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CHAIRMAN'S DRAFT
CONTENT OF TEXT OF ITEMS

ARTICLE 11
ARTICLES 15-22

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Article
11
CONFIDENTIAL INFORMATION

1. Parties receiving notifications shall respect the need to protect intellectual proprietary rights and confidential information relevant to living modified organisms. The information specified in Annex I shall not be regarded as confidential information, with respect to the Protocol.

2. The notifier should indicate any information submitted under the procedures of this protocol that it considers to be confidential and/or subject to intellectual property protection.Confidentiality and proprietary provisions shall not be excessive or broad so as to hinder information-sharing among parties which would undermine the ability of the national competent authority to take informed decisions. Any Party receiving such information shall establish appropriate internal procedures for the protection of information so received..

3. The competent authority shall decide, after consultation with the notifier, which information is confidential and shall inform the notifier of its decisions. If, for whatever reasons including in case the competent authority and notifier disagree, a notifier withdraws a notification, the confidentiality of all the information supplied must be respected by the competent authorities and focal points.

4. Competent authorities, focal points and the Secretariat shall not divulge any confidential information received under the Protocol and have the obligation to protect intellectual property rights relating to the data received.

Article 15
MINIMUM NATIONAL STANDARDS

1. Each Party shall ensure that appropriate legal, institutional and administrative frameworks with regard to the safe [research, manufacture, development]transfer, handling and use of LMOs are in place upon the date of the entry into force of this Protocol for it. Such regulations shall contain adequate measures for both contained and deliberate release. With regard to contained use each Party shall apply measures referred to in Annex [ ] (to be developed).

2. The national regulations shall as a minimum fulfil the requirements set out in this Protocol with regard to the safe transfer, handling and use of LMOs, including risk assessment procedures under Article 13 and enforcement of conditions or prohibitions under Article 14.

Article 16
UNINTENTIONAL TRANSBOUNDARY MOVEMENTS

1. The Parties shall take all possible precautions to prevent accidental and unintentional release and to reduce natural movements of intentionally released living modified organisms which may result in unintentional transboundary movements.

2. The Parties shall, whenever it comes to their knowledge, ensure that, in the case of an accident which may have transboundary effects on human health and/or the environment in other states, these states are immediately informed, and inform affected states about any planned activities associated with LMOs within their territories that are likely to have transboundary effects. The affected state(s) may ask for consultations between the concerned states.

3. The information supplied shall include, *inter alia*, the identity, relevant characteristics and numbers/volumes of the LMOs involved and any available information necessary to assess the effects of the accident and emergency measures taken or needed to be taken, including measures identified under Article 14 (1) of the Convention.

4. Parties shall immediately notify affected Parties, potentially affected Parties and the Clearing House, in case of known unintentional transboundary movements of living modified organisms, or of known domestic releases of living modified organisms which may result in unintentional transboundary movements. Such notification shall include, *inter alia:*
   a) circumstances of the unintentional movement;
   b) the identity and quantities released;
   c) an assessment of the risks to the conservation and sustainable use of biological diversity and/or human health;
   d) emergency measures taken or needed to be taken;
   e) any available information regarding the handling of the organisms and related risk management measures to be applied.

f) Information specified in Annex I.

5. The Party which is the origin of the unintentional transboundary movement shall take immediate action, in consultation with the affected Party, to minimise negative impact on the environment and to prevent further release or transboundary movement of the living modified organism.

6. A Party which suspects that an unintentional transboundary movement has occurred into its territory shall inform the Party from which the unintentional movement is suspected to have originated. The Party from which the unintentional movement is suspected to have originated, shall immediately investigate this possibility and, if confirmed, trigger the mechanisms described paragraphs 2 and 3 of this Article.

7. Each Party shall avoid any activity that may lead to accidental or unintended releases of aquatic living modified organisms to freshwater and marine ecosystems.

8. If necessary, the affected Party(ies) may request the Party from which the unintentional tranboundary movement originates, to assist in emergency measures with the aim of minimising adverse effects on conservation and sustainable use of biological diversity and human health.

9. In the event of an unintentional release occurring during the international transport of a living modified organism subject to the article on Advance Informed Agreement where such unintentional release is likely to present risks to the conservation and sustainable use of biodiversity, each Party shall, whenever it comes to its knowledge, ensure that the national focal point of each suspected affected Party is immediately informed and provided with all available relevant information. For purposes of this Article, international transport refers to that portion of movement that occurs after the LMO has left the area under the national jurisdiction of the exporting Party and before it has entered the area under the national jurisdiction of the importing Party.

Article 17
EMERGENCY MEASURES

1. Each Party shall endeavour to establish appropriate national measures and procedures, including national contingency plans, related to accidental transfers of LMOs which may have potential risks to its environment, in particular, the conservation and sustainable use of biological diversity, and the risks to human health and the emergency measures that need to be taken in regard therewith.

2. Parties shall take the necessary measures to ensure that, in the event of an accident, the user shall be required to inform immediately the competent authorities of the State(s) concerned. The information shall include, inter alia,

   a) the circumstances of the accident;
   b) other facts necessary to assess the effects of the accident on human and animal health, the environment, and the biological diversity;
   c) the emergency measures taken or needed to be taken together with any available information regarding the handling of the organisms; and

d) any other information considered relevant.

3. The States concerned shall, where information is provided under paragraph 2 above, ensure that in any emergency, the medium and long-term measures necessary are taken, including the immediate alerting of any other State which could be affected by the accident.

4. The Parties shall ensure that appropriate risk management strategies and measures, including emergency plans, are incorporated in the risk management strategies and measures under Article 14 above to prevent, mitigate or rectify any potential risks to the relevant Parties in case of any accidental or emergency release of LMO's.

Article 18
HANDLING TRANSPORT PACKAGING AND LABELLING

1. In order to maintain adequate safety levels during transport each exporting Contracting Party shall establish appropriate measures for handling, transportation, packaging and transit of LMOs for transboundary transfer.

2. The receiving Party shall have the right to impose such terms and conditions on the packaging, labelling and transportation of the LMO to or within the receiving country, for the protection of its environment, in particular the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health and taking into account also such social and ethical matters it deems fit for national interest purposes.

3. The Parties shall take into account international conventions, agreements and recommendations on classification , bottling , labeling and documentation established by appropriate international organizations related to transport, particularly , the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO), International Rules of Transport and Dangerous Goods by Road (RID) and the International Airway Transport Association (IATA).

4. Exporting Parties shall ensure that shipments containing living modified organism:
   a) are clearly identified as containing living modified organism;
   b) are handled and packaged in such a way as to prevent accidental release into the environment; and
   c) include names and contact details of Focal Points for exporting, importing and transit Parties, for use in the case of accidental release living modified organisms, consistent with Article 16 {Unintentional Transboundary Movements}.
   d) that LMOs exported from their territories are subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export.
   e) require that living modified organisms be accompanied by a movement document from the point at which the transfer commences to the point of use.

5. The Parties shall ensur that LMOs which have not been approved for use shall be handled and packaged in such a way as to ensure their complete isolation.

6. The Parties shall aim at developing standards with regard to packaging and transport practices under the Protocol.

Article 19
COMPETENT AUTHORITY/FOCAL POINT

1. To facilitate the implementation of this Protocol, each Party shall designate or establish a national focal point and one or more competent authority(s) which shall receive applications and notifications and communicate decisions on living modified organisms in accordance with the Advance Informed Agreement procedure set out in Article 3, 4 and 5 and Annex I and II. Where a Party designates more than one competent authority, it shall specify the areas of responsibility for each

2. Each Party shall inform the Secretariat no later than the date of entry into force of the Protocol for that Party in question, which agencies have been designated as its focal point/competent authority(ies).

3. The Secretariat shall forthwith inform the Parties of notifications received under paragraph 2. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1, and 2 above for inclusion in the Database provided for in Article 20 on information exchange.

4. Parties shall inform the Secretariat and the Biosafety Clearing House within [ ] days of the date of decision, of any changes regarding the designation made by it under paragraphs 1 and 2 above.

5. The Competent Authority of each Party shall be the authoritative/decision-making body regarding any intended transfer, handling or use LMOs to or within the receiving country. The Competent Authority shall be provided with adequate financial and technical assistance to establish and develop its infrastructure and human resources to carry out the responsibility assigned to it including as a minimum the responsibilities listed in Annex IV.

6. The Competent Authority of the receiving country Party may impose such conditions and/or national procedures it deems fit regarding the transfer, handling or use of the LMO by the intending Party in order to protect its environment, in particular the conservation and sustainable use of biological diversity, and the risks to human health.

Article 20
INFORMATION SHARING/BIOSAFETY CLEARING HOUSE

1. Subject to the national laws, regulations and procedures of each Party, and without prejudice to the obligation to provide information under the AIA procedure under Article 4 the Parties shall facilitate

through a clearing-house mechanism and/or national focal points of each Party, the exchange of information, relevant to safety in biotechnology and the transfer, handling or use of LMOs and its impacts thereof, taking into account the special needs of developing countries. Such information shall be transmitted to the Secretariat, the Biosafety Clearing House and other relevant bodies and Parties as the case may be.

2. Parties shall endeavour to co-operate with existing international agencies, organizations, mechanisms and regional networks for the dissemination of biosafety-related information and standards applicable in other countries.

3. A Database for international information exchange shall be established and administered by the Secretariat. The Biosafety Clearing House should be established no later than the date of entry into force of this Protocol on the basis of existing international Biosafety Exchange Mechanisms.

4. The Biosafety Clearing House shall serve as a body for information exchange, monitoring of implementation, and scientific and technical co-operation among Parties. It shall report regularly to the meeting of the parties on all aspects of its work and to the Secretariat regarding the implementation of procedures on notification and Advance Informed Agreement. The modalities of establishment of the Biosafety Clearing House shall be considered and decided upon by the Parties at their first meeting.

5. Each Party shall inform its public about the contents of, and mode of public accessibility to, the clearing-house mechanism.

6. The Secretariat shall keep this Database up-to-date and accurate; submit as soon as possible to the Conference of the Parties a proposal for the format to be used for the inclusion of information in the Database.

7. Without prejudice to Article 11 the Database shall contain and provide public access to information relevant to the implementation of the Protocol as follows

a) the information identified in Annex V:
b) information on risk assessments or environmental reviews generated by the regulatory process.
c) information on decisions regarding the importation, field testing, or commercial use of any LMO.
d) information concerning the development, use and transfer of LMOs
e) available results relating to risk assessment and management
f) national procedures for regulation, assessment and risk management ;
g) scientific references necessary to risk assessment and risk management;
h) information on transboundary movement
i) information on unintentional movements according to Article 16.

Article
21
CAPACITY BUILDING

1. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and Biosafety including where necessary, through the appropriate international and national institutions. They shall take due account of the needs of developing countries with respect to capacity building in order to promote the development and transfer of safe biotechnology and knowledge.

2. The Secretariat, in collaboration with the Biosafety Clearing House, shall develop and implement regional and global capacity building programmes based on the identified needs of the concerned Parties. The Secretariat and the Biosafety Clearing House shall, in particular, assist developing countries in their efforts to identify and plan their capacity building requirements and secure funds for the implementation of their capacity building programmes.

3. The Parties agree that, according to the specific needs of different regions and sub-regions, regional or sub-regional activities/centres for training and capacity building regarding the safe management of living modified organisms shall be established. with financial assistance provided through the financial mechanisms under the Convention on Biological Diversity (CBD).

4. The Parties shall promote technical and scientific cooperation, including the promotion of cooperation in the training of personnel and the exchange of experts, informational exchange and institutional capacity building in order to strengthen the ability of importing states to perform risk assessments and to develop and implement risk management procedures.

5. Capacity building programs should maximize the use of existing multilateral, regional and bilateral mechanisms where possible, including those addressed under the Convention. Technical assistance from the private sector should also be facilitated and encouraged.

6. Such capacity-building shall aim to ensure:

a) that Parties develop and strengthen their capacities to implement this Protocol;
b) that national legislation, frameworks and guidelines related to Biosafety are developed;
c) that states involved in the transfer, handling and use of LMOs and or products thereof are aware of any associated risks and have the means to assess and manage the risks;
d) that states are able to achieve safety through properrisk assessment and management when certain LMOs and or products thereof are transferred into and/or to be used in their territories and act adequately in cases of accidental release of LMOs.
e) the development of procedures for risk assessment and risk management of LMOs.

7. Any Party to this Protocol or any of its signatories will be able to make scientific-technical cooperation requests to the Secretariat for the purpose of applying the Protocol or participating in it, in particular:

   a) preparing or evaluating risk assessment reports or impact statements;

b) developing or evaluating risk management schemes and appropriate monitoring programmes. procedures and standards;
c) preparing emergency plans and other safety measures;
d) transmitting requests for assistance and relevant information in the event of accidents;
e) providing information that may be relevant to the settlement of disputes.

8. The developed country Parties shall establish effective measures for strengthening and/or development of human resources and institutional capacities in biotechnology and biosafety in developing country Parties, encompassing technical, financial and institutional provisions.

9. The developed country Parties shall establish such measures to enhance the capacity of developing country Parties to acquire and/or develop relevant biotechnology, and its proper and safe management, and the building up of their local, technological and institutional competence, thereby contributing to the distribution of benefits from the potentials of biotechnology. through training in science related to safety in biotechnology and in the use of risk assessment and risk management techniques and the transfer of relevant knowledge, in biotechnology and biosafety on fair and most favourable terms including on concessional and preferential terms.

Article 22
PUBLIC AWARENESS / PUBLIC PARTICIPATION

1. The Parties shall ensure that adequate information on the safe transfer, handling and use of LMOs is provided to the public in accordance with Article 13 and Article 14(1) of the Convention with regard to public participation Parties are encouraged to facilitate public participation in risk assessment decisions.

2. The Parties shall promote and facilitate, at the national, sub-regional and regional levels, as appropriate, and in accordance with national laws and regulations, and within their respective capacities, the development and implementation of educational, both formal and informal, and public awareness programmes on safety in biotechnology.

3. Each Party shall, in accordance with its national laws and regulations, provide the public which is likely to be affected by any activity or product involving living modified organisms, an opportunity for public hearings in the process of approving the release, transfer or use, contained or otherwise, of such living modified organisms.

4. While respecting the need to protect commercial-in-confidence information, Parties shall:

   a) promote and encourage understanding of the safe use, handling and management of living modified organisms in relation to the transboundary movements and the conservation and sustainable use of biological diversity, including human health;

   b) make available to the public risk assessment results and decisions concerning the transboundary movement of living modified organisms;

5. The Parties shall stipulate public participation by allowing access to information on which decisions are based and shall cooperate to favor public awareness on any possible effects for the environment and health in general that Living Modified Organisms release may produce.

6. The Parties shall cooperate as appropriate, with other States and international organizations in developing educational and public awareness programmes with respect to any risks and benefits associated to modern biotechnology.

7. Subject to relevant national legislation, Parties shall endeavour to disclose or make available information on biotechnology, safety in biotechnology and the results and impacts of any releases or use of any LMO thereof to the public.

ANNEX I

INFORMATION REQUIRED IN ORDER TO OBTAIN ADVANCE INFORMED AGREEMENT

1. The Competent Authority/exporter of living modified organisms shall provide the competent authorities of the States concerned with the following information in order to obtain advance informed agreement in accordance with Article 3 of the protocol:

a) name and address of exporting company/institution
b) name and address of receiving company/institution
c) origin, common name and taxonomic status of recipient organism
d) description of all traits introduced or modified and characteristics of the organism
e) purpose and methodology of the genetic modification (and stability of introduced genetic material
f) A complete risk assessment report on the living modified organism in accordance with the risk assessment parameters stated in Annex II of the protocol including as far as possible the conditions in the State of import. Taking particularly into account releases in centres of origin for the LMO, the State of export shall also evaluate whether the LMOs in question may establish viable populations or may hybridise with local species in the receiving environment
g) quantity of organisms to be transferred or volume or culture and physical state
h) any relevant requirements to ensure safe handling, storage, subsequent transport and use
i) intended dates of transfer/movement/release/activity
j) intended means of transport
k) intended use of the organism
l) methods for safe disposal and contingency plans in case of accidents/unintended movements
m) information on experiences with previous releases and the impacts on conservation and sustainable use of biological diversity human health of such releases
n) intended labelling of the LMO
o) any differences between the environment of the exporting country and the environment into which the organism is to be released.
p) Center of origin of the organism that has been modified and areas with high genetic diversity relevant to the living modified organism)
q) The applicable laws, procedures and guidelines of the State of export and the stage reached in the testing and observation of the living modified organism or the product thereof according to the legal and administrative requirements of the State of export
r) Any requirements to manage risks and to ensure safe handling (storage, transport) and use, and methods for safe disposal and appropriate emergency procedures in case of accidents.
s) Information relating to insurance (liability and compensation)
t) Declaration by the exporter (Competant Authority or the accredited agency of the Party of export) that the information is correct
u) Specific introductions or recommendations for storage and handling.
v) Name of person(s) responsible for planning and carrying out the release including those responsible for supervision, monitoring and safety, in particular, name and qualifications of the responsible scientist;
w) Information on training and qualifications of personnel involved in carrying out the release.

ANNEX II

RISK ASSESSMENT PARAMETERS

1. Prior to the use and release of living modified organisms an assessment as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies shall be performed. This assessment shall take the following parameters into consideration, including any other parameter deemed to be relevant:

A. General Principles:

Risk assessment should, *inter alia*, take into account:

a) all relevant scientific evidence and experience;
b) the general characteristics of both the living modified organism and the parent organism, the vector used, the genetic modification and the novel trait;
c) the intended use of the living modified organism and the nature of the receiving environment;
d) potential impact of the living modified organism on the environment , particularly on centres of origin and areas with high genetic diversity relevant to the living modified organism;
e) possible effects of the living modified organism on human health;
f) risk assessment techniques developed by relevant international organisations; and details of risk assessments completed elsewhere, as appropriate.

B. Specific information requirements:

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

a) Strain, cultivar or other name;
b) Species it is related to and degree of relatedness;
c) The degree of relatedness between the donor and recipient organisms, or between parental organisms; pathogenicity, toxicity and allergenicity (in the case of micro-organisms, it should be noted that there are internationally accepted classification lists for human pathogens. Similar lists exist at national level for plant and animal pathogens in some countries);
d) The natural habitat and the geographic origin of the organism, its distribution and its role in the environment;
e) All sites from where the donor and recipient organisms or parental organisms were collected, if known;
f) 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;
g) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
h) Phenotypic and genetic markers of interest;
i) Ability of the organisms to survive and colonise the environment to which release ,is intended or otherwise;
j) Genetic stability of the organisms, and factors affecting the stability;
k) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic

stability;

l) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;
m) Pathogenicity to humans or animals, if any;
n) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;
o) Known allogenicity and/or toxicity of biochemical and metabolic products;
p) Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

2. Characteristic of the vector(s):

a) Nature and source of the vector(s);
b) 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 maker gene(s);
c) Ability of the vector(s) to mobilise and transfer genes by integration and methods for determining the presence of the vector(s);
d) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
e) Potential for pathogenicity and virulence;
f) Natural and host range of vectors;
g) Natural habitat and geographic distribution of natural and potential hosts;
h) Potential impacts on human and animal health and the environment;
i) Measures for counteracting adverse impacts;
j) Potential to survive and multiply in the environment, or to form genetic recombinants;
k) Genetic stability of vector(s), such as hypermutability.

3. Characteristics of living modified organisms The LMO should be compared with the organism from which it is derived, examining, where relevant the following points:

a) The description of the modifications made using gene technology;
b) The function of the genetic modifications and/or the new insert, including any marker gene(s);
c) Purpose of the modification and intended use in relation to need or benefit;
d) Method of modification, and in case of transgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism;
e) Whether introduced gene(s) integrated or extra-chromosomal;
f) Number of insert(s) and its/their structure(s), for example, the copy number whether in tandem or other types of repeats;
g) Products of the transferred gene(s), levels of expression and methods for measuring expression;
h) Stability of the introduced gene(s) in terms of expression and integration;
i) Biochemical and metabolic differences of living modified organism compared with the unmodified organism;
j) Probability of vertical or horizontal gene transfer to other species;
k) activity of the expressed protein(s);
l) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;
m) sensitivity, reability (in quantitative terms) and specificity of detection and identification techniques;

n) health considerations:
o) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;
p) Allogencities, toxicities, pathogenicities and unintended effects;
q) Autecology of the living modified organism compared with that of the unmodified organism;
r) Susceptibility of the living modified organism to diseases and pests compared with the unmodified organism;
s) Detailed information on past uses including results on all experiments leading to previous releases.
t) History of previous genetic modifications
u) natural and potential range of geographical distribution of the LMO and its parental organisms including information on their natural habitats, predators, prey, parasites, competitors, symbionts, commonsals and hosts;
v) biochemical and metabolic differences of the LMO compared with those of the unmodified organisms;
w) probability of inserts or transferred genes to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;
x) Description of genetic traits which may prevent or minimize dispersal of genetic material

4. Safety considerations for human and animal health: Information on the living 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:

a) Capacity for colonisation;
b) If the living modified organism is pathogenic to humans or animals the following information is required:
   i) diseases caused and mechanism of pathogenicity, including invasiveness and virulence, and property of virulence;
   ii) communicability;
   iii) infective dose;
   iv) host range and possibilities of alteration;
   v) ability to survive outside of the human or animal host;
   vi) the existence of vectors or other means of transmission;
   vii) biological stability;
   viii) allergenicity;
   ix) availability of appropriate therapies.
   x) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
   xi) antibiotic-resistance patterns,
   xii) generation time in natural ecosystems, sexual and asexual reproductive cycle;
   xiii) information on ability to form survival structure e.g.: seeds, spores or sclerotia;
   xiv) Possible activation of latent viruses (porviruses).
   xv) Ability to colonize other organisms;
   xvi) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc
   xvii) classification of hazard according to existing rules concerning the protection of human health and/or the environment;

5. Environmental considerations: Information on the living 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:

a) Factors affecting the survival, reproduction and spread of the living modified organism in the environment;
b) Available techniques for detection, identification and monitoring of the living modified organism;
c) Available techniques for detecting transmission of genes from the living modified organism to other organisms;
d) Known and predicted habitats of the living modified organism;
e) Description of the ecosystems which could be affected by accidental release of the living modified organism;
f) Possible interactions between the living modified organism and other organisms in the ecosystem which might be affected by accidental release;
g) Known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, being a vector of pathogens, allergenicity, and colonisation;
h) Possible involvement in biogeochemical processes;
i) Availability of methods for decontamination of the area in case of accidental releases;
j) Effects on agricultural practices with possible undesirable impacts on the environment.
k) purpose and scale of the release;
l) geographical description and location of the release;
m) proximity to residences and human activities;
n) method and frequency of release;
o) training and supervision of personnel carrying out the work;
p) expected environmental conditions during the release
q) subsequent treatment of the site and plans for waste management;

6. Release of GMOs for biological control: Apart from compliance with the general principles, other specific factors that should be taken into consideration can include:

a) effect on species targeted for biological control, parent organism and probable effect on ecosystem;
b) host range specifiicities as to whether there will be possibilities of GMOs affecting non-target species;
c) secondary effect on predators and parasite of the target species;
d) effect of secondary metabolities produced by GMOs on other organisms in the food chain.

7. Release experiment of GMO for bioremediation: Apart from compliance with the general principles, other specific factors that should be taken into consideration can include:

a) effect of the parent organism on its target substrate;
b) effect of GMOs on target substrate;
c) effect of secondary metabolities produced by a GMO on other organisms in the community/site of release;
d) effect of GMO on water, air or soil quality;
e) possible toxicity effect to other organisms that ingest the GMO;
f) possible dispersal of GMO from site of application and its consequences.

g) the geographical location of the site, the identity and any special features of the receiving environments that expose them to damage;
h) the proximity of the site to humans and to significant biota;
i) any flora, fauna and ecosystems that could be affected by the release, including keystone, rare endangered or endemic species, potential competitive species and non-target organisms;
j) the potential of any organism in the potential receiving environment to receive genes from the released organism.

8. Socio-economic considerations:

a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the living modified organism or product thereof;
b) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;
c) 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;
d) 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 living modified organisms;
e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;
f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the living modified organism or product thereof.

ANNEX III

RISK MANAGEMENT SCHEMES

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

A. General Precautions

a) Appropriate information and training is provided for those involved in handling the organisms;
b) Monitoring procedures are applied in such a way that appropriate measures can be taken in case of unexpected effects during or after the release;
c) The dissemination of the released organisms and/or gene flow from the released organisms are controlled;
d) Controlling access to the release site.
e) All trials, experiments or observations shall be subjected to the procedures of approval by the institutional and national level bodies.
f) All experiments outside of strict laboratory isolation and initial experiments involving imported living modified organism shall be subject to approval.
g) Once approval from the appropriate national authority is obtained at the completion of the final stage of the trials, experiments or observations, the living modified organisms in question can be employed for its intended use. The appropriate national authority shall notify its decision in writing to the competent authority
h) Whenever there is a need to dispose of the living modified organism upon the completion of every trial or experiment, it shall be made through complete incineration or other approved means of complete destruction.
i) The release of living modified organism shall be monitored appropriately and emergency plans to prevent escape and accident shall always be in place.

B. For Plants

Applying reproductive isolation, by:

a) spatial separation;
b) temporal separation: use of plants that will flower either earlier or later than plants of nearby reproductively compatible species;
c) biological prevention of flowering (e.g. by omitting vernalisation);
d) removal of the male or female reproductive structures;
e) bagging of flowers
f) making use of sterility.
g) Controlling the persistence or reproductive structures structures such as propagules or seeds.
h) Destroying volunteer plants after harvest; control of volunteers nay be necessary during longer periods, depending on the species. The reports from releases in areas other then the State of import shall be thoroughly evaluated by the designated authority. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;

i) 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;

j) The observations will include the health of the living modified organism, the health of the organism within the area of limited release, the biological diversity and the ecology of the area;

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

C. For Animals

a) Confining by appropriate means such as fences, filters, islands, ponds;
b) Applying reproductive isolation by using sterile animals;
c) Isolation from feral animals of the same species.
d) Controlling the persistence or dispersal of reproductive structures such as larvae or eggs. The reports from releases in areas other than the State of import shall be thoroughly evaluated by the designated authority. Particular emphasis shall be given to whether the applicable controls in the previous release have been adequate to ensure safety;
e) If the controls 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;
f) 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.

D. For micro-organisms

a) Using organisms with impaired ability to grow or persist in the environment;
b) Minimising gene transfer by:
   i) Using organisms that do not contain known self-transmissible mobilizable or transposable genetic elements;
   ii) Ensuring that introduced traits are stably located on the chromosome.

These measures will often not be applicable once an LMO, such as a modified crop plant, is a result of testing during research and development, it has been shown that the risks are acceptable low.

ANNEX IV

FUNCTION OF FOCALPOINTS/COMPETENT AUTHORITIES

1. The competent authority/ies shall be responsible for procedures related to Advance Informed Agreement (AIA), notification and information exchange.

2. The competent authority in the State of import shall also be responsible for procedures related to risk assessment and risk management.

3. The Competent Authority shall fulfil the following responsibilities:
   a) to establish national guidelines and/or regulations for the implementation of the AIA procedures including detailed criteria for risk assessment within their competence;
   b) to receive from exporters applications for the AIA procedures;
   c) to conduct/evaluate risk assessment;
   d) to take a decision on result of the risk assessment;
   e) to transmit decisions on AIA to the notifier and other relevant agencies;
   f) making decisions on the transfer, handling or use of the LMO to or within the receiving country.
   g) to establish and impose such conditions as it deems appropriate regarding the movement of LMOs in order to protect its environment and human health;
   h) To establish appropriate procedures of control or mitigation, to finish release and eliminate wastes.
   i) To establish mechanisms for information exchange between countries and to develop national data bases.
   j) To keep a Registry of all activities related to Living Modified Organisms
   k) the rest as established by this Protocol
   l) Any other assigned by their corresponding governments

1. The focal point, which preferably shall be identical to the competent authority/ies, shall function as the contact point for the Protocol and shall be responsible for receiving and submitting information provided for in Articles 4, 5 & 6.

2. The focal point shall have the following responsibilities:
   a) to provide other Contracting Parties, through the Secretariat of the Protocol, with general information on the implementation of the Protocol at the national level including, in particular, information on competent authorities responsible for the AIA procedures and/or for LMOs;
   b) to collect information on the implementation of the protocol at its national level; and
   c) to assist communication between foreign, regional or international institutions established for the implementation of the Protocol on the one hand and the national competent authorities on the other.
   d) to serve as the focal point for handling inquiries and proposals regarding any intended transfer/transboundary movement/release which affects its country or any activity undertaken on LMOs within its national boundaries;
   e) ~~to be informed immediately~~ in the event of an adverse effect of the transfer of the LMOs which could affect it.

ANNEX V

INFORMATION TO BE PROVIDED TO THE SECRETARIAT UNDER INFORMATION SHARING/CLEARING HOUSE

1. The Parties shall facilitate and encourage the collection and exchange of information relevant to the implementation of this Protocol. The Parties shall provide the Secretariat with the following information *inter alia*:

a) designations of competent authorities/focal points and changes in such designations;;
b) the text of any national decisions/reviews about LMOs contained uses, releases, marketing and transboundary transfers under AIA;
c) general matters relevant to risk assessment/management associated with LMOs;
d) information on accidental/unintentional movements of LMOs
e) other relevant information ;
f) national risk management procedures for use and handling of living modified organisms;
g) national institutional framework for monitoring and compliance within their territories;
h) all living modified organisms which have been subject to bans or restrictions by that Party;
i) any unintentional/accidental transboundary movements of living modified organisms and biosafety measures implemented in that cases;
j) any releases of living modified organisms which could result in unintentional transboundary movements of living modified organisms; and biosafety measures implemented in that cases;
k) any incidents of unauthorized or otherwise illicit transboundary movements of living modified organisms
l) a list of living modified organisms subject to advance informed agreement which have been assessed for import into or use in its territory at the time of coming into force of this Protocol for that Party and a description of any conditions attached to imports of such living modified organisms.
m) general description of products consisting of or containing LMOs having received consent by a Party or Parties for placing on the market;
n) a summary of any methods and plans for monitoring of LMOs
o) national guidelines and/or regulations for the implementation of the Protocol, including information required for the AIA procedures and for risk assessment
p) any bilateral, regional and multinational agreements or arrangements as well as unilateral declarations on the exemption and/or the simplification of the AIA procedures.
t) Periodical report on the implementation of the AIA procedures, including statistics.
w) information on LMOs released on the market;
x) information on prohibited, approved and newly developed LMOs;
y) information on monitoring post-commercial release of LMOs;
z) lists of experts advisory bodies and training workshops/programmes;
