REVISED AFRICAN MODEL LAW ON BIOSAFETY

PREAMBLE

Whereas, modern biotechnology has promise for the improvement of human well-being, its potential adverse effects on the environment, biological diversity and human health are causing a growing public concern;

Whereas, it is the responsibility of the Government to ensure the safety of the people and the environment with respect to the risks arising from genetically modified organisms (GMOs) and products of genetically modified organisms resulting from modern biotechnology;

Whereas, with the potential risks posed by genetic modification it is consistent with the precautionary principle to regulate any undertaking for the making, import, contained use, release or placing on the market of genetically modified organisms and products of genetically modified organisms;

Whereas, it is important to enhance the capacity, which is necessary to cope with the nature and scale of known and potential risks, associated with genetically modified organisms and products of genetically modified organisms;

Whereas African countries need to deal with imports of genetically modified food through aid or trade;

Noting that the approach to genetically modified organisms will impact on African countries' trade with other countries;

Also noting that rights of local communities to have genetic modification free zones;

Recognising that many African countries are parties to the Convention on Biological Diversity and to its Cartagena Protocol on Biosafety;

Noting that African countries have, through the Cairo Declaration of the Extraordinary Conference of the African Ministerial Council on Science and Technology (AMCOST) re-affirmed that science and technology are key to socio-economic development, economic competitiveness and the attainment of the Millennium Development Goals (MDGs) thereby committing themselves to work together to develop a 20 year African Biotechnology Strategy and to develop and harmonize national and regional regulations that promote the safe use of modern biotechnology;

Noting further that, the Executive Council of the African Union has resolved to take a common approach to address issues pertaining to modern biotechnology and biosafety, through its decision EX. CL/Dec. 26(III);

Now, therefore, it is hereby legislated as follows:

ARTICLE 1: OBJECTIVE OF THE MODEL LAW

(a) To contribute to ensuring an adequate level of safety for the protection of biological diversity, human and animal health, socio-economic conditions and ethical values in the making, safe transfer, handling and use of genetically modified organisms and products of genetically modified organisms resulting from modern biotechnology.

(b) To enable countries that are members of the Cartagena Protocol on Biosafety to implement the provisions of the Protocol at the national level.

ARTICLE 2: DEFINITIONS

For the purposes of this law:

"Advance informed agreement" means consent given by the Competent Authority based upon the full disclosure and taking responsibility for the accuracy of all relevant information by the applicant before any import, export, transit is undertaken on any genetically modified organism or a product of a genetically modified.

"Adventitious presence of GMOs" is the thresholds levels set by the CA, as contemplated by Article 13.

"Applicant" means a person or country submitting an application for approval to make, import, export, use under containment, release or place on the market any genetically modified organism or any product of any genetically modified organism.

"**Biosafety Clearing House**" means the information exchange mechanism established under Article 20 of the Cartagena Protocol on Biosafety.

"**Competent Authority**" means the entity responsible for the implementation of this Law.

"Contained use" means any operation undertaken within an approved facility, installation or other physical structure involving any genetically modified organism or any product of a genetically modified organism that effectively prevent its contact with the external environment.

"Export" means the intentional transboundary movement of a GMO or a product of a GMO from one country to another.

"Exporter" means any person who arranges for a genetically modified organism or a product of a genetically modified organism to be exported.

"Genetically modified organism (GMO)" means any organism that possesses any novel combination or expression as a trait of genetic material obtained through the use of modern biotechnology.

"**Import**" means intentional transboundary movement into one country from another country

"Importer" means any person who arranges for a genetically modified organism or a product of a genetically modified organism to be imported.

"Organism" means any biological entity capable of transferring or replicating genetic material including sterile biological entities, viruses, viroids and plasmids.

"Making" a GMO or a product of a GMO means research on or development of a GMO or a product of a GMO under conditions of containment or release into the environment in field trials.

"**Modern biotechnology**" means the application of:

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

in vitro or in vivo modification of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) so as to change any trait of an organism, or

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.

"National Focal Point" means the entity designated to be responsible on behalf of a country for liaison with the Secretariat of the Cartagena Protocol on Biosafety and the Biosafety Clearing House to facilitate the exchange of information among the relevant bodies and authorities.

"Notification" means providing information to and where appropriate, the lodging of samples with, the Competent Authority, at the same time as taking responsibility for the accuracy and completeness of the information.

"Person" means a juridical or natural person.

"Placing on the market" means making a genetically modified organism or a product of a genetically modified organism available to third parties , whether there has been monetary exchange or not.

"Product of a genetically modified organism" means any material derived by processing, or howsoever otherwise, from any genetically modified organism or from a product of a genetically modified organism.

"Release" means any intentional introduction into the environment of a genetically modified organism or a product of a genetically modified organism. This includes release for: commercial purposes, aid food, remediation, research purposes in field experiments, use in a green houses or in an aqua-culture facility, as animal accommodation, disposal of waste, import, export or transport.

"Risk Assessment" means the identification and evaluation of the direct and indirect potential impacts of a GMO or a product of a GMO on the biological diversity, human and animal health, socio-economic consideration and ethical values of the country which may be posed by the making, import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism. This may include the evaluation of secondary and long-term effects.

"Socio-economic conditions" mean the conditions means the economic, social or cultural conditions, livelihoods, knowledge, innovations, practices and technologies of indigenous and local communities including the national economy.

"Unintentional release" release means a release that takes place without authorization under this law and takes place as a result of adventitious presence of GMOs with non-GMO shipments imported for direct use as food, feed or for processing but excludes an accident.

"Use" excludes the acquisition by purchase or any other legal means by a member of the general public and utilisation or dealing thereafter unless specific conditions are attached to the utilisation.

ARTICLE 3: SCOPE

This legislation shall apply to the making, import, export, transit, contained use, release or placing on the market of any genetically modified organism or any product of genetically modified organism.

ARTICLE 4: INSTITUTIONAL ARRANGEMENTS

1. ***National Focal Point***

The government shall designate or establish a National Focal Point to be responsible on its own behalf for liaison with the Secretariat of the Cartagena Protocol on Biosafety and its Clearing-House and facilitate the exchange of information among the relevant bodies and authorities.

2. ***Competent Authority***

The Government shall designate or establish a Competent Authority to regulate the implementation of this law. The powers and duties of the Competent Authority shall include the following:

a. to prescribe criteria, standards, guidelines and regulations as may be necessary for the fulfilment of the objectives of this law;
b. to take into account the policy recommendations of the National Biosafety Committee in taking decisions on the making, import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism;
c. to develop the terms of reference and rules of procedure of the National Biosafety Committee ;
d. to cause the establishment and monitor the activities of Institutional Biosafety Committees at relevant institutions or nominate independent panels or any other body of experts, as appropriate, as technical and scientific advisors on issues of biosafety;
e. to maintain and make available to the public, a data base on genetically modified organisms and products of genetically modified organisms;
f. to promote public awareness and education concerning the activities regulated under this Law, including through the publication of guidance and other materials that elaborate on the risk assessment, risk management and authorization processes;

g. to establish a mechanism to provide for the public participation in the decision-making process;

h. to establish administrative mechanisms to ensure the appropriate handling, dissemination, and storage of documents and data in connection with the processing of applications and notifications and other matters covered by this Law;

i. to receive applications for making, import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism;
j. to grant or deny approvals for making, import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism predicated on advance informed agreement; and
k. Any other functions as may be specified by the government.

3. National Biosafety Committee

A National Biosafety Committee comprising representatives of governmental and non-governmental organizations, and the private sector that are relevant to the issues of biotechnology and biosafety shall be established by the government to provide, as appropriate, policy recommendations to the Competent Authority.

4. Institutional Biosafety Committee

Institutions that are involved in the making, import, export, handling, contained use, release or placing on the market of genetically modified organisms or products of genetically modified organisms shall establish Institutional Biosafety Committees inter-alia to institute and control safety mechanisms and approval procedures at the institution level.

ARTICLE 5: CONFLICT OF INTEREST

Members of the Competent Authority and National Biosafety Committee shall declare their interests, on a case-by-case basis, with regard to the exercise of any functions as provided by this Law.

ARTICLE 6: APPLICATION

1. No person shall make, import, make contained use of, release, place on the market or cause the movement in transit of a genetically modified organism or a product of a genetically modified organism without the approval of the Competent Authority.
2. Any person who intends to make, import, release, make contained use of or place on the market a genetically modified organism or a product of a genetically modified organism shall submit an application in writing to the competent authority.
3. The application shall include:
    a. the information specified in Annex I and such other information as may be prescribed by the Competent Authority;
    b. risk assessment report with respect to the genetically modified organism or product of a genetically modified organism upon the environment, biological diversity or human health, including the consequences of unintentional release;
    c. information from previous or current release of the genetically modified organism or product of a genetically modified organism by any other country;
    d. If the request for approval is for the purposes of research and development

        i. the recommendations of the Institutional Biosafety Committee;

        ii. a clear and sequential description of the steps to be taken in the implementation of the project, and

        iii. the monitoring and evaluation that will be made at the end of each step, and the method of disposing of any waste.

    e. the place where and the purpose for which the genetically modified organism or the product of a genetically modified organism is planned to be developed, used, kept, released or marketed, including detailed instructions for use and a proposed labelling and packaging scheme in accordance with Annex II, part C of this law; and
    f. a declaration confirming that the information provided is correct.

4. Any person who wishes to import a genetically modified organism or a product of a genetically modified organism for direct use as food or feed, or for processing, shall submit an application in writing with a reference to the information on the item found in the Clearing-House of the Cartagena Protocol on Biosafety, to the Competent Authority.

ARTICLE 7: PUBLIC AWARENESS AND PARTICIPATION

1. The Competent Authority shall, upon receipt of the information referred to under Article 4(3) and Article 4(4), make available the said information to the public and relevant government authorities.
2. The Competent Authority shall take measures to provide for open and transparent consultation with the public, including the holding of public hearings in order to solicit the views of the public in regard to any matter dealt with in this law.
3. The Competent Authority shall make available to the public:

    i. Information on any genetically modified organism or a product of a genetically modified organism, which has been granted or denied approval for making, import, contained use, release or placing on the market; and
    ii. Any risk assessment report with respect to the genetically modified organism or the product of a genetically modified organism.

4. The Competent Authority shall promote awareness and education of the public and those conducting activities on genetically modified organisms or products of genetically modified organisms subject to the law concerning biosafety matters through the publication and dissemination of this law, as well as guidance documents and other materials aimed at improving the understanding of biosafety and related authorization and notification requirements.
5. The Competent Authority shall establish a mechanism of public participation and shall arrange for a public consultation and/or public hearing with regard to any proposed making, import, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism, this fact shall be announced nationally not less than 30 days before the decision is made shall be given for consultation without prejudice to Article 12(1).
6. The public may make comments within such a period and in such a manner as may be specified by the Competent Authority.
7. The Competent Authority shall, in making or reviewing its decision, take into account the views and concerns of the public expressed in accordance with paragraphs (2) and (3) of this Article.

ARTICLE 8: DECISION MAKING PROCEDURE

1. The Competent Authority shall evaluate the information presented by the applicant or given in the Clearing-House of the Cartagena Protocol on Biosafety, as the case may be, and may decide that the applicant:

   a. needs to furnish more information to enable it to make a decision
   b. may proceed with the request;
   c. may proceed with the request with such conditions as it may specify; or
   d. may not proceed with the request.

2. The Competent Authority shall notify the public and the Biosafety Clearing-House of the Cartagena Protocol on Biosafety of its decision.
3. Any approval shall specify that the activity approved shall be carried out step by step and that assessment of risk shall be conducted at each step of development or use, provided that the Competent Authority, may in appropriate cases, not require this procedure if it is satisfied that there would be no significant risk to the environment, biological diversity or human health.
4. Any approval for the making, import, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism shall require the applicant to carry out monitoring and evaluation of risks on a continuing basis.
5. No approval shall be given by the Competent Authority unless there is firm and sufficient evidence that the genetically modified organism or the product of a genetically modified organism poses no significant risks to the environment, biological diversity or human health.
6. In any event, where there is reason to suspect threats of serious damage, lack of scientific evidence shall not be used as a basis for not taking preventive measures.
7. No approval shall be given unless it is considered and duly determined by the Competent Authority that the making, import, contained use, release or placing on the market of the genetically modified organism or the product of a genetically modified organism will:

   a. benefit the country without causing any significant risk to the environment, biological diversity or human health;
   b. contribute to sustainable development;
   c. not have adverse socio-economic impacts; and
   d. accord with the ethical values and concerns of communities and does not undermine local community or indigenous knowledge and technologies.

8. The Competent Authority shall, as a condition for approval, require the applicant to furnish evidence of insurance cover or other financial guarantees sufficient to meet the obligations under this law that extended till the period of liability specified in Article 15(6).

ARTICLE 9: REVIEW OF DECISION

1. Any approval given may be revoked, or subjected to conditions in addition to those originally imposed, if there has been a change in circumstances, or if, in the opinion of the Competent Authority, new information obtained or a review of existing information about the genetically modified organism or the product of a genetically modified organism indicates risks to the environment, biological diversity or human health.
2. Where information becomes available after approval on the possible risks to the environment, biological diversity or human health, the applicant shall immediately notify the Competent Authority.

ARTICLE 10: RISK ASSESSMENT

1. The applicant shall carry out or cause to be carried out an assessment of any risks associated with a genetically modified organism or a product of a genetically modified organism which is subject of an application.
2. The advance informed agreement procedure shall not apply to any application on the import, export or transit of a GMO or a product of a GMO that has been identified in a decision of the COP-MOP as being not likely to have adverse effects on the environment, biological diversity or human health under Article 7(4) of the Cartagena Protocol on Biosafety*.*
3. The risk assessment of a genetically modified organisms or a product of a genetically modified organism shall be carried out by the applicant or the Competent Authority as appropriate, on a case by case basis and shall be done in accordance with Annex III
4. The Competent Authority shall evaluate or cause the evaluation of the risk assessment report and consider the result of such an evaluation in making a decision on any application to make, import, make contained use of, release or place on the market a genetically modified organism or a product of a genetically modified organism.
5. In any case where the evaluation of the assessment shows that risks cannot be avoided, the Competent Authority shall refuse approval for the making, import, contained use, release or placing on the market the genetically modified organism or a product of a genetically modified organism.
6. The Competent Authority may, as necessary, conduct or cause to be conducted the risk assessment.
7. The Competent Authority may require the applicant to bear all the costs for evaluating the risk assessment report or of carrying out the risk assessment, as the case may be.

ARTICLE 11: RISK MANAGEMENT

1. The Competent Authority shall impose such measures, as may be necessary, to avoid adverse effects on the environment, biological diversity and human health, including on the socio-economic conditions, arising from a genetically modified organism or a product of a genetically modified organism.
2. Without limiting the generality of paragraphs 9(1), the Competent Authority shall:

a. subject any genetically modified organism to undergo a period of observation commensurate with its life-cycle or generation time, at the cost of the applicant, before it is put to its intended use;
b. prohibit the making, import, contained use, release or placing on the market of any genetically modified organism or the product of a genetically modified organism if it contains characteristics or specific traits which pose unacceptable risks to the environment, biological diversity, human health, socio-economic conditions or cultural norms;
c. order the cessation of any activity, which is being undertaken in violation of any of the provisions of this law or any decisions made under it;
d. order the cessation of any activity involving a genetically modified organism or a product of a genetically modified organism that is known to cause risks to the environment, biological diversity or human health, socio-economic conditions or cultural norms;
e. require the person responsible for any activity under this law to take such measures as may be necessary to prevent or limit any harm to the environment, biological diversity, human health, socio-economic conditions or cultural norms, or to restore the environment to its previous state as far as is feasible.
f. undertake measures, as necessary, at the cost of the person responsible, in the event that the person responsible fails to undertake safety measures prescribed by the Competent Authority;
g. take measures, as necessary, in the case of imminent and serious danger to the environment, biological diversity, human health, socio-economic conditions, cultural norms or *ordre public* caused by a genetically modified organism or a product of a genetically modified organism, at the cost of the person responsible for the genetically modified organism or product of a genetically modified organism that is causing such danger; and

3. The applicant shall submit to the Competent Authority periodic reports for review in respect of the monitoring and evaluation of risks carried out after the approval of the making, import, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism.

ARTICLE 12: ACCIDENTS AND EMERGENCY MEASURES

1. The Competent Authority shall, as necessary, ensure, before any making, import, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism is made that:

   a. an emergency plan is drawn up by the applicant for the protection of the environment, biological diversity and human health in the event of an unintentional or accidental release; and

b. information on safety measures and procedures to adopt in the case of an accident is made available by the applicant to persons likely to be affected by the accident. The information shall be updated and made available periodically. It shall also be made available to the general public.

2. The applicant shall inform the Competent Authority immediately of any accident and provide the following information:

a. The circumstances of the accident;
b. The identity and quantity of the genetically modified organism or products of genetically modified organism released unintentionally;
c. Any measures necessary to assess the effects of the accident on the environment, biological diversity or human health; and
d. The emergency measures taken by the applicant or measures to be taken by the government.

3. Upon receipt of the information under Article 10(2), the Competent Authority shall:

a. Ensure that all measures possible have been taken to neutralize risks to human health and biological diversity;
b. Inform other relevant government and non-government organizations within the country; and
c. Inform the Competent Authorities or other relevant government organizations in countries likely to be affected and the Biosafety Clearing House.

ARTICLE 13: ADVENTITIOUS PRESENCE

1. The Competent Authority shall put in place appropriate thresholds for the adventitious presence of GMOs that are contained in non-GMO shipments imported for the purposes of aid food and placing on the market as direct use for food, feed and processing.
2. Notwithstanding the provisions of Article 13 (1) above, the Competent Authority shall endeavour to set threshold levels below a level of 0.9% for adventitious presence of GMOs.
3. The provisions of Article 13 (2) and 13 (3) shall not apply to GMOs imported where if there is a high probability that such GMOs may be cultivated.
4. An Exporter shall be required to declare that there is no adventitious presence in GMOs imported other than as aid food and placing on the market for direct use as food, feed and processing as contemplated in this section.

ARTICLE 14: IDENTIFICATION AND LABELLING

1. The Competent Authority shall put in place measures to ensure that any genetically modified organism or any product of a genetically modified organism is handled, packaged and transported under conditions of safety.
2. Any genetically modified organism or product of a genetically modified organism shall be clearly identified and labelled as such, and the identification shall specify the relevant traits and characteristics given in sufficient detail for purposes of traceability.
3. Any genetically modified organism or any product of a genetically modified organism shall be clearly labelled and packaged using the information specified in Annex II Part C, and shall comply with such further requirements imposed by the Competent Authority, to indicate that it is, or has been derived from, a genetically modified organism, and where applicable, whether it may cause allergies or pose other risks.

ARTICLE 13: DOCUMENTATION AND IDENTIFICATION

(1) Subject to the provisions of Article 13(2), the Competent Authority shall take measures to ensure the use of an appropriate document to accompany GMOs imported, in order to give effect to the Cartagena Protocol on Biosafety, taking into account international rules and practises for the identification of GMOs.

(2) The Competent Authority shall take measures to ensure the use of an appropriate document, including the stand alone document as set out in Annex V that should accompany GMOs imported as aid food, and placing on the market for the purposes of direct use as food, feed and processing.

(3) The Competent Authority shall ensure the documentation referred to in Article 13(2) above, clearly states:

   (a) that the shipment contains GMOs;
   (b) whether the GMOs constituting the shipment has been approved in the country of export;
   (c) that the GMOs are for aid food or placing on the market as direct use as food, feed or processing and no other use;
   (d) the common, scientific, and where available, commercial names of the GMO;
   (e) the transformation event code of the GMO or where available, as key to accessing information in the Biosafety Clearing-House, or its unique identifier code; and
   (f) The Internet address of the Biosafety Clearing-House for further information

(4) The Competent Authority shall provide for the taking of appropriate measures for redress in the event of non-compliance with the provisions contained in this Article, including the return and repatriation of the GMOs in question, at the expense of the exporter.

ARTICLE 14: CONFIDENTIAL BUSINESS INFORMATION

1. The Competent Authority shall protect information, which it determines as being confidential after a claim for confidentiality has been made by the applicant.

2. In no case may the following information supplied by the applicant be kept confidential:
   a. description of the genetically modified organism or the product of a genetically modified organism, names and addresses of the applicant, purpose and location of the making, import, contained use, release or placing on the market of the genetically modified organism or the product of a genetically modified organism;
   b. methods and plans for monitoring the genetically modified organism or the product of a genetically modified organism and for emergency response; and
   c. the risk assessment report, in particular any pathogenic and/or ecologically disruptive effects.

3. The Competent Authority may make available the information, referred to in Article 4(3) and 4(4), to the public pursuant to Article 5(1), notwithstanding that it may be commercially confidential if it decides that it is in the public interest to do so.

4. If the applicant withdraws the application before approval, the Competent Authority must respect the confidentiality of the information except for the information referred to in Article (2) and (3).

5. Any person carrying out any activity covered by this law shall supply information necessary for the Competent Authority to carry out its supervisory or monitoring or enforcement tasks or to deal with any emergency measures in relation to the activity and a claim of confidentiality shall not be a bar to availing such information.

ARTICLE 15: EXPORT

1. Any person who intends to export a genetically modified organism or a product of a genetically modified organism shall provide to the Competent Authority a written advance informed agreement of the Competent Authority of the importing country.
2. The presentation of the advance informed agreement from the Competent Authority of the importing country shall in no way absolve the exporter from complying with any other laws governing foreign trade.
3. The submission of the advance informed agreement shall not prevent the country of the exporter from taking into account other considerations in deciding whether or not to approve the export.
4. There shall be no authorization for the re-export of a genetically modified organism or product of a genetically modified organism that has been banned by the laws of the exporting country.

ARTICLE 16: CAPACITY-BUILDING

The Competent Authority shall put in place measures to ensure 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 law.

ARTICLE 17: LIABILITY AND REDRESS

1. Irrespective of the authorization given by the Competent Authority, a person who makes, imports, makes contained use of, releases or places on the market a genetically modified organism or a product of a genetically modified organism shall be liable for any harm caused by such a genetically modified organism.
2. Liability shall attach to the applicant as well as to the provider, supplier or developer of the genetically modified organism or of the product of a genetically modified organism for any damage, injury or loss caused by the genetically modified organism or the product of a genetically modified organism.
3. If there is more than one person responsible for the damage, injury or loss, then the liability shall be joint and several.
4. Any harm, damage, injury or loss caused by a GMO or a product of a GMO shall be fully compensated.
    a. In the case of harm to the environment or biological diversity, compensation shall include the costs of reinstatement, rehabilitation or clean-up measures which actually are being incurred and, where applicable, the cists of preventive measures.
    b. In case of harm to human and animal health legal action should be taken against the responsibly party, and the resulting decision will determine, as the case may be:

        i. The amount of medical expenses;
        ii. Compensation for any disability suffered; and
        iii. Compensation for loss of life.

5. Liability shall also extend to harm or damage caused directly or indirectly by the genetically modified organism or product of the genetically modified organism to the economy or social or cultural conditions or the livelihood or indigenous knowledge systems or technologies of a community or communities. Such harm includes: loss of life, disruption or damage to production systems, agricultural systems, reduction in yields, soil contamination, damage to the biological diversity, damage to the economy of an area or community, or any other consequential disorder.
6. The right to bring any action in respect of the harm caused by a genetically modified organism or a product of a genetically modified organism shall lapse only after a 10 years period from the date on which the affected person or the community could reasonably be expected to have learned of the harm, taking due account of:

a. The time the harm may take to manifest itself; and
b. The time that it may reasonably take to correlate the harm with the genetically modified organism or the product of the genetically modified organism having regard to the situation or circumstance of the person or community affected.

7. Any person, group of persons, or any private or state organisation is entitled to bring a claim and seek redress in respect of the breach or threatened breach of any provision relating to damage to the environment, to biological diversity, to human health or to socio economic conditions:

a. In that person's or group of person's interest;
b. In the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;
c. In the interest of, or on behalf of, a group or class of person whose interests are affected;
d. In the public interest; and
e. In the interest of protecting the environment or biological diversity.

8. No costs shall be awarded against any of the above persons who fail in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or in the interest of protecting human health, biological diversity and, in general, the environment or biological diversity.

ARTICLE 18: OFFENCES AND PENALTIES

1. Any person who

a. makes, imports, transits, releases, places on the market or makes contained use of, any genetically modified organism or products of a genetically modified organism without the written approval of the Competent Authority;

b. violates any conditions attached to the grant of approval under this law;

c. fails to furnish any information as required by the provisions of this law;

d. discloses any confidential information;

e. provides false, misleading or deceptive information in order to secure an approval under section 4.3;

f. does not provide additional information obtained on the possible risk to the environment, biological diversity or human health after approval has been granted as per Article 7 (2);

g. does not label, package or identify any genetically modified organism or products of a genetically modified organism in accordance with this law or with any conditions imposed under this law;

h. labels, packages or identifies any genetically modified organism or products of a genetically modified organism in a manner that is false, misleading or deceptive or is in contravention of any regulation made under this law;

i. exports a genetically modified organism or products of a genetically modified organism without the advance informed agreement of the importing country;

j. participates in any proceedings related to decision taking in respect of a subject matter covered by this law in which he/she has any direct or indirect interest of any kind;

k. violates any other provision of this law or any condition or requirement imposed under this law;

l. fails to report damage.

commits an offence.

2. Any person shall upon conviction of an offence be prohibited from engaging in any activity in relation to any genetically modified organism or any product of a genetically modified organism.

   Such order of prohibition shall extend to any corporation, body or legal entity that may be devised to avoid the effect of the said order.

3. Any person who repeatedly commits any other offence under this law may be prohibited from engaging in any activity in relation to any genetically modified organism and any product of a genetically modified organism.

4. Where the offence is committed by a corporation, and where the court feels that a custodial sentence ought to be imposed, the executive officer in charge at the time the offence is committed shall be liable to imprisonment.

ARTICLE 19: COMMUNITY RIGHTS FOR GM FREE ZONES

Taking into account the provisions of Article 26 of the Cartagena Protocol on Biosafety and the provisions of the Convention on Biological Diversity on the conservation and sustainable utilization of biological diversity:

1. The Competent Authority shall develop policies that protect the rights of communities to declare GMO free zones.
2. The Competent Authority shall take measures for the creation of geographical areas that are declared as 'GMO free zones' where the release of any GMO is prohibited.

ARTICLE 20: APPEAL

1. Any person aggrieved by any decision within and outside of the Competent Authority may, at any time within the period of … month(s) beginning from the date of notification of the decision, appeal to such adjudicatory and/or administrative authority as may be set up by law.
2. 'Decision' includes any act, omission, approval, refusal, direction, imposition of condition(s) or order of the Competent Authority.

ARTICLE 21: TRANSITIONAL PROVISIONS

1. With respect to any making, import, contained use, release, or placing on the market of a genetically modified organism or a product of a genetically modified organism that has already been carried out on the date when this law enters into force, an application for approval shall be made in accordance with Article 4 of this law.
2. The application shall be submitted to the Competent Authority within a time limit to be determined by the Competent Authority.
3. If the application has been made within the prescribed time limit, the activity in respect of which the application is made may continue until a decision is made by the Competent Authority under Article 6 of this law.
4. Any application pending at the date of the entry into force of this law shall be subject to the provisions of this law.

ARTICLE 22: ANNEXES

The annexes and any regulations made under or pursuant to this law shall be an integral part of this law

ARTICLE 23: ENTRY INTO FORCE

This law shall enter into force on the date of its publication in the official gazette.

ANNEX I

APPLICATION INFORMATION

Following is the information required for application to authorize the release to the environment of a genetically modified organism or a product of a genetically organism, including use in a closed system in quantities exceeding x cm^2, import for food, feed or processing, and pharmaceuticals which have no certification to the effect that they have been authorized by an agency with the mandate to do so both in the context of human health, and biological diversity of the country.

I. General information

A. Name and Address of Applicant
B. Information on Personnel and Training

Name, training and other qualifications of person(s) responsible for planning and carrying out the implementation of the project, including those responsible for supervision, monitoring and safety, in particular the name and qualifications of the responsible scientists.

II. Information relating to the genetically modified organism(s) or a product of a genetically modified organism

A. Characteristics of a) the donor, b) the recipient or c) (where appropriate) parental organism(s)

Scientific name

Additional taxonomic information

Other names (usual name, strain name, cultivar name etc.).

Phenotypic and genetic markers

Degree of relatedness between donor and recipient or between parental organisms

Description of identification and detection techniques

Sensitivity, reliability (in quantitative terms) and specificity of detention and identification techniques

Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys, parasites and competitors, symbionts and hosts

Potential for genetic transfer and exchange with other organisms

Verification of the genetic stability of the organisms and factors affecting it, taking into account the relevance of the laboratory experiments undertaken to the authentic ecological conditions under which the organisms live or are used

Pathological, ecological and physiological traits:

a. Classification of hazard according to existing national rules concerning the protection of human health and/or environment
b. Generation time in natural ecosystems, sexual and asexual reproductive cycle
c. Information on survival, including seasonability and the ability to form survival structures e.g.: seeds, spores or sclerotia
d. Pathogenicity: infectivity, toxigenicity, virulence, allergenicity, ability to be a carrier (vector) of pathogen, possible vectors, host range including non-target organisms. Possible activation of latent viruses (proviruses). Ability to colonize other organisms
e. Antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy
f. Involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

History of previous genetic modifications

B. Characteristics of the vector

1) Nature and source of the vector
2) Sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organism(s) or a product of a genetically modified organism and to make the introduced vector and insert function in the genetically modified organism(s) or a product of a genetically modified organism
3) Frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination
4) Information on the degree to which the vector is limited to the DNA required to perform the intended function
5) Factors (chemical, biological, climatic, etc.) influencing the functional level of the promoter/enhancer, and how the functional level is changed

C. Characteristics of the genetically modified organism(s) or a product of a genetically modified organism

1) Information relating to the genetic modification:
   a. Methods used for the modification
   b. Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence
   c. Description of the insert and/or vector construct
   d. Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function
   e. Number of intact and truncated vector inserts. Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence
   f. Sequence and methylation pattern of the recipient DNA as far as 100 kbp up and down stream from all DNA inserts

2) Information on the final GMO:

a. Description of genetic trait(s) of phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed

b. Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the genetically modified organism(s) or a product of a genetically modified organism

c. Stability of the genetic traits of organism in terms of both expression and structure

d. Rate and level of expression of the new genetic material. Method and sensitivity of measurement

e. Activity of the expressed protein(s)

f. Expression levels for the recipient's genes situated as far as 100 kbp up and down stream from all DNA inserts

g. Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques

h. History of previous releases or uses of the genetically modified organism(s) or a product of a genetically modified organism

i. Health considerations:

   a. Toxic or allergenic effects of the non-viable genetically modified organism(s) or a product of a genetically modified organism and/or their metabolic products

   b. Product hazards

   c. Comparison of the Genetically modified organism(s) or a product of a genetically modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity

   d. Capacity for colonization

   e. If the organism is pathogenic to humans who are immunocompetent

      - diseases caused and mechanism of pathogenicity including invasiveness and virulence
      - communicability
      - infective dose
      - host range, possibility of alteration
      - possibility of survival outside of human
      - presence of vectors or means of dissemination
      - biological stability
      - antibiotic-resistance patterns
      - allergenicity
      - availability of appropriate therapies

III. Information relating to the conditions of release and the receiving environment

A. Information on the release

1. Description of the proposed deliberate release, including the purpose(s) and foreseen products
2. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases
3. Preparation of the site previous to the release
4. Size of the site
5. Method(s) to be used for the release
6. Quantities of Genetically modified organism(s) or a product of a genetically modified organism to be released
7. Disturbance on the site (type and method of cultivation, mining, irrigation, or other activities)
8. Worker protection measures taken during the release
9. Post-release treatment of the site
10. Techniques foreseen for elimination or inactivation of the genetically modified organism(s) or a product of a genetically modified organism at the end of the experiment
11. Information on, and results of, previous releases of the genetically modified organism(s) or a product of a genetically modified organism, especially at different scales and in different ecosystems

B. Information on the environment

This should be for both the site and the wider environment. Note that in the case of genetically modified organisms or a product of a genetically modified organism destined to be used as food or feed or for processing, the environment includes the transportation routes and the market places as well as all the catchment areas of the market places.

1. Geographical location and grid reference of the site(s) (in case of notifications under part C the site(s) of release will be the foreseen areas of use of the product)
2. Physical or biological proximity to humans and other significant biota
3. Proximity to significant biotopes or protected areas
4. Size of local population
5. Economic activities of local populations which are based on the natural resources of the area
6. Distance to closest areas protected for drinking water and/or environmental purpose
7. Climatic characteristics of the region(s) likely to be affected
8. Geographical, geological and pedological characteristics
9. Flora and fauna, including crops, livestock and migratory species
10. Description of target and non-target ecosystems likely to be affected

11. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release
12. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release

IV. Information relating to the interactions between the genetically modified organism(s) or a product of a genetically modified organism and the environment

A. Characteristics and factors affecting survival, multiplication, gene expression and dissemination

1. Biological features which affect survival, multiplication and dispersal
2. Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals and others, etc.)
3. Sensitivity to specific agents

B. Interactions with the environment

1. Predicted habitat of the GMOs
2. Studies of the behaviour and characteristics of the GMOs or a product of a genetically modified organism and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses
3. Genetic transfer capability:
    a. post-release transfer of genetic material from GMOs or a product of a genetically modified organism into organisms in affected ecosystems
    b. post-release transfer of genetic material from indigenous organisms to the genetically modified organism(s) or a product of a genetically modified organism
4. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the GMOs or a product of a genetically modified organism
5. Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal or genetic material. Methods to verify stability
6. Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.
7. Description of ecosystems to which the genetically modified organism(s) or a product of a genetically modified organism could be disseminated

C. Potential environmental impact

1. Potential for excessive population increase in the environment

2. Competitive advantage of the genetically modified organism(s) or a product of a genetically modified organism in relation to the unmodified recipient or parental organism(s)
3. Identification and description of the target organisms
4. Anticipated mechanism and result of interaction between the released genetically modified organism(s) or a product of a genetically modified organism and the target organism
5. Identification and description of non-target organisms which may be affected indirectly.
6. Likelihood of post-release shifts in biological, or in host range
7. Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens
8. Known or predicted involvement in biogeochemical processes
9. Other potentially significant interactions with the environment

V. Information on monitoring, control, waste treatment and emergency response plans

A. Monitoring techniques

1. Methods for tracing the genetically modified organism(s) or a product of a genetically modified organism, and for monitoring their effects
2. Specificity (to identify the genetically modified organism(s) or a product of a genetically modified organism, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques
3. Techniques for detecting transfer of the donated genetic material to other organisms
4. Methods to detect aberrant gene expression

B. Control of the release

1. Methods and procedures to avoid and/or minimize the spread of the genetically modified organism(s) or a product of a genetically modified organism beyond the site of release or the designated area for use
2. Methods and procedures to protect the site from intrusion by unauthorized individuals
3. Methods and procedures to prevent other organisms from entering the site

C. Waste treatment

1. Type of waste generated
2. Expected amount of waste
3. Possible risks
4. Description of treatment envisaged

D. Emergency response plan

1. Methods and procedures for controlling the genetically modified organism(s) or a product of a genetically modified organism in case of unexpected spread
2. Methods for decontamination of the areas affected, e.g. eradication of the genetically modified organism(s) or a product of a genetically modified organism
3. Methods for disposal or sanitation of plants, animals, soils, etc. that were exposed during or after the spread
4. Methods for the isolation of the area affected by the spread
5. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect

ANNEX II

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET

A. The following information shall be provided in the notification for placing on the market products, in addition to that of Annex I:

1. Name of the product and name(s) of Genetically modified organism(s) contained therein
2. Name of the manufacturer or distributor and his address, including address in the country
3. Specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the country for which the product is suited
4. Type of expected use: industry, agriculture and skilled trades, consumer use by public at large

B. The following additional information shall be provided when required/relevant:

1) Measures to take in case of unintended release or misuse
2) Specific instructions or recommendations for storage and handling
3) Estimated production in and/or imports to the country
4) Proposed packaging. This must be appropriate so as to avoid unintended release of the Genetically modified organism(s) during storage, or at a later stage
5) Proposed labelling. This must include, at least in summarized form, the information referred to in points A.1, A.2, A.3, B.1 and B.2

C. The following information concerning labeling of a product of a genetically modified organism shall be provided on a label and/or in accompanying documents:

1. The words "This product contains Genetically modified organism(s)" whenever there is evidence of the presence of Genetically modified organism(s) in the product
2. The words "This product may contain Genetically modified organism(s)" where the presence of Genetically modified organism(s) in a product cannot be excluded but there is no evidence of any presence of Genetically modified organism(s)
3. The words "This product may cause....[specify the particular reactions, allergies or other side-effects]" where it is known that a particular reaction, allergy or other side-effect may be caused by the product
4. Where applicable, further or as a qualification to C.1 or C.2, the words "This product contains genetic material (nucleic acids) from Genetically modified organism(s)" or "This product is based on raw materials from Genetically modified organism(s)"

Annex III

RISK ASSESSMENT PARAMETERS IN ACCORDANCE WITH ARTICLE 8(3)

The user shall carry out an assessment prior to the use or release of a genetically modified organism or a product of a genetically modified organism as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies. This assessment shall take the following parameters into consideration including any other parameter deemed to be relevant:

A. Characteristics of donor and recipient organisms or parental organisms:

1) Scientific name and taxonomy;
2) Strain, cultivar or other name;
3) Species it is related to and degree of relatedness;
4) The degree of relatedness between the donor and recipient organisms, or between the parental organisms;
5) All sites from where the donor and recipient organisms or parental organisms were collected, if known;
6) Information on the type of reproduction (sexual/ asexual) and the length of reproductive cycle or generation time, as appropriate, as well as the formation of resting and survival stages;
7) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
8) Phenotypic and genetic markers of interest;
9) Description of identification and detection techniques for the organisms, and the sensitivities of these techniques;
10) Geographic distribution and natural habitats of the organisms including information on natural predators, prey, parasites, competitors, symbionts and hosts;
11) Climatic characteristics of original habitats;
12) Ability of the organisms to survive and colonize the environment to which release is intended or otherwise;
13) Genetic stability of the organisms, and factors affecting the stability;
14) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;
15) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;
16) Pathogenicity to humans or animals, if any;
17) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;
18) Known allogenicity and/or toxicity of biochemical and metabolic products;
19) Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

B. Characteristics of the vector(s):

1. Nature and source of the vector(s);
2. Genetic map of the vector(s), position of the gene(s) inserted for the transfer, other coding and non-coding sequences affecting the expression of introduced gene(s), and marker gene(s);
3. Ability of the vector(s) to mobilize and transfer genes by integration and methods for determining the presence of the vector(s);
4. History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
5. Potential for pathogenicity and virulence;
6. Natural and host range of vectors;
7. Natural habitat and geographic distribution of natural and potential hosts;
8. Potential impacts on human and animal health and the environment;
9. Measures for counteracting adverse impacts;
10. Potential to survive and multiply in the environment, or to form genetic recombinants;
11. Genetic stability of vector(s), such as hypermutability.

C.Characteristics of the genetically modified organism:

1. The description of the modifications made using gene technology;
2. The function of the genetic modifications and/or the new insert, including any marker gene(s);
3. Purpose of the modification and intended use in relation to need or benefit;
4. Method of modification, and in case of transgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism;
5. Whether introduced gene(s) integrated or extrachromosomal;
6. Number of insert(s), position(s) in the host genome, and its/their structure(s), for example, the copy number whether in tandem or other types of repeats;
7. Product(s) of the transferred gene(s), levels of expression and methods for measuring expression;
8. Stability of the introduced gene(s) in terms of expression(s), structure(s) and site(s) of integration;
9. Biochemical and metabolic differences of genetically modified organism compared with the unmodified organism;
10. Probability of vertical or horizontal gene transfer to other species;
11. Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;
12. Allogenicities, toxicities, pathogenicities and unintended effects;

13. Autecology of the genetically modified organism compared with that of the unmodified organism;
14. Susceptibility of the genetically modified organism to diseases and pests compared with the unmodified organism;
15. Detailed information on past uses including results on all experiments leading to previous releases.

D. Characteristics of resuscitated organism(s) and gene(s) and fossil DNA sequences:

4.1 Resuscitated organism

1. Scientific name and taxonomy;
2. Identity of nearest species and their characteristics which are of relevance to the intended use;
3. Site at which it was found;
4. Method used for resuscitation;
5. Purpose of introducing the organism and benefits, if any;
6. Impacts on human and animal health and the environment;
7. Measures for counteracting adverse impacts;
8. Length of time the organism has been in use;
9. Genetic stability;
10. Likelihood of gene transfer to other organisms;
11. Fossil and living nearest relative species;
12. Biological and biochemical differences from related living species;
13. Information on previous uses since resuscitation.

4.2 DNA sequences from fossils or from resuscitated organism

1. Scientific name and taxonomy of the species whether resuscitated or a fossil;
2. Site of origin of the fossil;
3. Site of the gene in the resuscitated genome, if known;
4. Base sequence of the extracted gene;
5. Method used in extracting the gene;
6. Function of gene, if known;
7. Purpose of use and benefits, if any;
8. Environment in which it lived before fossilization;
9. Fossil species related to the species from which the gene was taken;
10. Living species related to the species from which the gene was taken.

E. Safety considerations for human and animal health:

Information on the genetically modified organism and when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

1. Capacity for colonization;
2. If the genetically modified organism is pathogenic to humans or animals the following information is required:
    a. diseases caused and mechanism of pathogenicity, including invasiveness and virulence, and property of virulence;
    b. communicability;
    c. infective dose;
    d. host range and possibilities of alteration;
    e. ability to survive outside of the human or animal host;
    f. the existence of vectors or other means of transmission;
    g. biological stability;
    h. allergenicity;
    i. availability of appropriate therapies.

F. Environmental considerations:

Information on the genetically modified organism, and when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

1) Factors affecting the survival, reproduction and spread of the genetically modified organism in the environment;
2) Available techniques for detection, identification and monitoring of the genetically modified organism;
3) Available techniques for detecting transmission of genes from the genetically modified organism to other organisms;
4) Known and predicted habitats of the genetically modified organism;
5) Description of the ecosystems which could be affected by accidental release of the genetically modified organism;
6) Possible interactions between the genetically modified organism and other organisms in the ecosystem which might be affected by accidental release;
7) Known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, being a vector of pathogens, allergenicity, and colonization;
8) Possible involvement in biogeochemical processes;
9) Availability of methods for decontamination of the area in case of accidental releases;
10) Effects on agricultural practices with possible undesirable impacts on the environment.

G. Socio-economic considerations:

1) Anticipated changes in the existing social and economic patterns resulting from the introduction of the genetically modified organism or a product of a genetically modified organism;
2) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;
3) Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones;
4) Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities likely to be affected by the introduction of the genetically modified organisms or a product of a genetically modified organism;
5) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;
6) Possible effects, which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the genetically modified organism or a product of a genetically modified organism.

ANNEX IV

RISK MANAGEMENT SCHEMES IN ACCORDANCEWITH ARTICLE 9(2)

The user shall employ the following risk management schemes and procedures from the development, through all stages of testing of the genetically modified organism or a product of a genetically modified organism, to its intended use or commercialisation.

1. Imported products of genetically modified organisms used for human or animal health (e.g. antibodies, drugs and hormones):
    a. Observation to ensure that changes in food habits, nutrition and other factors that could conceivably modify the expected impacts are insignificant;
    b. Such observation can be limited in scope when it is shown that adequate trials on the specific products have been made on humans or animals, as appropriate, in areas other than the State of import.
2. Imported microbial genetically modified organisms for human and animal health:

Besides the limited observation specified in 1, experiments shall be carried out to evaluate viability and risks of reacquiring virulence or lending virulence to other micro-organisms when in the body and in the environment, since some spilling is inevitable.

3. Imported genetically modified organisms for contained use:
    a. The products of genetically modified organisms will be treated as in 1 above;
    b. Experiments will be made in complete laboratory containment to determine: (i) longevity of the genetically modified organism in cases of unintended release in the premises and in the surrounding environment, and (ii) genetic transfer into other micro-organisms and implications thereof on human and animal health and the environment; and
    c. Methods for counteracting adverse impacts resulting from unintended releases should be specified.
4. Products of genetically modified organism made locally:
    a. Trial on experimental animals will be made when the product of the genetically modified organisms is intended to be used on humans;
    b. In all other cases, trials will be made on species for which the product of the genetically modified organism has been designed.
5. Genetically modified organisms made locally for use as human or animal vaccines:
    a. Initial molecular, tissue culture, serological and other related studies in the laboratory in complete containment;
    b. Trials with experimental animals under strict containment;
    c. Experiments in complete containment to evaluate the extent of transfer of the genes of the vector introduced or of other genes

through the agency of the vector to the genetically modified organism or to other species which will be found in association with the genetically modified organism to ensure that virulence is not acquired by the genetically modified organism in question or by other micro-organisms;

d. Trials on animals completely contained from their species and from related species and species known to be susceptible to the gene recipient micro-organism from which the genetically modified organisms has been made;

e. Statistically valid trials in conditions in which the vaccinated individuals live in their communities.

6. Imported plant or microbial genetically modified organism for release:

   a. The reports from releases in areas other than the State of import shall be thoroughly evaluated by the National Biosafety Committee. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;

   b. If the regulations mentioned in (a) above have not been found adequate, the National Biosafety Committee will decide at which step in item 8 the observations should begin;

   c. If it is decided that the previous release mechanisms have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but otherwise kept at the same soil community, moisture, air temperature and plant and animal community conditions as the intended area of release;

   d. The observations will include the health of the genetically modified organism, the health of the organism within the area of limited release, and the biological diversity and the ecology of the area;

   e. Nationally approved limited field releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

7. Imported animal genetically modified organism for release:

   a. The reports from releases in areas other than the State of import shall be thoroughly evaluated by the National Biosafety Committee. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;

   b. If the regulations mentioned in (a) above have not been found adequate, the National Biosafety Committee will decide at which step in item 9 the observations should begin;

   c. If it is decided that the regulations used in the previous release have been rigorous enough, then observations will be made in complete containment in the expected ambient climatic, nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers;

d. When the results have met the stated requirements, then a trial release may be authorized with adequate emergency plans put in place to deal with cases of escape.

8. Plant or microbial genetically modified organisms produced locally for eventual release:
   a. Laboratory biomolecular experiments on transformation or resuscitation and other phenomena will be carried out in complete containment;
   b. Tissue culture experiments to develop the genetically modified organism, when required, will be carried out in complete containment;
   c. Observations aimed at understanding the nature of the genetically modified organism shall be carried out in complete containment;
   d. Experiments with the soil, soil micro-organisms, plant and animal species, under the environmental conditions of the area of intended release, will be carried out in complete containment;
   e. Complete observations of the interactions of the genetically modified organism with the environment (soil including micro-organisms and terrestrial communities) will be made in enclosed fields but not fully contained. At the end of the experiment, the products of the genetically modified micro-organisms may be used on an experimental basis, otherwise they shall be destroyed;
   f. The product from the genetically modified organism shall be subjected to the procedure in 4;
   g. The monitoring of the spread and behaviour of any released plant or micro-organism genetically modified organism shall continue for at least 150 years in the case of trees, and for at least 30 years in the case of annuals and micro-organisms, the duration for perennials which live shorter than trees being in between. The user who was responsible for releasing the genetically modified organisms or its successor shall provide annual reports to the competent authority.
9. Animal genetically modified organism produced locally for eventual release:
   a. Laboratory biomolecular experiments on transformation (or resuscitation if it is possible) and other phenomena will be carried out in complete containment;
   b. Methods of incubating the transformed generative cell or the resuscitated animal will be carried out in complete containment;
   c. The rearing of and observations on the genetically modified organism will be carried out under complete containment;
   d. The genetically modified organism shall be observed under complete containment in an experimental environment which simulates the intended area of release in climatic, microbial, animal and plant communities. The observations shall include the condition of the transgenic animal and those of its micro-organisms especially in the context of gene transfer and those of the microbial,

plant and animal communities in the experiment, again including gene transfer;

e. A limited release will be carried out in an area with appropriate enclosure and emergency measures put in place to prevent escape. Observations will include the condition of the genetically modified organism, its micro-organisms focusing on gene transfer, and the ecology of the microbial, plant and animal communities in the area, again including gene transfer;

f. If the animal is intended to yield a product, the regulation of the product will follow the procedure in item 4;

g. The monitoring of the spread and behaviour of any released animal genetically modified organism will continue for at least 30 years.

10. General Requirements:

a. All trials, experiments or observations specified in all the above cases (1-9) are put in their logical sequence and shall be subjected to the hierarchical procedures of approval by the lower institutional and the higher national level bodies, namely the Institutional Biosafety Committees or the National Biosafety Sub-committees and the National Biosafety Committee.

b. Experiments starting from transformation of living organisms or resuscitation of fossil organisms carried out under completely contained laboratory conditions and continuing in the development of a genetically modified organism or a product of a genetically modified organism shall be subject to approval by the Institutional Biosafety Committee or by National Biosafety Committees as the case may be. All experiments outside of strict laboratory isolation and initial experiments involving an imported genetically modified organism or a product of a genetically modified organism shall be subject to approval by the National Biosafety Committee. All final approval for the use of a genetically modified organism or a product of a genetically modified organism shall be made by the National Biosafety Committee.

c. Once approval from the National Biosafety Committee is obtained at the completion of the final stage of the trials, experiments or observations, the genetically modified organism in question or the product of a genetically modified organism can be employed for its intended use. The National Biosafety Committee shall notify its decision in writing to the Competent Authority.

d. Whenever there is a need to dispose of the genetically modified organism or a product of a genetically modified organism upon the completion of every trial or experiment, it shall be made through complete incineration or other approved means of complete destruction.

e. The release of genetically modified organisms or a product of a genetically modified organism shall be monitored appropriately and emergency plans to prevent escape and accident shall always be in place.

ANNEX V

TEMPLATE FOR ARTICLE 18.2 (b) AND 18.2 (c) OF THE CARTAGENA PROTOCOL ON DOCUMENTATION AND IDENTIFICATION OF GMOs DESTINED FOR CONTAINED USE AND FOR INTENTIONAL INTERODUCTION INTO THE ENVIRONMENT

Date:

Transport documentation of GMOs in accordance with the Cartagena Protocol on Biosafety
Article 18.2 (b) – LMOs destined for contained use only

	Exporter	**Importer**	**Contact point**
Company or institution			
Contact person			
Street			
City, Postal Code			
Country			
Phone			
Fax			
E-mail			

Ordinary name of the GMO	
Taxonomic name	
Unique identification number, if existing	
Reference to BCH, if relevant	
Risk categorization, if relevant	
Type of intended use: Commercial Research Other	

If required by importing country:

Reference to import approval	
Contact details to approving authorities: Address; Phone; Fax; E-mail	

Any requirements for safe: handling storage transport use	• As provided under applicable international requirements • As provided under domestic regulations of importing country or in the import approval • Any other requirements agreed to by the importer and exporter or • In the event there is no requirement, indicate that there is no specific requirement.

Shipping details:

Shipper reference number:		Shipper contact details:	

Item	**Amount**	**Weight / Volume**	**Value**

I declare that the information above and this shipment of GMOs is in conformity with the requirements of the Cartagena Protocol on Biosafety and any import requirements by the authorities of the importing country.

Signature of exporter:_____ Date:___

Date:

Transport documentation of GMOs in accordance with the Cartagena Protocol on Biosafety
Article 18.2 (c) – LMOs destined for intentional introduction into the environment

	Exporter	Importer	Contact point
Company or institution			
Contact person			
Street			
City, Postal Code			
Country			
Phone			
Fax			
E-mail			

Unique identification number in BCH:

Description of the LMO:

Ordinary name of the GMO (including variety and transformation event if relevant)	
Taxonomic name	
Risk categorization, if relevant	
Gene modification (characteristics, including inserted or changed traits and genes)	
Type of intended use: Commercial Research Other	

Requirements by importing country:

Reference to import approval (e.g. in accordance with AIA)	
Contact details to approving authorities: Address; Phone; Fax; E-mail	

Any requirements for safe: handling storage transport use	• As provided under applicable international requirements • As provided under domestic regulations of importing country or in the import approval • Any other requirements agreed to by the importer and exporter or • In the event there is no requirement, indicate that there is no specific requirement

Shipping details:

Shipper reference number:		Shipper contact details:	

Item	Amount	Weight / Volume	Value

I declare that the information above and this shipment of GMOs is in conformity with the requirements of the Cartagena Protocol on Biosafety and any import requirements by the authorities of the importing country.

Signature of exporter:_____ Date:_____