Draft Model
NATIONAL LEGISLATION ON SAFETY IN BIOTECHNOLOGY

PREAMBLE

Whereas, modern biotechnology might have much promise for the improvement of human well-being, its potential adverse effects on the environment, biological diversity and 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 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 to import, contained use, release, or place on the market 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;

Now, therefore, it is hereby legislated as follows:

ARTICLE 1
DEFINITIONS

Unless the context requires otherwise in this legislation:

'advance informed agreement' means consent obtained based upon full disclosure of all relevant information before any activity is undertaken.

'applicant' means any person who submits an application in writing to the competent authority seeking approval to, import, make contained use, release or place on the market genetically modified organisms or products of genetically modified organisms, or where the context so requires, any person to whom the approval is already granted.

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

'contained use' means any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a closed system in which physical barriers are employed, either alone or together with chemical and/or biological barriers, to effectively limit their contact with, and

their impact on, humans and the external environment.

'deliberate release' or 'release' means any intentional introduction into the environment of a genetically modified organisms or products of genetically modified organisms; this includes releases for: commercial purposes, remediation, research purposes in field experiments, use of genetically modified organisms in greenhouses, aqua-culture facilities, animal accommodation unless the facility is approved for contained use, as part of an approved laboratory or other installations**,** disposal of waste containing genetically modified organisms, transport of genetically modified organisms or products of genetically modified organisms.

'export' means the intentional transboundary movement from one country to another country.

'gene technology' means techniques that involve the isolation, characterization, modification induction of DNA into living cells or viruses.

'genetically modified organism' means any biological entity, capable of replication or of transferring genetic material, and includes plants, animals, micro-organisms such as viruses, bacteria, plasmids, or other vector systems, cell culture in which the genetic material has been altered by means of cell or gene technology.

'import' means the intentional transboundary movement into one country from another country.

'notification' means providing information to, and where appropriate, the deposit of samples with, the competent authority.

'person' includes both natural and legal entities.

'placing on the market' means supplying or making available to third parties a genetically modified organism or products of a genetically modified organism.

'products of genetically modified organisms' means any material derived by processing, or howsoever otherwise, from any genetically modified organism or product of genetically modified organism.

'risk assessment' means the evaluation of the direct and indirect risk to the environment, biological diversity and health, including to the socio-economic conditions and ethical values of the country which may be posed by the import, contained use, release or placing on the market of the genetically modified organism or of a product of genetically modified organism. This may include the evaluation of secondary and long-term effects.

'socio-economic impact' means the direct or indirect effect on the economy or social or cultural practices or the livelihood or indigenous knowledge systems or technologies of a community or communities including on the economy of the country of a genetically modified organism or products of a genetically

modified organism.

'use' excludes the acquisition by purchase or otherwise by a member of the general public and utilisation or dealing thereafter unless specific conditions are attached to the utilisation.

ARTICLE 2
SCOPE

This legislation shall apply to the import, contained use, release or place on the market of any genetically modified organism or a product of genetically modified organism.

ARTICLE 3
INSTITUTIONAL ARRANGEMENTS

1. ***Competent Authority***

The Government shall designate or establish a competent authority to follow up, supervise and control the implementation of this legislation. The competent authority shall have the powers and duties:

(a) specified in the relevant provisions of this legislation and as may be further specified by the Government;

(b) to prescribe criteria, standards, guidelines and regulations as may be necessary for the fulfillment of the objectives of this legislation;

(c) to take into account the policy recommendations and other guidelines of the National Biosafety Committee in making decisions on the import, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism;

(d) to cause the establishment of biosafety committees at relevant institutions or nominate independent panels or any other body of experts, as appropriate, as technical and scientific advisors.

2. ***National Biosafety Committee***

(a) 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 and guidelines to the competent authority.

(b) The National Biosafety Committee, shall further develop, based on its general responsibility specified in 2(a) of this Article, its terms of reference, and may draw up its own rules of procedure.

3. ***Institutional Biosafety Committee***

Institutions that are involved in the import, contained use, release or placing on the market of genetically modified organisms or products of genetically modified organisms shall establish Institutional Biosafety Committees to ensure and control safety mechanisms and approval requirements at the institution level.

ARTICLE 4
APPLICATION AND APPROVAL

1. No person shall import, make contained use, release or place on the market 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 any import, deliberate release, contained use or place on the market a genetically modified organism or a product of 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) assessment report on risks that may be caused by the genetically modified organism or product of a genetically modified organism into the environment, biological diversity and health, including the consequences of unintentional release;

   (c) information from previous or current release of the genetically modified organism or product of genetically modified organism in the country or in any other country;

   (d) information on previous approvals or rejections of the genetically modified organism, or the product of the genetically modified organism by any other country;

   (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 proposed labeling and packaging scheme in accordance with Annex II, part C of this legislation; and

   (f) the applicant shall produce a declaration confirming that the information provided is correct.

ARTICLE 5
PUBLIC PARTICIPATION

1. The competent authority shall, upon receipt of the information referred to under Article 4.3 make available the said information to the public and relevant government authorities.

2. The public may make comments within such period as may be specified by the competent authority.

3. In cases where the competent authority arranges for a public consultation with regard to any proposed import, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism, shall be announced in a media with national coverage and a period of not less than…days before the decision is made shall be given for consultation without prejudice to Article 12(1).

4. 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.

5. The competent authority shall make available to the public:

   (a) information on any genetically modified organism or a product of a genetically modified organism which have been granted or denied approval for import, contained use, release or placing on the market;

   (b) risk assessment report with respect to the genetically modified organism or the product of a genetically modified organism

ARTICLE 6
DECISION MAKING PROCEDURE

1. The competent authority shall examine the application and may decide that the application may:

   i) proceed; or

   ii) may proceed with such conditions as it may specify; or

   iii) not proceed with his request.

2. The competent authority shall notify in writing of its decisions.

3. The competent authority may request for further information as it may deem necessary to make decision.

4. Any approval shall state that the activity approved shall be carried out step by step and that assessment of risk should be conducted at each step of development, provided that the competent authority may in appropriate cases

not require this procedure if it is satisfied that it would not cause any risk to the environment, biological diversity or health.

5. Any approval for import, contained use, release or placing in the market of a genetically modified organism shall require the applicant to carry out monitoring and evaluation of risks.

6. No approval shall be given unless there is a firm and sufficient evidence that the genetically modified organism or the product of a genetically modified organism pose no risks to the environment, biological diversity or health.

7. In any event, where there is reason to suspect threats of serious damage, lack of scientific evidence should not be used as a basis for not taking preventive measures.

8. No approval shall be given unless it is considered and duly determined by the competent authority that the import, contained use, release or placing on the market of the genetically modified organism or the product of genetically modified organism will:

   (a) benefits the country without causing any significant risk to the environment, biological diversity or 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 traditional knowledge and technologies.

9 The competent authority shall, as a condition for approval, require the applicant to furnish evidence of insurance cover or some other arrangements sufficient to meet its obligations under this legislation.

ARTICLE 7
REVIEW OF DECISION

1. Any approval given may be revoked, or subjected to conditions in addition to those originally imposed, 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 health.

2. Where information becomes available after approval on the possible risks to the environment, biological diversity or health, the applicant shall immediately notify the competent authority.

ARTICLE 8
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.

2. No decision on any application to import, make contained use, release or place on the market of a genetically modified organism or a product of a genetically modified organism may be made by the competent authority without the assessment of risks to the environment, biological diversity and health, including the socio-economic conditions.

3. The risk assessment of a genetically modified organism 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 the guidelines set out in 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 decision on any application to import, make contained use, release or place on the market of a genetically modified organism or a product of a genetically modified organism.

5. In case where the evaluation of the assessment shows that risks cannot be avoided the competent authority shall refuse approval to the import, contained use, release or place on the market of the genetically modified organism or the product of a genetically 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 carrying out the risk assessment, as the case may be.

ARTICLE 9
RISK MANAGEMENT

1. The competent authority shall impose such measures, as may be necessary, to avoid adverse effects on the environment, biological diversity and 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 paragraph 9(1), the competent authority may:

   (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 import, contained use, release or place on the market of any genetically modified organism or the product of a genetically modified organism, if it is satisfied that it contains characteristics or specific traits which pose unacceptable risks to the environment, biological diversity, or to health;

(c) order the cessation of any activity, which is being undertaken in violation of any of the provisions or any decisions, made under this legislation;

(d) order the cessation of any activity involving genetically modified organism or a product of a genetically modified organism that are proven to cause risks to the environment, biological diversity or health;

(e) require the person responsible for any activity under this legislation to take such measures as may be necessary to prevent or limit any harm to the environment, biological diversity or health, or to restore the environment to its previous state as far as feasible;

(f) undertake measures, as necessary, at the cost of the person responsible in the event when the person responsible fails to undertake safety measures to which the competent authority has issued notification;

(g) take measures, as necessary, in the case of imminent and serious danger to the environment, biological diversity or health caused by a genetically modified organism or a product of a genetically modified organism at the cost of the person responsible for causing such danger; and

(h) require the applicant to submit reports periodically in respect of the monitoring and evaluation of risks carried out after the approval of the import contained use, release or place on the market of a genetically modified organism or a product of genetically modified organism.

ARTICLE 10
UNINTENTIONAL RELEASE AND EMERGENCY MEASURES

1. The competent authority shall, as necessary, ensure, before any 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 health in the event of an accident or unintentional 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 of any accident immediately 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 measure necessary to assess the effects of the accident on the environment, biological diversity or health; and

(d) the emergency measures taken or to be taken.

ARTICLE 11
IDENTIFICATION AND LABELING

1. Any genetically modified organism or product of a genetically modified organism shall be clearly identified and labeled as such, and such identification shall specify the relevant traits and characteristics given in sufficient detail for purposes of traceability.

2. Any product of genetically modified organism shall be clearly labeled and packaged using the words in accordance with Annex II, part C, and shall comply with such further requirements, if any, imposed by the competent authority, to indicate that it is, or has been derived from, genetically modified organism, and, where applicable, whether, it may cause reactions, allergies or other risks.

ARTICLE 12
CONFIDENTIAL BUSINESS INFORMATION

1. The competent authority shall protect information which it determines as being confidential after a claim for confidentiality is 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 products of a genetically modified organism, names and addresses of the applicant, purpose and location of the import, contained use, release or place 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 evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

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

2. 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 (2) and (3).

ARTICLE 13
EXPORT OF A GMO OR PRODUCT OF A GMO

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 by an exporter 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 preclude the country of the exporter from taking into account other considerations before approving the export.
4. There shall be no authorization for the export of a genetically modified organisms or products of genetically modified organisms that are banned by the laws of the exporting country.

ARTICLE 14
LIABILITY AND REDRESS

1. A person who, imports, makes contained use, releases or places on the market a genetically modified organism or a product of a genetically modified organism shall be strictly liable for any harm caused by such genetically modified organism or a product of a genetically modified organism. The harm shall be fully compensated.
2. Liability shall attach to the person responsible for the activity which results in the damage, injury or loss as well as the provider, supplier or developer of the genetically modified organism or products of the 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. 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 costs of preventive measures.
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 practices or the livelihood or indigenous knowledge systems or technologies of a community or

communities. Such harm includes the following: disruption or damage to production systems, agricultural systems, reduction in yields, soil contamination, damage to the biological mass, and damage to the economy of an area or community.

6. Any action in respect of the harm caused by a genetically modified organism or products a genetically modified organism shall lapse only after a reasonable 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 products of the genetically modified organism, having regard to the situation or circumstance of the person or community affected.

7. Any person or group of persons may be entitled to bring a claim and seek redress in respect of the breach or threatened breach of any provision of this Act, including any provision relating to damage to the environment and biological diversity; relating to socio-economic:

   (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 persons whose interests are affected;

   (d) in the public interest; and

   (e) in the interest of protecting the environment or biological diversity.

1. 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 the environment or biological diversity.

ARTICLE 15
OFFENCES AND PENALTIES

1. Any person who

   (a) imports, 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 Act;

   (c) fails to furnish any information as required by the provisions of this Act

   (d) provides false, misleading or deceptive information in order to secure an approval under section 4.3;

(e) does not label, package or identify any genetically modified organism or products of a genetically modified organism in accordance with this Act or with any conditions imposed under this Act;

(f) 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 in contravention of any regulation made under this Act;

(g) exports a genetically modified organism or products of a genetically modified organism without the advance informed agreement of the importing country;

(h) participates in any proceedings in respect of a subject matter in which he/she has any direct or indirect interest of any kind;

(i) violates any other provision of this Act or any condition or requirement imposed under this Act;

(j) commits an offense and is liable on conviction to imprisonment for a term not exceeding …… years or to a fine or to both.

1. Any person shall upon conviction of an offense under section 15.1(a), (b) or (d), be prohibited from engaging in any activity in relation to genetically modified organism or products 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.

2. Any person who repeatedly commits any other offense under this Act may be prohibited from engaging in any activity in relation to a genetically modified organism or product of a genetically modified organism.

3. Where the offense 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 offense is committed, shall be liable to imprisonment.

ARTICLE 16
APPEAL

1. Any person aggrieved by any decision of the competent authority may, at any time within the period of …… month(s) beginning from the date of receipt of the decision, appeal to such a judicatory and/or administrative authority as may be set up by law.

2. In this section ‘decision’ includes any act, omission, refusal, direction, imposition of condition(s) or order.

ARTICLE 17
TRANSITIONAL PROVISIONS

1. Any import, contained use, release, or placing on the market of a genetically modified organism or a product of a genetically modified organism that has been carried out on the date when this legislation enters into force, an application for approval shall be made in accordance with Article 4 of this legislation.
2. This 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 section 6 of this Act**.**
3. Any application pending at the date of the entry into force of this Act shall be subject to the provisions of this Act.

ARTICLE 18
ANNEXES

The Annexes and any regulations made under or pursuant to this legislation shall be an integral part of this legislation.

ARTICLE 19
ENTRY INTO FORCE

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