugation, transduction, transformation or any other natural process; and
(iii) in polyploidy induction;

(c) in which genetically modified organisms as recipient or parental organisms are not employed-

(i) in mutagenesis;
(ii) in the construction and use of somatic hybridoma cells; and
(iii) in cell fusion (including protoplast fusion) of plant cells.

3. **Executive Council of Genetically Modified Organisms**

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

[Amended by s. 2(a) of Act No. 23 of 2006]

(1A) 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.

[Inserted by s. 2(b) of Act No. 23 of 2006]

(2) The members referred to in subsection (1)—

(a) shall be one officer of each of the following national departments of State, nominated by the relevant department:

(i) The Department of Agriculture;
(ii) the Department of Science and Technology;
(iii) the Department of Environmental Affairs and Tourism;
(iv) the Department of Health;
(v) the Department of Labour;
(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 organisms with regard to the sector represented by his or her department, including any existing policies and legislation applicable within that sector;

[Amended by s. 2(c) of Act No. 23 of 2006]

(b) shall include the chairperson of the Committee; and

(c) may include any other person.

(3) The Minister shall designate a chairperson and a deputy chairperson from among the members of the Council.

(4) The deputy chairperson shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to do so.

4. **Objectives of Council**

The Council shall advise the Minister on all aspects concerning activities relating to genetically modified organisms, and ensure that such activities are performed in accordance with this Act.

[Amended by s. 3 of Act No. 23 of 2006]

5. **Powers and duties of Council**

(1) The Council shall—

(a) where an applicant applies in the prescribed 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 to 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 of—

(i) an intentional change in the use of a facility or an activity for which approval was granted; and
(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 with article 8 of the Protocol;

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

(g) advise the Minister on ways to avoid accidents in the future 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 and, 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 presented 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 take the 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 aid animal health and the environment is not lower than the level of protection provided for in the Protocol, and shall advise the Minister accordingly;

(l) inform the Minister—

(i) of any approval to conduct an activity contemplated in this Act and 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 the event of an accident, of the proposed control measures to be implemented to contain that accident; and
(iv) of any other matter with regard to genetically modified organisms;

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

(n) where the Council 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 under this Act, determine—

(i) a place or facility whereto a genetically 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 genetically modified organism used in 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 consider 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 subsection (1)(c) or paragraph (a), authorise the registrar, in writing, to issue a permit on such terms and conditions as the Council considers necessary;

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

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

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

(f) with the consent of the Minister, approve and issue guidelines for activities with genetically modified 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 terms of this Act, which may 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 Council in order to advise the Council on matters where the Council considers it necessary;

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

[Section 5 substituted by s. 4 of Act No. 23 of 2006]

6. **Vacancies in Council**

(1) A vacancy in the Council shall occur when a member-

(a) ceases to be an officer;

(b) is absent without leave from more than three consecutive meetings of the Council;

(c) resigns;

(d) is removed from the office in terms of subsection (2);

(e) dies.

(2) The Minister may at any time remove a member of the Council from office if the Minister is of the opinion that such member is no longer competent to fill his or her office or that he or she has misconducted himself or herself.

(3) A vacancy in the Council shall be filled as soon as practicable in accordance with section 3.

(4) Whenever the Minister is satisfied that any member of the Council is prevented by illness or any other reason from performing the duties of his or her office, the Minister may appoint any other person whom he or she considers suitable to act as the deputy of that member while such member is so prevented, and such deputy shall during the period he or she so acts, perform the functions of the member in whose stead he or she has been appointed so to act: Provided that a person appointed as the deputy of the chairperson or the deputy chairperson shall only perform the duties of an ordinary member, unless the Minister otherwise directs.

7. **Meetings of Council**

(1) Meetings of the Council shall be held at such times and places as the chairperson may determine from time to time: Provided that the first meeting shall be held at a time and place determined by the Minister.

(2) The quorum for any meeting of the Council shall be a majority of the members.

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

(b) In the event that the Council fails to reach consensus on a decision such decision shall be considered as having been refused.

[Sub.s 3(a) and (b) substituted by s. 5(a) of Act No. 23 of 2006]

(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 event of an accident contemplated in section 5(1)(f).

[Sub.s (3A) inserted by s. 5(b) of Act No. 23 of 2006]

(4) The Council may determine its own procedures to be followed at its meetings and cause minutes to be kept of its proceedings.

(5) The Council may co-opt other knowledgeable persons to serve on the Council in order to advise the Council whenever the Council deems it necessary.

(6) The Council may invite written comment from knowledgeable persons on any aspect of genetic modification which lies within the Council's brief.

8. **Appointment of registrar**

(1)(a) As soon as possible after the composition of the Council and whenever necessary thereafter the Minister shall, after consultation with the Council, appoint a suitably qualified and experienced person as registrar.

(b) An appointment under paragraph (a)-

(i) shall terminate if the person resigns as registrar;
(ii) may be terminated by the Minister if the registrar does not perform his or her duties satisfactorily.

(2) The registrar-

(a) is charged with the administration of this Act;

(b) may exercise such powers and perform such duties as may be conferred upon or delegated or assigned to him or her by or under this Act or by the Council.

(3) Whenever the registrar is for any reason absent or unable to perform his or her functions, or whenever a vacancy in the office of the registrar occurs, the Council may designate a member of its staff to act in that capacity until the registrar resumes his or her functions, or a registrar is appointed in terms of subsection (1), and that member has, while so acting, such powers and shall perform such duties of the registrar as may be delegated or assigned to him or her by the Council.

(4) Any action of the registrar may at any time be withdrawn or amended by the Minister.

(5) The Director-General shall designate, subject to the provisions of the Public Service Act, 1994 (Proclamation No. 103 of 1994), as many officers of the department as may be necessary to assist the registrar in the exercise of his or her powers and the performance of his or her duties.

9. **Functions of registrar**

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

(a) examine whether an application conforms 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 the appropriate 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 other matter with regard to biosafety of genetically modified organisms.

(2) The registrar shall—

(a) having regard to section 18, maintain a register 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 that 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 Biosafety Clearing-House the information specified in the regulations.

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

[Section 9 substituted by s. 6 of Act No. 23 of 2006]

10. **Advisory Committee**

(1) There is hereby established an Advisory Committee which shall consist of not more than ten persons appointed by the Minister after the recommendation of the council for a period not exceeding five years of whom-

(a) not more than eight members shall be knowledgeable persons in those fields of science applicable to the development and release of genetically modified organisms;

(b) two persons shall be from the public sector, 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.

[para (b) amended by s. 7 of Act No. 23 of 2006]

(2) The Council shall, in recommending members for appointment to the Committee, endeavour to achieve representation from all the fields of expertise involved with genetically modified organisms.

(3) The Minister shall, after the recommendation of the Council, designate any member of the Committee as chairperson.

(4) In the absence of the chairperson the remaining members of the Committee shall elect an acting chairperson from their number.

(5) The acting chairperson shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to do so.

(6) A member of the Committee whose period of office has expired shall be eligible for reappointment.

11. **Functions of Committee**

(1) The Committee shall-

(a) act as the national advisory body on all matters concerning or related to the genetic modification of organisms;

(b) 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 of organisms and, inter alia, advise them—

[para (b) amended by s. 8(a) of Act No. 23 of 2006]

(i) on all aspects relating to the introduction of genetically modified organisms into the environment;
(ii) on proposals for specific activities or projects concerning the genetic modification of organisms;
(iii) on all aspects concerning the contained use of genetically modified organisms;
(iv) on the importation and exportation of genetically modified organisms; and
(v) on proposed regulations and written guidelines;

(c) liaise, through the relevant national departments, with international groups or organisations concerned with biosafety; and

(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.

[para (d) amended by s. 8(b) of Act No. 23 of 2006]

(2) The Committee may appoint subcommittees to deal with specific matters as required.

12. **Funding**

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

[Sub.s (1) amended by s. 9 of Act No. 23 of 2006]

(2) The Committee shall annually and in accordance with the departmental budgetary programme submit a budget to the Council.

13. **Conflict of interest**

A person appointed to the Committee shall immediately recuse himself or herself as a member of the Committee if a subject matter is in issue in which he or she has any direct or indirect interest or if, for any other reason, there is or there is likely to be a conflict of interest as a result of his or her participation in the proceedings of the Committee.

14. **Prohibition of activities concerning genetically modified organisms**

The Minister may, on the recommendation of the Council, by notice in the *Gazette* prohibit any activity involving genetically modified organisms.

15. **Inspectors**

(1) The registrar may appoint any officer, or with the approval of the Minister, any person who is not an officer, as an inspector to exercise and perform the functions referred to in subsection (4) and in section 16.

(2) Every inspector shall be furnished with a certificate signed by the registrar stating that he or she has been appointed as inspector under this Act.

(3) An inspector shall, at the request of any person affected by the exercise or performance of a function by such an inspector, exhibit the certificate referred to in subsection (2) to such a person.

(4) An inspector may, on the authority of a warrant issued in terms of subsection (5), conduct an investigation to determine whether the provisions of this Act are being or have been complied with, and may, for that purpose during normal office hours and without giving prior notice, enter any place or facility in respect of which he or she has reason to believe that a contravention of the provisions of this Act is taking place-

(a) to inspect any activity or process carried out in or upon such place or facility in connection with any activities referred to in this Act;

(b) to request any information regarding such an activity or process from the owner or person in charge of such place or facility or from any person carrying out or in charge of the carrying out of such activities;

(c) to seize any appliance, book, statement, document or genetically modified organism and take samples of material or substances which appear to provide proof of a contravention of any provision of this Act;

(d) to give notice to the owner of any material, substance, genetically modified organism, appliance, book, statement or document seized under paragraph (c) or to the person who had control over it immediately before any seizure under 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

[paras (c) and (d) amended by s. 10(a) of Act No. 23 of 2006]

(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.

[para (e) added by s. 10(b) of Act No. 23 of 2006]

(5)(a) A warrant referred to in subsection (4) shall be issued by a magistrate who has jurisdiction in the area in which the place or facility in question is situated, and shall only be issued if it appears from information on oath that there are reasonable grounds to believe that any material, substance, appliance, book, statement or document that may relate to a contravention of this Act, is upon or in such place or facility.

(b) A warrant issued in terms of this section shall be executed with strict regard to decency and order.

(6)(a) If no criminal proceedings are instituted in connection with any item referred to in subsection (5)(a), seized in terms of subsection (4), or if it appears that such item is not required at any trial for the purpose of evidence or an order of court, that item shall be returned as soon as possible to the person from whom it was seized.

(b) After the conclusion of criminal proceedings any item seized in terms of subsection (4) and which served as an exhibit in proceedings in which a person was convicted, shall be handed over to the inspector to be destroyed or otherwise dealt with as instructed by the registrar.

16. **Routine inspections by inspectors**

An inspector may during office hours, without warrant, enter any place or facility registered in terms of this Act in order to-

(a) open any container found in or upon such place or facility and which the inspector believes on reasonable grounds to contain material of any genetically modified organism;

(b) examine the material of any genetically modified organism and take samples thereof,

(c) inspect any activity or process carried out in or upon the place or facility in connection with genetically modified organisms; and

(d) require the owner or occupier thereof to produce for inspection or for the purpose of obtaining copies or extracts, thereof or therefrom any book, label, shipping bill, bill of lading or other document with respect to the administration of this Act.

17. **Determination of risks and liability**

(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.

[Sub.s (1) amended by s. 11(a) of Act No. 23 of 2006]

(1A) In the event of damage, a user shall immediately inform the registrar of the damage and in consultation with the registrar investigate, assess and evaluate the damage caused by the activity on the environment and human and animal health and implement measures including but not limited to—

(a) cease, modify or control any act, activity or process causing the damage;

(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.

[Sub.s (1A) inserted by s. 11(b) of Act No. 23 of 2006]

(2) The liability for damage caused by the 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 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.

[Sub.s (2) amended by s. 11(c) of Act No. 23 of 2006]

(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.

[Sub.s (3) inserted by s. 11(c) of Act No. 23 of 2006]

17A. **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).

(3) 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 judgement 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.

[Section (17A) inserted by s. 12 of Act No. 23 of 2006]

18. **Confidentiality**

(1) No person shall disclose any information acquired by him or her through the exercise of his or her powers or the performance of his or her duties in terms of this Act, except—

(a) in so far as it is necessary for the proper application of the provisions of this Act;

(b) for the purposes of any legal proceedings under this Act;

(c) when ordered to do so by any competent court; or

(d) if he or she is authorised to do so by the Minister.

(2) The Council shall decide, after consultation with the applicant, which information will be kept confidential and shall inform the applicant of its decision: Provided that the following information shall not be kept confidential—

(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;

[para (a) amended by s. 12(a) of Act No. 23 of 2006]

(b) the methods and plans for the monitoring of the genetically modified organisms and for emergency measures in the case of an accident; and

(c) the summary of the scientifically based risk assessment of the impact on the environment and human and animal health.

[para (c) substituted by s. 12(b) of Act No. 23 of 2006]

(3) Notwithstanding the provisions of subsection (2), the Council may after consultation with the applicant and if the Council is satisfied on the grounds of information furnished by the applicant that certain information should be withheld in order to protect the intellectual property of the applicant, withhold such information for the period needed to protect such rights.

(4) If, for whatever reasons, the applicant withdraws an application, any party who has knowledge of the details of the application must respect the confidentiality of the information supplied.

19. **Appeals**

(1) A person who feels aggrieved by any decision or action taken by the Council, the registrar or an inspector in terms of this Act may, within the period and in the manner prescribed and upon the payment of the prescribed fee, appeal against such decision or action to the Minister, who shall appoint an appeal board for the purpose of the appeal concerned.

(2)(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 of another 30 days and shall consist of persons who, in the opinion of the Minister, have expert knowledge of the matter on appeal and who are otherwise suitable to make a decision on the appeal concerned.

(b) The Minister shall designate one of the members of the appeal board as chairperson of that appeal board.

[paras (a) and (b) amended by s. 13(a) of Act No. 23 of 2006]

(c) A person appointed under paragraph (a), shall recuse himself or herself as a member of the appeal board if he or she has any direct or indirect interest in the subject matter of the appeal or if, for any other reason, there is or there is likely to be a conflict of interests as a result of his or her participation in the proceedings of the appeal board.

(3) There may be paid to a member of an appeal board who is not in the full-time employment of the State, from money appropriated by Parliament for such purpose, such remuneration or allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

(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;

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

[paras (a), (b) and (c) amended by s. 13(b) of Act No. 23 of 2006]

(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.

[para (d) added by s. 13(b) of Act No. 23 of 2006]

(5) If a decision or action which is the subject of an appeal-

(a) is set aside, the fee referred to in subsection (1) shall be refunded to the appellant concerned; or

(b) is amended, such portion of the fee referred to in subsection (1) as the appeal board concerned may determine, shall be refunded to the appellant.

(6) The full decision of an appeal board, together with the reasons therefor, shall be reduced to writing and 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: Provided that the Minister may take such further action as he or she may consider necessary.

[Sub.s (6) amended by s. 13(c) of Act No. 23 of 2006]

20. **Regulations**

(1) The Minister may make regulations-

(a) regarding the application for and 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, environmental impact assessments, socio-economic considerations and risk management measures, for submission to the Council in terms of this Act;

[paras (a) and (b) amended by s. 14(a) of Act No. 23 of 2006]

(c) prescribing the fees payable in respect of any application, matter or document;

(d) regarding the classification and types of genetically modified organisms;

(e) regarding requirements for the contained use of genetically modified organisms;

(f) regarding requirements for laboratory development of genetically modified organisms;

(g) regarding the standards to which facilities for activities involving genetically modified organisms should conform;

(h) regarding requirements for trial release of genetically modified organisms;

(i) regarding requirements for the effective management of waste;

(j) regarding information to be submitted to the Council in the case of a notification in terms of this Act;

(k) regarding requirements for the general release and marketing of genetically modified organisms;

(l) regarding the importation and exportation of genetically modified organisms;

(m) regarding the registration of a place or facility where activities concerning genetically modified organisms are undertaken;

(n) prescribing-

(i) the manner in which and period within which an appeal under section 18 should be lodged;
(ii) the fee payable in respect of such an appeal;
(iii) the procedure at the proceedings of an appeal board; and
(iv) the period within which an appeal board shall decide on an appeal;

(o) prescribing control measures which shall be complied with by a user;

(p) regarding classes of genetically modified organisms exempted from control under this Act; and

(pA) 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;

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

(pC) regarding matters concerning the Biosafety Clearing-House;

(pD) regarding the manner and content of the notification procedures contemplated in section 5(1)(e).

[paras (pA), (pB), (pC) and (pD) inserted by s. 14(b) of Act No. 23 of 2006]

(q) concerning, generally, any matter which he or she considers necessary or expedient to prescribe in order that the objects of this Act may be better achieved, the generality of the powers conferred by this paragraph not being limited by the provisions of the preceding paragraphs.

(2) Any regulations made under subsection (1) may provide that any person who contravenes or fails to comply with a provision thereof, shall be guilty of an offence and liable on conviction to a fine, or to imprisonment for a period not exceeding two years.

21. **Offences and penalties**

(1) Any person who-

(a) contravenes or fails to comply with this Act, any condition, restriction, prohibition, reservation or directive imposed or issued in terms of this Act;

[paras (a) amended by s. 15 of Act No. 23 of 2006]

(b) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties in terms of this Act or refuses to furnish information as required in terms of this Act to the registrar;

(c) refuses or fails to furnish information or give an explanation or to reply to the best of his or her knowledge to a question lawfully demanded 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

[paras (c) amended by s. 15 of Act No. 23 of 2006]

(d) falsely holds himself or herself out to he an inspector or any other officer appointed in terms of this Act,

shall be guilty of an offence.

(2) Any person convicted of an offence under this Act, shall-

(a) on a first conviction be liable to a fine, or to imprisonment for a period not exceeding two years; and

(b) on a second or subsequent conviction be liable to a fine, or to imprisonment for a period not exceeding four years.

(3) Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty or make any order prescribed by this Act.

22. **Delegation of powers**

The Minister may, subject to such conditions as he or she may determine, in writing delegate any power conferred upon him or her by this Act, other than a power referred to in section 20, to an officer employed by the department, but shall not be divested of any power so delegated and may amend or set aside any decision of the delegate made in the exercise of such power.

23. **Short title and commencement**

This Act shall be called the Genetically Modified Organisms Act, 1997, and shall come into operation on a date to be fixed by the President by proclamation in the *Gazette*.

AMENDMENTS

Genetically Modified Organisms Amendment Act No. 23 of 2006

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)* and 17 of the Convention,

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

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

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

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

Recognising 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,

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

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

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

Have agreed as follows:

Article 1

OBJECTIVE

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

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

Article 2

GENERAL PROVISIONS

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

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

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

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

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

Article 3

USE OF TERMS

For the purposes of this Protocol:

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

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

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

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

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

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

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

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

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

a. In vitro nucleic acid techniques, including recombinant deoxyribo-nucleic 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 organisation" means an organisation 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 authorised, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

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

Article 4

SCOPE

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

Article 5

PHARMACEUTICALS

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

Article 6

TRANSIT AND CONTAINED USE

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

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

Article 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

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

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

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

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

Article 8

NOTIFICATION

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

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

Article 9

ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

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

2. The acknowledgement shall state:

   (a) The date of receipt of the notification;

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

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

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

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

Article 10

DECISION PROCEDURE

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

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

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

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

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

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

   (b) Prohibiting the import;

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

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

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

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

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

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

Article 11

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

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

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

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

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

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

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

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

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

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

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

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

Article 12

REVIEW OF DECISIONS

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

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

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

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

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

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

Article 13

SIMPLIFIED PROCEDURE

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

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

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

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

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

Article 14

BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

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

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

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

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

Article 15

RISK ASSESSMENT

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

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

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

Article 16

RISK MANAGEMENT

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

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

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

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

5. Parties shall cooperate with a view to:

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

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

Article 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

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

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

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

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

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

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

(d) Any other relevant information; and

(e) A point of contact for further information.

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

Article 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

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

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

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

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

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

declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

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

Article 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

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

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

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

Article 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

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

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

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

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

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

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

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

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

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

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

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

Article 21

CONFIDENTIAL INFORMATION

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

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

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

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

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

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

   (a) The name and address of the notifier;

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

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

   (d) Any methods and plans for emergency response.

Article 22

CAPACITY-BUILDING

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

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

Article 23

PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

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

health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

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

Article 24

NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and Non-parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with Non-parties regarding such transboundary movements.

2. The Parties shall encourage Non-parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25

ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalising 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 utilise, where appropriate, the services and cooperation of, and information provided by, competent international organisations 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 specialised 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 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 organisations 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 organisations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organisation 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 organisation 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 organisation, whichever shall be the later.

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

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 authorised to that effect, have signed this Protocol.

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

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8,10 AND 13

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

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

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

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

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

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

(k) A previous and existing risk assessment report consistent with Annex III.

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

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

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

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

Annex II

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

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

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

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

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

Annex III

RISK ASSESSMENT

Objective

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

Use of risk assessment

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

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organisations.

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

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

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

Methodology

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

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

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

   (b) An evaluation of the likelihood of these adverse effects being realised, 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 realised;

(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 realised;

(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.