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Article 3 ADVANCE INFORMED AGREEMENT

AFRICAN GROUP

1. A Party shall permit the export of living modified organisms or products thereof only when it confirms that the agreement of the State of import has been obtained in advance based on the necessary information that the State of import has received in accordance with the provisions of Article 4 and Annex I.

2. The competent authority of the State of export shall require the exporter to submit, *inter alia*, information identified in Annex I.

3. The competent authority of the State of import shall provide information to the exporter, through th competent authority of the State of export concerning its laws, regulations, guidelines, legal and administrative procedures and other requirements related to the safe development, handling and use of living modified organisms and products thereof.

4. No transboundary transfer of living modified organisms or products thereof shall be allowed without the advance informed agreement of the State of import. The State of export shall not allow th exporter to commence the transboundary transfer until it has received written confirmation that th applicant has received the advance informed agreement of the State of import.

5. No transboundary transfer of living modified organisms or products thereof shall be allowed by th State of export unless risk assessment has been undertaken and such organisms or products are adequately and effectively tested by well recognized procedures and test methods in the State of export or State of origin, as agreed to by the State of import, so as to fully evaluate their safety in the various anticipated conditions in the State of import.

6. Any transboundary transfer shall be covered by insurance, bond or other guarantee as may be required by the States concerned and/or recommended by the Biosafety Clearing House.

7. The Parties shall, whenever it comes to their knowledge, ensure in the case of any unintended or deliberate release or any accident occurring during or subsequent to the transboundary transfer of living modified organisms, which are likely to present risks to human and animal health, biological diversity, the environment or the socio-economic welfare of societies in other States, that those states are immediately informed.

BELARUS

1. All initial transfers of LMOs to another country shall be subject to the AIA procedure. No transboundary transfer of LMOs shall be allowed without the AIA. The State of Export shall not allow the export and the State of Import shall not allow the import of LMOs until the Exporter has received the AIA. Explicit consent should be a requirement for initial shipment of all LMOs. Implicit consent shall apply to subsequent shipments of LMOs. In that case transboundary transfer of th LMOs shall be carried out according to the common procedure adopted in the State of Import for transboundary transfer of organisms which are not LMOs.

BRAZIL

1. Explicit Advanced Informed Agreement shall be required for the first import of living modified organisms, and/or products thereof, resulting from modern biotechnology, which may have advers effects on the conservation and sustainable use of biological diversity, taking also into account human health.

COLOMBIA

1. Each Party shall apply the PIC procedure provided under article (PIC) with regard to th transboundary movement of any LMO.

2. Each Party shall ensure that any LMO leaving its territory shall be furnished with du authorization of the designated national authority of the receiving Party.

3. Parties which receive information and notifications of transboundary movements under the present Protocol shall ensure the confidentiality of the information of that natur which they have received.

CUBA

1. It is established an advance informed agreement procedure on Living Modified Organisms subject to international trade which may have adverse effects on human health and the environment.

2. The Living Modified Organism prohibited or severely limited for health or environmental reasons shall be submitted to advance informed agreement.

3. In their first meeting , the Parties will establish the scope, the documents and the mechanisms for th information and previous consent procedure and the criteria to select the Living Modified Organisms which would be included in the previous fundamental consent procedure.

4. The Parties exporting a Living Modified Organism on which no field tests were allowed in the country shall communicate the reasons and all the information concerning this to any other country where they intend to export it.

EUROPEAN COMMUNITY

1. The Parties shall cooperate with a view to deciding, as soon as possible, to what extent in relation to the procedures, and in which cases, to be specified in Annex (es), the intentional transboundary movement cannot proceed without an explicit consent.

INDIA

1. "Advance informed agreement" means an agreement by the competent authority of the State of import to the transfer of any living modified organisms or products thereof based on the information supplied by the competent authority of the State of export with the understanding that the information is accurate and complete."

2. A Party shall permit the export of living modified organisms or products thereof only when it confirms that the advance informed agreement of the State of import has been obtained based on the necessary information that the State of import has received in accordance with the provisions of Article 4 and

Annex I.

3. No transboundary transfer of living modified organisms or products thereof shall be allowed without the advance informed agreement of the State of import. The State of export shall not allow th exporter to commence the transboundary transfer until it has received written confirmation that th applicant has received the advance informed agreement of the State of import.

4. No transboundary transfer of 1iving modified organisms or products thereof shall b allowed by the State of export unless risk assessment has been undertaken that these organisms or products ar adequately and effectively tested for the safety in the various anticipated conditions in the State of import.

5. Every State shall take legal measures that the transboundary transfer originating fro it be covered by insurance, bond or other guarantee.

6. The Parties shall, whenever it comes to their know1edge, ensure in the case of any unintended or deliberate release or any accident occurring during or subsequent to the transboundary transfer of living modified organisms, which are likely to present risks to human and animal health, biological diversity or the environment in other States, that those states are immediately informed.

JAPAN

1. The Contracting Parties to the Protocol (Hereinafter referred to as ontracting Parties") shall establish national measures to implement the Advance Informed Agreement (hereinafter referred to as IA") procedures which ensures that an Exporter intending to transfer beyond its national boundary living modified organisms (hereinafter referred to as MOs") resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity shall provide th competent authorities of the recipient Contracting Party with information on the transboundary transfer of the LMOs in question and receive the recipient Contracting Party agreement in advance.

2. The AIA procedures shall be initiated by the Exporter by submitting an application to the competent authority of the recipient Contracting party. The application shall be accompanied by information necessary for the AIA procedures.

3. LMOs Subject to the AIA Procedure;
   (a) All transboundary transfers of LMOs resulting from modern biotechnology, except thos mentioned in #4 below, sha ll be within the scope of the application of the AIA procedures.
   (b) Organic materials which are components of LMOs but are not self-reproducible in th environment, such as DNA or RNA segments, plasmids and peptides, shall, by definition, not be regarded as LMOs and be thus excluded from the application of the AIA procedures.
   (c) LMO products which do not contain live cells shall also be excluded from the application of the AIA procedures.

4. Exclusion from the Application of the AIA procedures;
   (a) The LMOs which are ubject to any other international agreement related to transboundary transfer of LMOs shall be excluded from the application of the AIA procedures.
   (b) The LMOs requested to be imported by the competent authority of the recipient Contracting Party for the purpose of carrying out risk assessment as a process of the AI procedures stipulated in this Protocol shall be excluded from the application of the AI procedures.

(c) Those LMOs shall be excluded from the application of the AIA procedures if they are to be used, such as for experimental purposes, exclusively under confined conditions defined in this Protocol and if it is established by the Conference of the Parties to the Protocol that there does not exist any risk to the environment and human health by the use of thos LMOs under the conditions so defined.

MADAGASCAR

(d) The advanced informed agreement is a means of providing official information on LMOs and products thereof, which are to be introduced into a particular country.

(e) The advance informed agreement is designed to trigger a decision-making process on the futur importation of LMOs and products thereof. Its aim is to promote responsibility-sharing between exporting and importing countries, in the area of the protection of human health, biological diversity, the environment and social and economic welfare, against the adverse effects of LMOs.

(f) LMOs and products thereof may not be introduced into a country without the prior agreement of th State of import based on the various necessary reports received.

(g) The advanced informed agreement may cover both unrestricted imports and limited imports.

MALAYSIA

1. Each Party shall apply the Advance Informed Agreement procedure with respect to all living modified organisms defined in this Protocol.

2. No transfer, handling or use of LMOs to or within any receiving country Party shall be allowed without the advance informed agreement of the receiving country Party in accordance with the Advanc Informed Agreement procedures defined below.

3. No intending country Party shall transfer, handle or use LMOs to or within a receiving country Party without first obtaining the receiving Party consent. Any Party exercising jurisdiction over an individual person or entity shall ensure that no such person or entity shall transfer, handle or use LMOs to or within the receiving country Party without first obtaining the receiving Party consent, through the receiving Party National Competent Authority.

MEXICO

1. To effect a transboundary movement, the exporter must submit an application, in the official format used by the importing country, to the competent authority of the importing country and before shipping the product, with all the information required by that competent authority and in accordance with th national law in force in the importing country.

NORWAY

1. All first intentional transboundary movements of a specific LMO for specific purposes or uses into a

new country, shall be subject to the procedure for Advance Informed Agreement (hereafter referred to as AIA). The State of import may, however, declare that low-risk micro-organisms and other lo -risk research organisms intended for contained use shall not be covered by the AIA procedure.

PERU

1. The exporter must notify in writing the competent national authority of the importing country regarding his intention to export, through his own competent national authority.

2. No transboundary movement of LMOs or products derived from them shall be allowed without th Advance Informed Agr ment of the importing country.

3. When a country has knowledge of an deliberate or unintended release or of any accident occurring in a neighbouring country which may constitute a risk its own biosafety, it should inform the competent national authorities of the Parties that participated in the agreed transboundary movement concerned. At the same time, the country should inform the international agencies, indicating its concern about th risk involved.

4. The present protocol assumes that the only valid procedure for the importation of LMOs or products derived from them is the Advance Informed Agreement.

SOUTH AFRICA

1. Subject to Article 9 paragraph 1, all initial transfers of LMOs to another country which is Party to this Protocol, will be subject to the AIA procedure.

2. In accordance with para. 1, no transboundary transfer of LMOs shall be allowed without an AIA of th State of import. The Competent Authority of the State of export shall not allow the exporterto commence the transboundary transfer until it has received the AIA from the Competent Authority of the State of import.

SRI LANKA

1. Each Party shall apply the Advance Informed Agreement procedure with respect to all living modified organisms (LMOs) and products thereof that come under its jurisdiction as defined in this Protocol.

2. No export or transfer of any LMOs or products thereof in any receiving party shall be allowed without the Advance Informed Agreement of the receiving party in accordance with the AIA procedures defined in Article 2.

3. No export of LMOs or products thereof shall be allowed by the State of Export unless risk assessment has been carried out with the said LMOs or products thereof by testing them adequately by scientifically accepted methods in the State of Export or State of Origin, as agreed to by the State of Import.

4. Every export of LMOs shall be covered by insurance, bond or other guarantee as may be required by the Parties concerned and/or as stipulated in the Biosafety protocol.

SWITZERLAND

1. Each exporting Contracting Party shall, with respect to the export of living modified organisms within the scope of this Protocol:

   (a) take appropriate legislative and/or administrative measures to ensure compliance by exporters with importing Contracting Party responses under Article 6;
   (b) assist, upon request and as appropriate, focal points in importing Contracting Parties in obtaining further information relating to decisions with respect to Article 6.

UNITED STATES OF AMERICA

1. Scop. An LMO is subject to this Article where:

   (a) The LMO has not been imported into the importing Party and the LMO is not being produced in the importing Party, and
   (b) The LMO is on
      (1) that is intended for field testing or first field growth in the importing Party, including in particular field testing or first field growth in a center of origin or genetic diversity for that product;
      (2) that has been banned or refused approval in the exporting Party because of potential adverse effects on the conservation and sustainable use of biodiversity that wer identified during the review process;
      (3) for which approval is in the process of being sought in the exporting Party;
      (4) for which approval in the exporting Party would have been required had the LMO been intended for domestic commercialization or growth in the exporting Party but for which approval was not sought because the LMO was not intended for commercialization, field testing, or field growth in the exporting Party; or
      (5) for which approval in the exporting Party would have been required had the LMO been intended for domestic commercialization or growth in the exporting Party but for which an application or request for approval was withdrawn.

Article 4
NOTIFICATION PROCEDURE FOR AIA

AFRICAN GROUP

1. The State of export shall notify, or shall require the exporter to notify by application in writing, through the channel of the competent authority of the State of export, the competent authority of the states concerned of any proposed transboundary transfer of living modified organisms or products thereof. Such application shall contain the declarations and information specified in Annex I, written in a language acceptable to the State of import. One application or notification shall be sent to each of th States concerned and to the Biosafety Clearing House.

2. The State of export shall, through its competent authority, examine the conformity to the notifications

under paragraphs 1 above with the requirements of this protocol and the State of import, and shall stand surety for the accuracy and completeness of the information supplied by the exporter, on th basis of which the advance informed agreement is made.

AUSTRALIA

1. The exporting Party shall notify, or shall require that notification be given to, in writing, the Focal Point of the importing Party, intent to export a living modified organism for the first time into an importing Party. The information to be provided with the notification is set out in Annex I to this Protocol.

2. The importing Party shall acknowledge the notification, in writing, within a reasonable period of time. This acknowledgment shall include:

    1. advice that a risk assessment has been or is to be carried out; and
    2. a request, as necessary, for any further information which remains to be provided in accordance with this Article.

BELARUS

1. The AIA procedure shall be triggered by the Exporter. The application shall be submitted to th competent authority/focal point in the State of Import. The Exporter has to supply all the information about the LMO necessary for implementation of adequate risk assessment.

2. The competent authority/focal point in the State of Import shall provide information to the Exporter concerning its laws, regulations, guidelines, legal and administrative procedures and other requirements related to the biosafety.

3. If at any time before, during or after the transboundary transfer, the exporter/importer becomes awar of relevant new information on the LMO in questions, which could have significant consequences for the associated risks, th competent authority/focal point of the State of Import shall be informed within 30 days. In that cases the new AIA should be obtained for further export/import of LMOs.

BRAZIL

1. The procedure for Advanced Informed Agreement is as follows:

    (a) The exporting Party shall submit the information identified in Annex I, in writing, to th importing Party

    (b) the competent authority of the importing Party shall acknowledge receipt of the notification of intent to export, in writing, within ten working days;

    (c) the competent authority of the importing Party may request additional information, as deemed appropriate, at any point prior to final decision;

    (d) the importing Party will undertake a risk assessment, according to scientific principles and supported by the best available scientific evidence;

CANADA

1. Each Party of import shall require notification to be given, by the importer, to the Party of import of the first proposed transboundary movement of a living modified organism (LMO) subject to AI before it is imported.

2. Each Party of import shall require importers to immediately, and in no case later than thirty days, after learning of such information, notify the Party of import of:

   (a) any new available information regarding potential adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, including within th Party of import, and
   (b) new information on change in use, containment or conditions of release.

3. Each Party shall make its importers responsible for the accuracy of the information provided in a notification and for any new information provided pursuant to this Article.

COLOMBIA

1. The PIC procedure shall be triggered by notification of a request for transboundary movement of any LMO by the designated national authority of the Party of origin addressed to the designated national authority of the receiving Party and, where applicable, to the designated national authority of the Party of transit.

2. The request for transboundary movement shall contain the information specified in annex I to th present Protocol.

Each Party of origin shall:

(a) Provide all the information necessary, in accordance with the provisions of articl (Notification);

(b) Apply adequate legislative and/or administrative requirements to communicate th responses of the receiving Party to the individuals and bodies corporate concerned in its territory;

(c) Respect the conditions established in the response from the receiving Party no later than XXX days following the date of receipt of the communication in question;

(d) Take adequate legislative or administrative measures to ensure that the transboundary movement of the LMOs complies with the stipulations in:

(i) The response from the receiving Party;

(ii) The provisions of the article (Handling, transport and packaging);

(e) Advise and assist, on the request of the designated national authority of the receiving country, in obtaining additional information on decisions of other designated national authorities relating to the LMO involved in the transboundary movement.

CUBA

1. The Parties that take provisions to prohibit or limit severely the use and manipulation of a living modified organism to protect health and environment shall notify the International Registry th measures adopted.
2. The Parties shall ado pt pertinent legislation to secure the exporter and the importer provide th documents established by the International Registry on Living Modified Organisms befor commercializing it as a product or as part of it.

EUROPEAN COMMUNITY

1. For the intentional transboundary movement of LMOs, the exporter shall notify in advance the party of import in writing of that movement and shall only proceed with such movement in compliance with Articles 5 and 6 [these articles address Acknowledgment of Receipt, Procedures and AIA]. Information to be provided in the notification is specified in Annex I.

2. The Party of import shall within 30 days of the date of receipt of the notification acknowledge to th notifier the date of receipt of the notification.

3. The Party of import shall within the period referred to in Article 6 {Acknowledgment of Receipt} [30 days of the date of receipt of the notification] inform the notifier to proceed according to:

    a) either its regulatory framework implementing Article 8(g) of the CBD, provided the framework includes a control mechanism for transboundary movement consistent with the protocol;
    b) or the procedure provided for in Article 4 {AIA}.

4. All decisions by the Party of import shall be based on scientific risk assessment of the adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

INDIA

1. The competent authority of the State of export shall require the exporter to submit, *inter alia*, the information identified in Annex I.

2. The competent authority of the State of import/export shall provide information concerning its laws, regulation, guidelines, legal and administrative procedures and other requirements related to the saf development, handling and use of living modified organisms and products thereof.

3. The State of export shall notify, or shall require the exporter to notify in writing, through the channel of the competent authority of the State of export, the competent authority of the States concerned of any proposed transboundary transfer of living modified organisms or products thereof. Such application shall contain the declarations and information specified in Annex I, written in a language acceptable to the State of import. Only one notification needs to be sent to each of the States concerned and to th Clearing house.

4. If, at any time before, during or after the transboundary transfer, the exporter becomes aware of relevant new information on the living modified organism or the product in question which could have significant consequences for the associated risks, the competent authorities of the State concerned and the Clearing House shall be informed immediately on being aware but in any case not later than 15 days from being aware.

5. The State of export shall, through its competent authority, examine the conformity to the notification under paragraphs 1 and 2 above with the requirements of this Protocol and the State of import, and shall stand surety for the accuracy and completeness of the information suppli d by the exporter, on the basis of which the advance informed agreement is made.

JAPAN

1. The information to be provided to the competent authorities of the recipient Contracting Party for th implementation of the AIA procedures shall be specified and enumerated in a list by the Conference of the Parties to the Protocol. The list shall be reviewed, by the Conference of the Parties to the Protocol, periodically in the light of the most recent and best available scientific knowledge and experience, as well as other relevant information. The Conference of the Parties to the Protocol may establish a technical advisory body with the task of providing the Contracting Parties with scientific backgrounds for reviewing the list.

2. The competent authorities of the recipient Contracting Party may request the Exporter to provid additional relevant information if necessary.

3. The competent authorities of the exporting Contracting Party shall respond to inquiries from th recipient Contracting Party on the contents and the authenticity of the information provided by th Exporter.

MADAGASCAR

1. The exporter will officially submit information to the competent authority of the State on the LMOs in question or on the products thereof, which are the object of introduction or transfer, in accordance with an annexed list of the protocol (taxonomy, handling method and mode of utilization. etc.)

2. The competent national authority of the State of import shall provide information to the exporting country concerning the laws, regulations, legal and administrative procedures existing and in force in the country.

3. The reporting procedure should to be a general procedure whether it involves an initial introduction or reintroduction of LMOs and products thereof.

4. The exporter has to submit in writing all information regarding any transboundary movement of LMOs and products thereof.

5. The exporter (public organization, company, university, research centre or export agent) operating in

the State of import, can submit a request to transfer LMOs. The notification shall be addressed to th competent national authority.

MALAYSIA

1. Any Party who intends to transfer, handle or use any LMO to or within any receiving country Party shall give prior notice to, through its National Competent Authority, the National Competent Authority of the receiving country Party, by application in writing of its intention to do so.

2. Each Party shall ensure that any individual person or entity under its jurisdiction who intends to undertake any transfer, handling or use of LMOs to or within any receiving country Party shall giv prior notice to the National Competent Authority of the receiving country Party by application in writing, of its intention to do so. Such notification shall be done through the National Competent Authority exercising jurisdiction over such individual person or entity. However the notification may b made directly to the National Competent Authority of the receiving country Party provided the Party exercising jurisdiction over that individual person or entity ensures, through its national legislation, that all the conditions satisfying the provisions of this Protocol are fulfilled, and that such Party shall b responsible and liable for the individual person or entity actions regarding the transfer, handling or use of LMOs to or within the receiving country Party.

NORWAY

1. The State of export shall require the exporter to supply either through the channel of, or by providing a copy to the competent authority of the State of export the information included in Annex I to the Stat of import, prior to the first intentional transboundary movement of LMOs.

2. If at any time before, during or after the intentional transboundary movement the State of export or import has gained new experience or becomes aware of relevant new information related to the LMO in question, which could have consequences for the risks, the States concerned shall be informed within 30 days and the AIA decision may be changed accordingly.

PERU

1. Such applications should include the declaration and information required in accordance with th Advance Informed Agreement procedure, in a language acceptable to the importing country. Each on of the parties involved should receive a copy of the document. Should there be intermediate ports of loading (transit countries), these should also receive a notification requesting their consent.

2. The competent national authority shall analyse the information provided by the exporting country, and shall be entitled to request additional information if considered necessary, while maintaining a discreet reserve in respect of any information the applicant may list as confidential. After a prudent length of time (established by the internal regulations of the importing country), it shall authorize or refuse th application.

3. The basic criterion for Advance Informed Agreement shall be:

a) The exporting party shall only cause to be brought into an importing country, a modified organism or organisms or products derived from them, when the prior consent of that importing country has been obtained in advance after the presentation in writing, through the national competent authority, of an application in an official language, attaching the information required by the importing country.

4. The competent authority of the importing State shall provide information to the exporter, through th competent authority of the exporting State concerning its laws, regulations, guidelines, legal and administrative procedures and other requirements related to the safe development, handling and use of living modified organisms and products derived from them.

SOUTH AFRICA

1. In cases where the Competent Authority of the Stat of import considers that the documentation provided by the Competent Authority of the State of export is not sufficient in order to determine th potential or anticipated adverse effects of an LMO, the Competent Authority of the State of import may request such additional information as it deems necessary for this purpose. The Competent Authority of the State of export, or the exporter, may require the Competent Authority of the State of import to enter into an agreement of confidentiality, regarding, such additional information requested by the Competent Authority of the State of import.

2. All Parties to this Protocol will, whenever it comes to their knowledge, ensure in the case of any unintended or deliberate release or any accident occurring during or subsequent to the transboundary transfer of living modified organisms, which are likely to present risk to the biological diversity, th environment or human and animal health in other States, that those states are immediately informed.

SRI LANKA

1. Any Party who intends to export or transfer any LMOs to any recipient Party shall notify the National Competent Authority or its accredited agency.

2. The exporter shall not commence the transboundary movement until it has received written confirmation that the applicant has received the AIA of the Party of Import.

3. Any Party who intends to export or transfer any LMO to any receiving Party shall notify, through its National Competent Authority or its accredited agency, the National Competent Authority of th receiving party, by application in writing of its intention to do so.

SWITZERLAND

1. Prior to the first shipment of a living modified organism, the exporter has to supply the national focal point in the importing Contracting Party with an application containing the information listed in Annex I.

UNITED STATES OF AMERICA

1. Each exporting Party shall notify, or require a natural or legal person under its jurisdiction to notify, in writing, the importing Party through the importing Party's national focal point prior to the first export

to the importing Party of an LMO that is subject to AIA (those LMOs which may present risks to th conservation and sustainable use of biodiversity). The notification need be sent to only one focal point in the importing Party concerned. The notification shall include the information contained in the annex to this protocol.

Article 5
DECISION PROCEDURE FOR AIA

AFRICAN GROUP

1. The States of import and transit shall respond to the applicant in writing, consenting to the transfer with or without conditions, denying permission for the transfer, or requesting additional information. A copy of the advance informed agreement of the State of import, if obtained, or any final decisions thereto, shall be submitted to the competent authority of the State of export and to the Biosafety Clearing House.

AUSTRALIA

1. The importing Party shall make all import decisions. Decisions shall be based on scientific principles and supported by the best available scientific evidence. Decisions shall consist of :

    1. approval to import, without conditions; or
    2. approval to import, with specified conditions; or
    3. prohibition to import.

2. The importing Party shall provide full details to the exporting Party or exporter, in writing, and th Clearing House on:

    1. the basis for the decisions, including full details of risk assessments;
    2. whether the decision applies, either in whole or in part, to other potential imports of th same living modified organism; and
    3. whether notification is required for subsequent imports of the same living modified organism, in accordance with Article 10 {Notification for Subsequent Imports}.

BELARUS

1. The respond of the competent authority of the State of Import may consist of either:
    a) explicit consent to import;
    b) not consent to (or prohibit) import;
    c) consent to import only under specified conditions;
    d) statement that final decision needs additional period of time;
    e) request of additional information about the LMO. In cases where competent authority/focal point in the State of Import considers that the documentation provided is not sufficient, th burden of proof lies with the Exporter.

2. A copy of the AIA, if obtained, or any final decision thereto, shall be submitted by the competent authority/focal point of the State of Import to the competent authority/focal point of the State of Export

and to the Biosafety Clearing House (Biosafety Centralized Data Base).

BRAZIL

1. the importing Party shall make a decision, which may consists of:
   (a) approval to import, without conditions;
   (b) approval to import, with specified conditions; or
   (c) prohibition of import.

COLOMBIA

1. The designated national authority of the receiving Party shall review the content of the request and, if found in order, shall, within XXX days following notification, communicate such finding in writing to the designated national authority of th Party of origin.

2. In the event that the request is found not to be in order, the designated national authority of th receiving country may request, within the period specified above, the missing information, in which event the deadlines specified for these purposes shall be suspended until the requested information is provided.

INDIA

1. The States of import shall respond to the notification in writing, consenting to the transfer with or without conditions, denying permission for the transfer, or requesting additional information. Th States of import shall submit any final decision to the competent authority of the State of export and to the Clearing House.

MADAGASCAR

1. The importing country's consent must be explicit and notified in writing in the official language of th country.

2. All notifications are addressed to the exporter by the competent natural authority of the State of import, which shall always have ultimate authority in the matter and shall inform the clearing house of its decisions.

3. The decisions shall relate either to transfer consent with or without conditions, or to requests for further information or to transfer bans.

MALAYSIA

1. The Parties hereby agree that the receiving country Party has the right to make its own decisions on th application referred above in any manner it deems fit.

2. Upon receipt of the application by the National Competent Authority of the receiving country Party,

the receiving country Party shall provide an acknowledgement to the National Competent Authority of the intending country Party indicating either;

(a) request for additional information if the receiving Party feels that the information provided by the intending Party is incomplete; or
(b) upon satisfactory completion of the assessment of the information suppli d to it by the intending Party, consent to the transfer, handling or use of the LMO with or without conditions; or
(c) reject the application, absolutely or provisionally, with or without conditions.

MEXICO

(a) One of the following answers shall be given:

(a) Explicit consent for the transboundary movement;

(b) Conditional consent for the importation with certain biosafety measures indicated by th competent authority;

(c) An interim reply which allows either a longer period for the assessment committees to make an appropriate response, or to ask the exporter for further information and/or test data;

(d) Ban on transboundary movement.

1. The transboundary movement shall not be effected until an official reply is obtained.

2. A favourable official reply shall be accompanied by information on the regulations and norms indicating to the exporter, step by step, the requirements for importation, as well as the basis of th decision taken. If there is no explicit reply it means that the importation is banned.

NORWAY

1. The State of import shall respond to the notifier in writing:

1. consenting to the intended movement with or without conditions;
2. deny permission for the movement; or
3. provide an interim response, that may contain a statement to import with or without specified conditions or prohibiting import during the interim period. This may include a statement that a final decision is under consideration and/or a request for further information and/or extended period of time to respond.

2. In cases where the State of import considers that the documentation provided by the State of export is not sufficient in order to determine the potential adverse effects of an LMO, the State of import has th right to prohibit import of the LMO in question.

PERU

1. The importing country must respond in writing through the competent national authority, stating its approval or refusal or requiring additional information for the importation, and the countries of transit must also express their agreement in writing, and both one and the others should indicate if there ar particular conditions attached to such a transfer. The written replies shall be sent to all interested parties.

SOUTH AFRICA

1. The competent authority of the State of import shall respond in writing to the State of export within 60 days, indicating either;

    (a) explicit consent to import;
    (b) consent to import only under specified conditions or an interim response, that may contain a statement to import with or without specified conditions or prohibiting import during th interim period, which may include for example a statement that a final decision is under consideration and/or a request for further information.

SRI LANKA

1. The Competent Authority of the Party of Import shall be obliged to respond to the Party of Export within a period of six months. A response may consist of any of the following:

    a) explicit consent to import;
    b) explicit refusal to import;
    c) consent to import only under sp cified conditions;
    d) an interim response that further information is needed for a final decision.

2. Where the Party of Import considers that the documentation provided by the Party of Export is insufficient in order to assess the potential adverse effects of an LMO, the burden of proof of biosafety lies with the Party of Export.

SWITZERLAND

1. This response shall consist of either:

    (a) A final decision to consent to importation with or without specified conditions, or to deny to importation;

    (b) An interim respons which may include a statement that a final decision is under consideration and a request for further information and/or a request to the focal point of the exporting Contracting Party for assistance in assessing the application.

2. A final decision shall be accompanied by information describing the legislative and/or administrativ measures on which the decision is based. The same conditions, if any, shall apply to the imported and domestic produced living modified organisms.

UNITED STATES OF AMERICA

1. The importing Party shall so respond to the notifier by (a) consenting to the import with or without conditions, (b) denying permission for the import, or (c) requesting additional relevant technical information.

2. The importing Party's national focal point shall transmit its decision in writing to the notifier, to th exporting Party's national focal point(s), and to the central clearinghouse/database. The importing Party shall notify the aforementioned of any change in its decision.

Article 6
RESPONSE TO AIA NOTIFICATION

AUSTRALIA

1. Decisions regarding import should be made within a time frame agreed between the importing and exporting Parties.

BELARUS

1. The competent authority/focal point in the State of Import shall be obliged to respond to the application within 90 days. The absence of a reply within this time is not consent. In delay with reply the question on obtaining AIA can be addressed according to the Protocol's dispute settling mechanism.

BRAZIL

1. The importing Party will communicate its decision to the exporting Party in due time; and

2. The decision of the importing Party shall be justified, in writing, to both the exporting Party and th Clearing House Mechanism.

CANADA

1. Each Party of import shall acknowledge to the importer, not later than X days after receiving th notification under this Article, that the notification contains *prima facie* the information described under Annex I. Such acknowledgment does not limit the possibility to require further scientific information under Article 13.

COLOMBIA

1. The response of the designated national authority of the receiving Party to a request for transboundary movement shall take one of the following forms;

(a) A firm decision to:

(i) Permit the transboundary movement;

(ii) Prohibit the transboundary movement, in which case the Party of origin shall only be able, through its designated national authority, to request the receiving Party to conduct a risk assessment with a view to reviewing its decision. In this case, the receiving Party shall b able to call for payment of all or part of the costs of the assessment.

(b) An interim response which:

(i) States the need to conduct a risk assessment;

(ii) Requests additional information.

1. Should the designated national authority of the receiving Party decide to conduct the risk assessment, the deadlines established by the article (Obligations of the receiving Party) shall b suspended;

2. Once the risk assessment has been carried out, the designated national authority of the receiving Party shall be able:

   (a) To permit the transboundary movement;

   (b) To permit the transboundary movement subject to certain conditions;

   (c) To refuse the transboundary movement, in which case no further recourse is possible.

1. The Party of transit shall be able, with due substantiation to object to or to place conditions on th passage of the LMO through its territory.

2. The designated national authority of the receiving Party shall, within XXX days of the notification, inform the designated national authority of the Party of origin of its decision in accordance with article (Possible forms of response).

3. Each receiving Party shall convey to the secretariat its response no later that XXX days following its transmittal to the designated national authority of the country of origin.

EUROPEAN COMMUNITY

1. The Party of import shall within the period referred to in Article 6 [30 day s of the date of receipt of the notification] communicate to the exporter:

   1. that, unless it has not, with justification, asked for additional information, imposed conditions or refused permission for the notified movement within 150 days after the dat of receipt of the notification, the movement may proceed;
   2. or that the movement may proceed only after the Party of import has given its written consent, with or without conditions. The Party of import shall decide within 150 days after the date of receipt of the notification.

2. The Party of import may inform the notifier with justification that this period [150 days] is extended by a defined period no longer than 60 days. When calculating the period referred to in paragraph 1, th number of days for which the Party of import is waiting for additional information which it has requested from the notifier shall not be taken into account.

JAPAN

1. The competent authorities of the recipient Contracting Party shall inform, in writing, without delay th Exporter of the receipt of the application, including its date.

2. The competent authorities of the recipient Contracting Party shall reply to the Exporter within [ ] days from the date of receipt of the application. This timing of reply may be extended by any length of time specified by the competent authorities if risk assessment of AIA procedures require additional period, such as for conducting field trials in the recipient Contracting party or obtaining additional relevant information from the Exporter. Once it is decided to extend such timing the competent authorities shall inform the Exporter accordingly.

3. Should competent authorities of the recipient Contracting Party fail to reply to the Exporter within th period mentioned in (2) above, the competent authorities are deemed to have given to the Exporter an implicit agreement to the import of the LMOs concerned.

MALAYSIA

1. Upon receipt of the application by the National Competent Authority of the receiving country Party, the receiving country Party shall provide an acknowledgement to the National Competent Authority of the intending country Party within 14 days. Thereafter, the receiving country Party will respond to th National Competent Authority within [working days] but subject always to the right of the receiving Party's right at any time to extend the relevant time period for such periods it deems fit:

2. If the receiving Party does not provide any response within 60 days, it shall be deemed to be a rejection of the application.

3. Notwithstanding paragraph 1 above, the receiving country Party shall be allowed as much time as is necessary to assess the information it has received from the intending country Party so as to enable it to reach an informed decision on the application and make its own risk assessment decisions on th transfer, handling or use of the LMO.

NORWAY

1. The State of import shall promptly acknowledge to the exporter the date of receipt of the notification. The competent authority in the State of import shall be obliged to respond to the State of export within 90 days after the date of acknowledging the receipt of the notification.

SOUTH AFRICA

1. The competent authority of the State of import shall respond in writing to the State of export within 60 days.

2. If the Competent Authority of the State of export is not notified by the Competent Authority of th State of import of any objection or reservations to the intended transfer within 30 days of the date of notification of intent to transfer, subject to the provisions of (general provisions and notification), th State of import will be deemed to have given consent for the intended transfer.

SRI LANKA

1. The Competent Authority of the Party of Import shall be obliged to respond to the Party of Export within a period of six months.

2. Where the Party of Import considers that the documentation provided by the Party of Export is insufficient in order to assess the potential adverse effects of an LMO, the burden of proof of biosafety

lies with the Party of Export.

SWITZERLAND

1. The importing Contracting Party shall take appropriate legislative and/or administrative measures to ensure response to the application referred to in Article 4 in writing to the exporter and the Secretariat within [120] days of receiving the application.

2. If the importing Contracting Party fails to transmit a final decision or an interim response within th period specified in paragraph 1 of this Article, the living modified organism concerned shall not b exported without the explicit consent of the importing Contracting Party.

UNITED STATES OF AMERICA

1. An importing Party shall respond to notification of intention to export to the importing Party an LMO that is subject to Article 4 as soon as possible but not later than x days after transmission of such notification.

2. When calculating the period referred to in this Article, the number of days for which the importing Party is waiting for additional information which it has requested from the notifier, shall not be taken into account.

Article 7
NOTIFICATION OF TRANSIT

AUSTRIALIA

1. Parties may require notification, in writing, through their Focal Points, of other Parties' intent to transit a living modified organism through their territory. Where such notification is required, Parties shall provide information to the Clearing House on:

   a) details of the categories of living modified organisms for which notification is required, and;
   b) information to be provided with the notification, based on that set out in Annex I.

2. On receipt of such notification, the Party shall advise, within a reasonable period of time, the exporting Party or the exporter, and the Clearing House, of any transport, handling, packaging and labeling provisions for transit of the living modified organisms or other requirements in addition to thos contained in Article 18.

BRAZIL

1. Parties may require notification, in writing, of other Parties' intent to transit a living modified organis or product through their territory.

2. Parties that require notification of intent to transit living modified organisms, or products thereof, through their territory shall stipulate to the Clearing House:

a) details of the categories of living modified organisms, and products thereof, for which notification is required; and
b) information to be provided with the notification.

3. When such notification is required, exporting Parties shall provide information, in writing, to the Party whose territory is to be transited.

4. Upon receipt of this information, the Party whose territory is to be transited shall inform the exporting Party, within a reasonable period of time, of any provisions that may be required.

MEXICO

4. The Party effecting the export must obtain the necessary permits from Party and non-party countries through which the LMOs will be in transit, as well as assuming responsibility for any cases of accidental release in those countries.

PERU

5. Any LMO or products derived from it may be located in transit between the country of export and country of import, provided that this status is accepted in writing.

6. All the requirements in labelling, packaging and transportation shall be met.

7. The documentation provided for the transport of LMOs must specify the care needed during their transit.

MALAYSIA

1. Provided prior notification, consent and labelling is given, and subject to the national laws, regulations and procedures, each Party undertakes to facilitate the transit of LMOs through its territory. For th purposes of this Article, transit shall mean the temporary stop-over of an LMO which is on a continuous journey to another destination. For the avoidance of doubt, transit shall not mean th transfer to another Party of LMOs used for field testing, which is bound for another destination after th field testing.

NORWAY

1. The State of export shall require the exporter to notify either through the channel of the competent authority in the State of export, or by providing a copy to this authority, the State of transit of th first intended transit movement of a specific LMO for a specified use or purpose. In these cases, the State of export shall supply the information included in Annex III to the State of transit. Th State of transit shall promptly acknowledge the receipt of the notification to the notifier. It may subsequently respond to the notifier in writing, within 30 days:

    1. consenting to the transit movement with or without conditions;
    2. denying permission for the movement; or

3. provide an interim response, that may contain a statement to import with or without specified conditions or prohibiting import during the interim period. This may include a statement that a final decision is under consideration and/or a request for further information and/or extended period of time to respond.

2. The State of transit may declare in writing whether a notification is required for subsequent transit movements of the same LMO or whether this is not the case and it shall inform the Secretariat and previous notifiers of such decisions. The handling and transport requirements for LMOs referred to in Article 18) shall be followed in all transit movements.

PERU

8. Any LMO or products derived from it may be located in transit between the country of export and country of import, provided that this status is accepted in writing.

9. All the requirements in labelling, packaging and transportation shall be met.

10. The documentation provided for the transport of LMOs must specify the care needed during their transit.

Article 8
REVIEW OF DECISION UNDER AIA

AFRICAN GROUP

1. If, at any time before, during or after the transboundary transfer, the exporter becomes aware of relevant new information on the living modified organism or the product in question which could hav significant consequences for the associated risks, the competent authorities of the States concerned and the Biosafety Clearing House shall be informed within 30 days of being aware and the notification under Article 4 and the terms of the agreement under Article 6 above changed accordingly.

AUSTRALIA

1. Exporting Parties may request importing Parties to review import decisions, in cases wher exporting Parties consider that:

    1. a change in circumstances has occurred which may influence the outcome of the risk assessment; or
    2. there is reasonable evidence that the decision has not been based on scientific principles and supported by the best available scientific evidence; or
    3. additional relevant scientific or technical information has become available.

2. Exporting Parties may provide any additional information which they consider relevant to a review of the import decision.

3. Importing Parties shall respond to such requests, in writing, within a reasonable period of time, and provide full details on the basis for their decision.

BRAZIL

1. Exporting Parties may request importing Parties to review import decisions, in cases where exporting Parties consider that:

   (a) a change in circumstances has occurred which may influence the outcome of the risk assessment; or
   (b) additional relevant scientific or technical information has become available.

2. Importing Parties shall respond to such requests, in writing, within a reasonable period of time.

MALAYSIA

1. A receiving country Party may at any time in light of new information or evidence, unilaterally review its decisions on any transfer, handling or use of LMOs into its country and employ any review mechanism established through its national legislation or any other national procedures.

2. In light of new scientific evidence and information made available to the receiving country Party, a new application may be submitted in respect of a previously rejected application.

PERU

1. In cases where the importation is refused, the exporting country may request a review of the case, always provided it has relevant information that was not presented in the first export application.

SOUTH AFRICA

1. If, at any time before, during or after the transboundary transfer, the Competent Authorities or th exporter become aware of relevant new information on the LMO, which may have significant consequences for the associated risks, the competent authorities of the States concerned and th Secretariat and Clearing House will be informed within 30 days of such information becoming available.

SRI LANKA

1. If at any time before, during or after the transboundary movement, the party of Export/Import becomes aware of relevant new information on the LMOs in question, which could have significant consequences on the accompanying risks, the Competent Authorities of the Parties concerned shall b informed immediately and the terms of the Advance Informed Agreement be changed accordingly.

SIMPLIFIED PROCEDURE

AFRICAN GROUP

1. The State of export may, subject to the written agreement of the States concerned, use or allow th exporter to use a general notification where living modified organisms or the products thereof having the same characteristics as transferred regularly to the same user via the same customs office of th exit of the State of export, via the same customs office of entry of the State of import.

EUROPEAN COMMUNITY

1. Without prejudice to Article 4 paragraph 1 {Procedures}, a party of import can with justification specify, in advance, to other Parties cases:

    1. for which the intentional transboundary movement of LMOs to that Party may proceed according to its regulatory framework implementing Article 8(g) of the CBD, provided th framework includes a control mechanism for transboundary movement consistent with th protocol;

    2. for which the intentional transboundary movement can take place at the same time that movement is notified to the relevant instance in the Party of import. Such notifications may apply to subsequent similar movement to the same Party.

2. Information to be provided in the notification is specified in Annex I.

INDIA

1. The State of export may, subject to the written agreement of the States concerned, use or allow th exporter to use a general notification where living modified organism or the products thereof having th same characteristics as transferred regularly to the same user.

JAPAN

1. If it is established that there does not exist any risk by the use and release of certain LMOs on the basis of the best available scientific knowledge and experience, as well as relevant information, a recipient Contracting party by means of unilateral declaration or bilateral, regional or multilateral agreement or arrangement, may exempt such LMOs from the application of the AIA procedures, by which no explicit agreement by the competent authority of the recipient Contracting party is required.

2. Moreover, in the case of repeated transboundary transfers of LMOs, a recipient Contracting Party may decide that the application of the AIA procedures be exempted or replaced by simple notification procedures provided for in 1 above.

3. If a recipient Contracting Party decides to exempt certain LMOs from the application of the AI procedures or to apply simple notification procedures to certain LMOs, it shall inform the Secretariat of the Protocol accordingly. The Secretariat shall forthwith inform all Contracting Parties of such decisions.

NORWAY

1. The State of import shall communicate in its response to the State of export whether an AIA procedur with explicit consent or implicit consent is required for subsequent imports of the same LMO or whether a simple notification in accordance with Article 9 shall be applied

SOUTH AFRICA

1. If it is established by the State of import, on the basis of the best available scientific knowledge and experience, as well as all relevant information, that there is no significant risk associated with the us and release of certain LMOs, a Contracting Party which is a State of import may substitute the AI procedure regarding such LMOs with a notification procedure in which case no AIA will be required by the recipient State.

2. The Competent Authority of the State of export may, subject to the provisions (general provisions and notification), substitute or allow the exporter to substitute, an AIA with notification of intent to export LMOs to the recipient State of import.

3. Notification of intent to export LMO's in terms of para. 2 -, will contain the following information;

   (a) name and address of exporting company/institution
   (b) name and address of receiving company/institution
   (c) origin, name and taxonomic status of donor and recipient organisms
   (d) information on previous exports of same LMO to recipient Stat
   (e) date of intended transfer, which will not be less than 30 days from the date of notification

4. If the Competent Authority of the State of export is not notified by the Competent Authority of th State of import of any objection or reservations to the intended transfer within 30 days of the dat of notification of intent to transfer, subject to the provisions of Article 3, the State of import will b deemed to have given consent for the intended transfer.

5. If, at any time before, during or after the transboundary transfer, the exporter becomes aware of relevant new information on the LMO, which may have significant consequences for the associated risks, the competent authorities of the States concerned and the Secretariat and Clearing House will be informed within 30 days of such information becoming available.

Article 10
SUBSEQUENT IMPORTS

AUSTRALIA

1. Notification of subsequent imports of the same living modified organism into the same importing party shall not be required unless specifically requested, in writing, by the importing Party, in cases where there may be:

   1. a change in the intended use of the living modified organism; or
   2. a variation in the receiving environment; or
   3. other factors likely to affect the risk assessment or risk management.

2. Where notification for subsequent imports is specifically requested by the importing Party, full details regarding the infor ation required shall be provided, in writing, to exporting Parties or exporters and to the Clearing House. The information required shall be based on that identified in Annex I {Information Required for Notification of Import of a Living Modified Organism}.

3. The importing Party shall acknowledge the notification, in writing, within a reasonable period of time. This acknowledgment shall include:

    1. advice that a risk assessment has been or is to be carried out, in accordance with Article 13 {Risk Assessment}; and
    2. a request for any further information which remains to be provided in accordance with this Article.

BRAZIL

1. Notification in writing is required for all subsequent imports of the same living modified organism into the same importing Party.

2. The importing Party will acknowledge receipt of notification as quickly as possible and will inform th exporting Party that:

(a) importation can proceed; or
(b) a new risk assessment procedure will be undertaken.

EUROPEAN COMMUNITY

1. A single notification as well as a consent given in response to a notification may cover several similar, including subsequent, transboundary movements to the same Party of import.

MEXICO

1. The exporter must submit a new application for subsequent imports even though the competent authority may have given a positive clearance for the importation of a specific LMO.

2. The regulations applied to imports shall be identical to those applied to LMOs produced in the country.

NORWAY

1. A State of import may at any time declare that subsequent imports of a specific LMO into its territory for specified uses or purposes, are exempted from the requirement of AIA in Article 4. Such an exemption may specify a procedure for simple notification indicating that the intentional transboundary movement can take place at the same time that specific movement is notified to the State of import.

2. The Parties shall inform the Secretariat and previous notifiers of such declarations followed by a verification that a risk assessment has been carried out earlier, and of any requirements concerning movements, handling and use applicable to such LMOs. Such a declaration may be withdrawn at any time by the State of import and the Secretariat and notifiers who have been previously notified

movements of such LMOs to it in accordance with this Protocol shall be informed no later than 30 days prior to the withdrawal.

3. The Secretariat shall inform all parties of the information it has received pursuant to paragraph 1 and 2. The Secretariat shall be responsible for transmitting this information for inclusion in the databas established under Article 20.

PERU

1. No application or any corresponding study shall be in any way influenced by the existence of a prior acceptance of the same LMOs or products derived from them in the importing country or any other country Party.
   1. The importation of an LMO or any of its products is permitted for a specific use; if the us changes, a fresh application must be made to the competent national authority for a new clearanc for the new use.

SWITZERLAND

1. 30 days prior to subsequent transboundary movements of a living modified organisms falling into th scope of this Protocol, the exporter shall notify the national focal point of the importing Contracting Party. If no response is received within this 30 days period, the exporter may proceed with th transboundary movement.

When the conditions described in Annex [ ] are fulfilled subsequent transboundary movements may proceed without notifying the national focal point of the importing Contracting Party. In this case, th exporter must ensure that appropriate relevant information is provided to the importer and/or the final user.

Article 11
CONFIDENTIAL INFORMATION

AUSTRALIA

1. Parties shall respect the need to protect commercial -in-confidence information rel vant to living modified organisms. The information specified in Annex I shall not be regarded as commercial-in-confidence information, with respect to the Protocol.

BRAZIL

1. Parties shall respect the need to protect commercial -in-confidence information relevant to living modified organisms and products thereof. However, all information requested by the importing Party for the purpose of decision making must be provided by the exporting Party.

COLOMBIA

1. The request for transboundary movement shall identify, in a duly substantiated manner, th information subject to confidential treatment.

2. In no event shall the following information be considered confidential:

   (a) The following information relating to the host organism:

   - Pathogenicity, toxicity, allergenicity with respect to humans, and, wher applicable, to other species;

   - Capacity to transfer genetic material and potential diffusion routes;

   - Methods to detect the organism in the environment and to detect the transfer of th donated nucleic acid;

   - Potential of the organism to affect ecosystem characteristics;

   (b) A summary of the risk assessment relating to the effects on the conservation and sustainable use of biological diversity, including on domestic animals and human health;

   (c) Any contingency method or plan;

   (d) Methods of preventing or mitigating accidents.

EUROPEAN COMMUNITY

1. 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.

2. The notifier may indicate the information submitted under the procedures of this Protocol that should be treated as confidential. Verifiable justification must be given in such cases.

3. The competent authority or focal points shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions.

4. Without prejudice to Article 11 [confidentiality of data], in nocase may the following information be kept confidential:

   1. the general description of the LMO or LMOs, name and address of the notifier, purpose of the movement;
   2. a summary of the risk assessment of effects on the conservation and sustainable use of

biological diversity, taking also into account human health;

3. any methods and plans for emergency response;

5. 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.

MADAGASCAR

1. The Protocol shall contain a provision to safeguard the confidential nature of the information.

MEXICO

1. Pending the assessment and management of risk, the Parties shall, as far as possible and as best they can, maintain the confidentiality of information protected by industrial secrecy and pay due attention to the conservation and sustainable use of biodiversity, together with possible adverse effects onhuman health.

NORWAY

1. Parties receiving notifications and information regarding intentional transboundary movements shall take account of the need to protect intellectual proprietary rights and confidentiality of data received. The notifier may indicate the information in the notification, the disclosure of which might harm his competitive position, that shall therefore be treated as confidential. The data referred to in Annex I shall, however, not be regarded as confidential. [The Annex referred to in this paragraph addresses information to be supplied by the State of export under the AIA Procedure].

SRI LANKA

1. 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 tak informed decisions.

UNITED STATES OF AMERICA

1. 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.

2. Any Party receiving such information shall not divulge any confidential information received under this protocol and shall protect intellectual property rights relating to data so received and shall establish appropriate internal procedures for the protection of information so received.. The notifier should indicate any information submitted under this protocol that it considers confidential and/or subject to intellectual property protection.

Article

12
BILATERAL & REGIONAL AGREEMENTS

AFRICAN GROUP

INTERNATIONAL COOPERATION

1. The Parties shall co-operate among themselves in exchanging information, developing appropriat technical guidelines and/or codes of practice, and monitoring the effects of risks posed by living modified organisms and products thereof on human and animal health, biological diversity, th environment and socio-economic welfare of societies with a view to promoting the safe management of these organisms and products.

2. The Parties shall employ appropriate means to co-operate in order to assist developing countries in th implementation of this Protocol. 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.

3. The Parties may enter into bilateral or multi-lateral agreements or other arrangements in order to implement their obligations under this Protocol.

AUSTRALIA

Bilateral, Regional and Multilateral Agreements

1. Parties may enter into bilateral, regional or multilateral agreements or arrangements regarding transboundary movements of living modified organisms with Parties or Non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of living modified organism resulting from modern biotechnology, in accordance with the objectives of this Protocol. The provisions of this Protocol shall not affect transboundary movements that take place pursuant to such agreements and arrangements as bet een the Parties to that agreement or arrangement.

2. Parties shall notify the Secretariat of any such bilateral, regional and multilateral agreements or arrangements entered into:

    1. prior to entry into force of this Protocol and which will continue to operate after entry into force of the Protocol; or
    2. after entry into force of the Protocol.

EUROPEAN COMMUNITY

Multilateral Agreements

1. Parties may enter into multilateral agreements or arrangements regarding procedures and information exchange relating to transb oundary movement of LMOs provided that such agreements or arrangements do not result in a lower level of protection than the one provided for by the Protocol.

2. Parties shall notify the Secretariat of any multilateral agreements or arrangements referred to in paragraph 1 and those which they have entered prior to the entry into force of the Protocol, for th purpose of controlling tranboundary movements of LMOs which take place entirely among the Parties to such agreements. The provisions of the Protocol shall not affect transboundary movements which

take place pursuant to such agreements.

SWITZERLAND

Bilateral, Multilateral and Regional Agreements

1. Contracting Parties may enter into bilateral, multilateral, or regional agreements or arrangements regarding transboundary movement of living modified organisms falling within the scope of this Protocol provided that such arrangements do not derogate from the environmentally sound management of living modified organisms as required by this Protocol. These agreements or arrangements shall stipulate provisions which are not less environmentally sound than those provided for by this Protocol in particular taking into account the interests of developing countries.

2. Contracting Parties shall notify the Secretariat of any bilateral, multilateral or regional agreements or arrangements referred to in paragraph 1 of this Article and those which they have entered into prior to the entry into force of this Protocol for them. The provisions of this Protocol shall not affect transboundary movements which take place pursuant to such agreements provided such agreements ar compatible with the environmentally sound management of living modified organisms as required by this Protocol.

UNITED STATES OF AMERICA

Mutual Cooperation Agreements and Voluntary Participation as an Importing Party

1. Parties to this protocol may enter into bilateral or multilateral agreements or arrangements regarding requirements relating to the import and/or export of LMOs between or among them, in lieu of the advance informed agreement requirements.

2. Any Party may notify the Secretariat at any time that the advance informed agreement provisions shall not apply with respect to imports to such Party.

Article 13
RISK ASSESSMENT

AFRICAN GROUP

1. Each Party shall ensure that, in accordance with the provisions of this Protocol, assessments prior to th use, transfer and release of living modified organisms or products thereof are undertaken as regards th risks or possible adverse impacts in their respective t rritories as well as in the transboundary effects to human and animal health, the environment, biological diversity and the socio-economic welfare of societies.

2. Such assessments shall identify and characterise the risks associated with the living modified organis in question or the product thereof and specify actions to be taken in response. The risk assessment documentation to be submitted to the competent authorities of the States concerned shall contain, as a minimum, the information described in Ann x II.

3. Each Party shall ensure that appropriate decisions are taken based on the outcome of the risk assessment and on a cas -by-case basis. If the assessment shows that risks cannot be avoided or

reduced to an acceptable level, the States concerned shall refuse authorization to the development, use, release, import, export or transfer of that particular living modified organism or product thereof.

AUSTRALIA

1. On receipt of a notification for first import of a living modified organism, the importing Party shall undertake, or have undertaken, an assessment of the risk of the living modified organism having an adverse effect on the conservation and sustainable use of biological diversity in the importing Party. Parties may take into account the details of risk assessments completed elsewhere, as appropriate.

2. Risk assessments shall be carried out in a scientifically sound and transparent manner.

3. Risk assessments should, inter alia, take into account the information provided in Annex II

4. Risk assessments shall not be required for subsequent imports of the same living modified organis into the same Party, except in cases where there may be:

    a) a change in the intended use of the living modified organism; or
    b) a variation in the receiving environment; or
    c) other factors likely to affect the risk assessment or risk management.

BELARUS

1. Adequate risk assessment of possible adverse effects of LMOs on the conservation and sustainable us of biological diversity and adverse impacts on human health in the State of Import is the basis for AIA and also is necessary requirement for decision on handling, use and release of any LMO in that country.

2. A complete risk assessment shall be carried out prior to the transfer of an LMO for the first time into a new country. "Case by case" approach should be used in this process. The Exporter shall provide th competent authority/focal point in the State of Import with information related to the risk assessment carried out by it, and other relevant information, in order for the State of Import to conduct its own risk assessment on the basis of this information. The exporter is responsible for the reliability of th information provided.

3. The assessment of the risks associated with a transfer, handling, use and release of LMOs shall b based on up-to-date scientific data and experience and take account of the information identified in Annex II:

BRAZIL

1. Upon receipt of a notification for first import of a living modified organism or product, the importing Party shall undertake a risk assessment of the living modified organism or product thereof.

2. Risk assessments shall be carried out in a scientifically sound and transparent manner.

3. Risk assessment should, inter alia, take into account the information provided in Annex II

4. Risk assessment for subsequent imports is at the discretion of the receiving Party, but should b undertaken where there may be:

a) a change in the intended use of the living modified organism;
b) a variation in the receiving environment; or
c) other factors likely to affect the risk assessment or risk management.

CANADA

1. Upon providing acknowledgement to the importer of receipt of the notification the competent authority of the Party of import shall conduct a scienc -based risk assessment to evaluate the potential advers effects of the living modified organism to the conservation and sustainable use of biological diversity within the territory of the Party of import, within predetermined time frames (Consideration should be given to re-assessment following receipt of new information).

2. On or before the expiration of the period in Article6 and based on the result of the scienc -based risk assessment conducted under Article 13, the competent authority of the Party of import shall:

(a) allow the import,

or decide to:
(b) allow the import, subject to conditions;
(c) prohibit the import; or
(d) request from the importer further scientific information which the competent authority reasonably requires before allowing or prohibiting the import.

3. The competent authority of the Party of import shall provide an importer, subject to decisions under this Article, with reasons for such decisions.

COLOMBIA

1. Each country shall determine for itself, in accordance with its own legislation, the institutional arrangements for the conduct of risk assessments and for the preparation of technical findings with regard to requests for transboundary movement.

2. To conduct risk assessments, the receiving country, shall, ~~inter alia~~:

(a) Take into account information submitted by the country of origin;
(b) Consider the actual and/or potential effects on human health, the environment and agricultural production, including the population balance of the related organisms;
(c) Ensure that the risk assessment and management processes of micro-organisms of all kinds are conducted in contained conditions.

CUBA

1.- The Parties shall inspect the risk study and assessment mechanisms they have in order to determine if they are appropriate to provide for safe application of Living Modified Organisms both for human health and the environment.

2.- The Parties shall adopt the national legislation and ordinance to guarantee that any release of Living Modified Organisms be submitted to a process to assess any possible risks associated to this release and propose the corresponding control measures. The applied national standards should be fl xible and able to be adapted concerning up-to-date scientific information.

3.- The Parties should assess risks basing themselves on sound scientific principles and have them effected by scientifically competent bodies which are independent from the researcher or author of the releas proposal.

4.- The national authority or authorities appointed by the Parties should create inspecting bodies at national level having required scientific and multidisciplinarian competence.

5.- The Parties should perform risk assessment in each process phase, "step by step", from laboratory research to release in the environment on a small or large scale, and concentrate preferably on th characteristics of the final product which human beings, animals and environment will be exposed to.

6.- The Parties shall take as standard th □ase by case" assessment until they have acquired enough experience and the knowledge required to make classifications and generalizations.

EUROPEAN COMMUNITY

1. Decisions under the Protocol, in regard to adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health shall be based on scientific grounds and experience and take account of:

    1. the characteristics of the organisms involved, including any introduced sequences or modified traits;
    2. the characteristics of the intended application;
    3. the characteristics of the potential receiving environment;
    4. and the interaction between these.

2. The risk assessment referred to in paragraph 1 shall, as appropriate, be based on he information and principles set out in Annex II.

INDIA

1. Each Party shall ensure that, in accordance with the provisions of this Protocol, assessments prior to the use, transfer and release of living modified organisms or products thereof are undertaken as regards the risks or possible adverse impacts to human and animal halth in their respective territories as well as in the territories of the States of import.

2. Such assessments shall identify the risks associated with the living modified organism in question or th product thereof and specify actions to be taken in response. The risk assessment documentation to b submitted to the competent authorities of the States concerned shall contain, as a minimum, th information described in Annex II.

3. Each Party shall ensure that appropriate decisions are taken based on the outcome of the risk assessment and on a cas -by-case basis.

JAPAN

1. The Contracting Parties shall establish measures to undertake, within the AIA procedures, risk assessment, which serves as a mechanism providing the basis for the decisions of the competent authorities of the recipient Contracting Party whether to agree to the transboundary transfer of LMOs or not.

2. Recipient Contracting Parties shall assess the risk in view of the conservation and sustainable use of biological diversity. The Conference of the Parties to the Protocol shall establish a minimum standard of risk assessment of LMOs. The minimum standard shall be reviewed periodically by the Conference of the Parties in the light of the most recent and best available scientific knowledge and experience, as well as other relevant information. The Conference of the Parties to the Protocol may establish a technical advisory body for providing the Contracting Parties with scientific backgrounds for reviewing the standard.

Responsibility of Risk Assessment

a) Responsibility of risk assessment shall lie in the competent authorities of the recipient Contracting Party.

b) The competent authorities of the recipient Contracting Party may request assistance from the Exporter or the competent authorities of the exporting Contracting Party, who should respond to the request to the extent possible. Especially in cases where the competent authorities of the recipient Contracting Party do not have sufficient experiences with the LMOs in question.

Bases for Decision Making on Risk Assessment

a) The competent authorities of the recipient Contracting Party should conduct risk assessment exclusively on the basis of sci ntific information provided in the process of the application by th Exporter and other scientific evidence.

MADAGASCAR

1. The Protocol, a legally binding international instrument, shall define the general principles relative to a decision whether or not to import LMOs and products thereof, in accordance with the foreseeable risks caused by their introduction, transfer, use and release (intentional or non intentional).

2. Biotechnological risk assessment of LMOs and products thereof shall be carried out in accordance with standard scientific and technological methods, though adaptable to different cases and following stag - by-stage procedures.

3. Risk assessment identifies the possible adverse effects of transboundary transfer on human and animal health, the environment, biological diversity and the social and economic welfare.

4. Risk assessment shall be carried out in relation to the characteristics of the LMOs and the introduced genetic modifications and shall take into account the genetic diversity of the country.

5. The Protocol shall determine the respective responsibilities of the exporting Party and importing Party with regard to risk assessment.

MALAYSIA

The objective of a risk assessment is to provide a basis to enable the receiving country Party to evaluat possible risk or likelihood of it occurring in the receiving country Party and its environment, as a result of the transfer, handling or use of the LMOs by the intending country party, in particular, to the conservation and sustainable use of biological diversity, socio-economic imperatives, and the risks to agriculture and human health.

Submission of Risk Assessment

1. Each Party who intends to undertake a transfer, handling or use of LMOs to or within the receving Party shall ensure that a risk assessment report is prepared by it and submitted to the National Competent Authority of the receiving country Party.

2. Each Party shall ensure that any individual person or entity under its jurisdiction who intends to undertake a transfer, handling or use of any LMO to any receiving country, shall prepare a risk assessment is that such risk assessment is submitted to the National Competent Authority of th receiving Party. Such Party shall also ensure through its national laws that such individual person or entity submits the risk assessment through the intending Party's National Competent Authority. For the avoidance of doubt, the intending country Party shall also be reponsible over the risk assessment prepared by the individual person or entity under its jurisdiction.

3. The financial responsibility for such risk assessment shall rest with the intending country Party.

4. The risk assessment shall be submitted prior to the transfer, handling or use of the LMO and shall b submitted together with the notification under the AIA procedure defined above.

Parameters of Risk Assessment

1. The risk assessment must be relevant to the environment of the receiving country.

2. It should cover expected probabilities of events occurring and the magnitude of their effects.

3. Risk assessment should not only be based solely on scientific data that would take into account th characteristics of the LMO and its possible adverse effect on the environment, but also other data to address its possible impacts on the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health.

4. Evaluation of risk should be conducted, where applicable, at each step of development rom the research laboratory to small-scale and larg -scale release for production and testing, including commercial use. A multi-disciplinary approach is necessary. Risk assessment should be applied for safety in biotechnology including a step-wise and cas -by-case approach.

5. Special considerations should be incorporated into risk assessment in the transfer, handling or use of LMOs into centres of origin and genetic diversity.

6. The key parameters of the risk assessment are further defined in detail in Annex II.

The Receiving Country Party

1. The risk assessment shall not be the only basis upon which the receiving country Party can mak decisions on the proposed transfer, handling and use of LMOs.

2. The receiving country Party shall take into account other factors including without limitation, social, socio-economic and ethical considerations, in making decisions regarding such transfer, handling or use.

3. Subject to the capacity and capability of the receiving country Party to do so, after considering the risk assessment, the receiving country Party may make its own risk assessment decisions on such transfer, handling or use of LMOs.

4. If the receiving country Party lacks the financial and technical capacity to do so, the intending country Party shall technically and financially assist and collaborate with the receiving country Party in the risk assessment evaluation.

MEXICO

1. The decisions taken by the competent authority with respect to an application to bring an LMO into th country, including its parts, products, subproducts and derivatives, that might have adverse effects on conservation and sustainable use of biodiversity, or on human health, should be based on scientific principles, on the characteristics of the LMO in question, on the characteristics of the proposed use, as well as on the particular characteristics of the recipient environment. Special importance should b attached to countries with rich biological diversity, that may be the originating centres and/or present a high level of endemic disease.

NORWAY

1. Each Party shall require any natural or legal person under its jurisdiction to submit an application to th competent authority for approval before undertaking a release into the environment. Parties shall undertake measures for contained use in accordance with Annex [ ] (to be developed).

2. Each Party shall carry out, or shall require any natural or legal person under its jurisdiction providing an LMO to carry out, a risk assessment in accordance with the provisions of Annex II before any release of an LMO into the environment. The aim of the risk assessment is to evaluate possible advers effects on human health or conservation and sustainable use of biological diversity.

3. The State of export shall provide or shall require the exporter to provide, the State of import, information on the risk assessment as required by Annex II, and other relevant information, in order for the State of import to conduct its own risk assessment. The State of import shall in its assessment particularly take into account the characteristics of the receiving environment.

4. The risk assessment shall take due account of possible effects to the environment of neighboring states or effects to the environment outside national jurisdictions or to global commons.

PERU

1. The assessment of the risks involved in the transboundary movements, handling and release of LMOs or products derived from them, shall be carried out by the competent national authority of th importing country in agreement with the procedure of Advance Informed Agreement and in accordanc with provisions of the law of the country and its internal regulations.

2. After taking into account the documents analyzed, the data submitted and, if applicable, the results of consultations, additional information and observations carried out, a decision will be taken concerning the requested release, either authorizing it or refusing it, depending on whether or not the established risk requirements are fulfilled. The decision authorizing the release shall set out the conditions required for its implementation.

SRI LANKA

1. Each Party shall ensure that, in accordance with the provisions of the Biosafety Protocol, assessments prior to the transfer, release and use of LMOs or products thereof are undertaken as regards the risks or possible adverse impacts in their respective territories as well as in the territories of States of import, including the transboundary effects to human and animal health, the environment, biological diversity and the socio-economic welfare of societies.

2. Such assessments shall identify and characterise the risks associated with the LMOs in question or th products thereof and specify actions to be taken in response. The risk assessment documentation to b submitted to the Competent Authority of the States concerned shall contain, as minimum, th information described in Annex II.

SWITZERLAND

1. Decisions implying risk assessment and risk management, in particular under Article 6 (which addresses responses to trnasboundary movement of LMOs), in regard to adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks for human health shall be based on up-to-date scientific data and experience and take account of the characteristics of the living modified organism involved, the characteristics of the intended application and the potential receiving environment.

UNITED STATES OF AMERICA

1. Decisions by importing Parties regarding risk assessment and risk management in regard to potential adverse effects on the conservation and sustainable use of biodiversity should make use, as appropriate, of existing guidelines relevant to biosafety.

2. Decisions shall be based on scientific principles, and in this context, should take into account relevant technical experience.

3. Parties are encouraged to assist importing Parties with importing Parties' risk assessment and risk management decisions through the sharing of information and expertise.

Article 14
RISK MANAGEMENT

AFRICAN GROUP

1. Each Party shall ensure that, in accordance with the provisions of this Protocol, appropriat management of the risks identified is undertaken until such risks have been avoided or reduced to an acceptable level. The type of risk management and the practices thereto set out in Annex III shall b employed as a minimum.

2. Without prejudice to paragraph 1 above, each contracting Party in order to ensure genomic and trait stability in the environment, any living modified organism whether imported or locally developed shall undergo a period of observation commensurate with its life cycle or generation time as the case may b before it is put to its intended use. Risk management schemes shall take due account of the differenc purposes or uses for which the livi ng modified organisms or the products thereof are developed or produced.

AUSTRALIA

1. Parties shall establish or maintain national means to regulate, manage or control risks associated with the safe use, handling and transboundary movement of living modified organisms, in accordance with Article 8(g) of the Convention. Importing Parties and exporting Parties are encouraged, wher appropriate, to cooperate in the development of risk management procedures

BELARUS

1. If the risk assessment shows that the level of identified risks associated with the LMO is not acceptable, risk management measures are to be taken by the exporter (the applicant) and implemented until the risks have been minimised to an acceptable level. It is up to the State of Import (competent authority/focal point of the country) to decide what is to be considered as "acceptable level of risk". The competent authority/focal point in the State of Import shall estimate the reliability of risk management measures provided and possibility of their effective implementation in the country. If th risk cannot be minimised to an acceptable level by use of the risk management measures, the competent authority/focal point shall decide not to allow the transfer, use and release of the LMO.

CANADA

1. Import-restrictive measures such as those referred to in Article 13 shall be imposed to the extent necessary to prevent the adverse effects of the living modified organism on the conservation and sustainable use of biological diversity within the territory of t he Party of import, as demonstrated by the risk assessment conducted under Article 13.

2. Where the competent authority of the Party of import requires as a condition under sub-paragraph this Article that subsequent imports be notified, it shall establish for this purpose:

   (a) notification procedures;
   (b) information requirements to be contained in the notification; and
   procedures for risk assessment and decision making,

COLOMBIA

1. Each country shall determine for itself, in accordance with its own legisl ation, the institutional arrangements for the conduct of risk assessments and for the preparation of technical findings with regard to requests for transboundary movement.

2. To conduct risk assessments, the receiving country, shall, inter alia:

(a) Take into account information submitted by the country of origin;

(b) Consider the actual and/or potential effects on human health, the environment and agricultural production, including the population balance of the related organisms;

(c) Ensure that the risk assessment and management processes of micro -organisms of all kinds are conducted in contained conditions.

CUBA

1. The Parties, in their national legislation, shall take into account that the type of risk management to b applied depends on each particular Living Modified Organisms. The adequate risk management measures shall be determined by risk assessment, employed organisms and way of release. The risk management measure should correspond to confirmed risks. If risk assessment exposes that foreseen application of a Living Modified Organism is not acceptable, further risk management measures should be taken and assessed.

INDIA.

1. Each Party shall ensure that, in accordance with the provisions of this Protocol, appropriat management of the risks identified is undertaken until such risks have been avoided or reduced to an acceptable level. The risk management set out in Annex III shall be employed as a minimum.

2. Without prejudice to paragraph 1 above, each Contracting Party shall ensure genomic and trait stability in the environment. To this end, any living modified organism shall undergo appropriat observation.

MADAGASCAR

1. Each Party shall ensure that identified risk management be carried out in such a manner as to avoid or to reduce the risks to an acceptable level (including the treatment of waste resulting from the use of LMOs).

2. Provision shall be made for an observation period with respect to the lif -cycle and reproductive cycl of LMOs, before any planned use.

MALAYSIA

1. For the avoidance of doubt, Article 8(g) of the Convention on Biological Diversity shall not preclude th obligation under this Article to formulate appropriate risk management strategies and measures as stated below.

2. The Party intending to undertake any transfer, handling or use of LMOs to or within the receiving country shall formulate appropriate risk management measures and strategies that may be implemented in the receiving country Party for the management of risks and harm associated with the transfer, handling and use of the LMO and the protection and mitigation of potential harm to the receiving country party, and incorporate such measures and strategies with the risk assessment under Article 13 {Risk Assessment} above.

3. The intending country Party shall ensure that any individual person or entity under its jurisdiction who intends to undertake the transfer, handling or use of any LMO to or within the receiving country shall formulate appropriate risk management measures and strategies that may be implemented in th receiving Party for the management of risks and harm associated with the transfer, handling and use of the LMO and the protection and mitigation of potential harm to the receiving country Party and incorporate such measures and strategies in the risk assessment under Article 13 {Risk Assessment} above.

4. The type of risk management to be employed shall depend on the LMOs and the activity in question and such risk management strategies and measures shall be commensurate with the risk assessment.

5. The risk management strategies and measures shall consist of such measures and strategies applicable at any/all stages of transfer, handling, release and/or use of the LMO to or within the receiving country and shall address the ways and means to manage the risks associated with the transfer, handling, or us of the LMO to or within the receiving country.

6. Where applicable, obligatory risk management measures shall be implemented by the intending country Party or person or entity undertaking such transfer, handling or use

7. If the receiving country party lacks the technical and financial capacity to do so, the intending country party shall technically and financially assist and collaborate with the receiving country party in the risk management.

NORWAY

1. The Parties shall base their risk management decisions on a risk assessment as appropriate to the LMO in question. Examples of appropriate risk management measures to be applied are contained in Annex III.

2. The Parties shall aim at phasing out, or shall require the producers to phase out, antibiotic resistanc marker genes in living modified organisms by the year 2002.

SRI LANKA

1. Each Party shall ensure that appropriate decisions are taken based on the outcome of the risk assessment and on a cas -by-case basis. If the assessment shows that risk cannot be avoided or reduced to an acceptable level, the States concerned shall refuse authorization to the development, use,

release, import, export or transfer of such LMOs or product thereof.

2. Each Party shall ensure that, in accordance with the provisions of this Protocol, appropriat management of the risks

3. The Parties shall take appropriate risk management decisions and measures based on the risk assessment to minimise the risks to acceptable levels as may be decided upon by the Competent Authority of the Importing Party (see Annex III)

SWITZERLAND

1. The Contracting Parties shall, taking into account in particular the needs of the developing countries and the countries with economies in transition, cooperate in order to promote international harmonization in risk assessment and risk management procedures.

Article 15
MINIMUM NATIONAL STANDARDS

AFRICAN GROUP

1. This protocol shall constitute the minimum standards and conditions of safety in biotechnology for Parties, when they adopt relevant laws, regulations and guidelines at the national level.

CANADA

1. Each Party shall:

(a) establish at the national level, or co-operate in establishing at the multi-national regional level, procedures to assess the risks of living modified organisms under Article 13;
(b) ensure that it has appropriate domestic laws in place to manage the risks identified under its risk assessment procedures under Article 13; and
(c) ensure that it has appropriate domestic laws in place to enforce any conditions or prohibitions decided under Article 14.

MEXICO

1. The Parties should prepare national laws to regulate the transfer, handling and use of any LMOs that result from biotechnology.

NORWAY

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 [at th national level] 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.

3. [An appropriately formulated Environmental Impact Assessment shall be carried out with each LMO introduced to the country as recommended by the national Competent Authority and approved by th same authority].

PERU

1. The laws and internal regulations of each country Party and the minimum national standards established for the use, commercialization and transboundary movement of LMOs, shall be established in accordance with the agreement stipulated in the present protocol, ensuring the appropriate legal, institutional and administrative frameworks for the safety of the transfer, manipulation and utilization of LMOs.

Article 16
UNINTENTIONAL TRANSBOUNDARY MOVEMENTS

AUSTRALIA

1. Parties shall immediately notify affected Parties and non-Parties, potentially affected Parties and non-Parties, and the Clearing House, in cases of known unintentional transboundary movements of living modified organisms, or of known unintentional domestic releases of living modified organisms which may result in unintentional transboundary movements of living modified organisms. Information to b provided with the notification is included below:

- Contact details for the Party providing the notification.
- Taxonomic identification of the living modified organism.
- Taxonomic identification of donor organism.
- Nature of introduced trait.
- Quantity of living modified organisms unintentionally released or transferred.
- Centre of origin of the organism that has been modified.
- Site of the unintentional release.
- Details of any action taken to prevent further release or movement of the living modified organism.

2. The Party which is the origin of the unintentional transboundary release or transboundary movement shall take appropriate action to prevent further release or transboundary movement of the living modified organism and to minimize any associated risks.

BELARUS

1. The Parties shall:

a) whenever it comes to their knowledge, ensure that, in the case of an accident which may hav transboundary effects on human health and/or the environment in other states, these states are immediately informed;
b) inform affected states about any planned activities associated with LMOs within their territories that ar likely to have transboundary effects.

2. 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.

3. The affected state(s) may ask for consultations between the concerned states.

BRAZIL

1. All possible precautions are to be taken to prevent accidental and unintentional release and to reduc natural movements of intentionally released living modified organisms which may result in unintentional transboundary movements.

2. 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 the same information required for intentional transboundary movements, in addition to, *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 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.

4. 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.

EUROPEAN COMMUNITY

1. In the case that an unintentional transboundary movement of LMOs is likely to have significant advers effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, the Party from which the unintentional movement originates shall ensure that any affected Party(ies) and non-Party(ies) receives, as soon as possible, all relevant information concerning th unintentional transboundary movement and risks to the conservation and sustainable use of biological diversity, taking also into account risks to human health, and their management.

2. Information to be provided is specified in Annex I.

MALAYSIA

1. The Parties shall, as soon as it has come to their knowledge, ensure that, in the case of an unintentional transfer of an LMO, including accidental or emergency cases, which have potential risks to th environment, in particular, the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health of other Parties, those Parties ar immediately informed.

MEXICO

1. Cases of unintended movements of LMOs shall be resolved in accordance with the rules governing international responsibility of the State for damage to the environment of other States or any other area situated outside the national jurisdiction.

NORWAY

1. The Parties shall apply Article 14(1) of the Convention.

2. In the case that an unintentional transboundary movement of LMOs is likely to have advers effects on the conservation and sustainable use of biological diversity or human health, the Party from which the unintentional movement originates, shall immediately provide any affected Party/ies with all information relating to the unintentional transboundary movement. This information shall include:
   1. circumstances of the unintentional ovement;
   2. the identity and quantities released;
   3. an assessment of the risks to the conservation and sustainable use of biological diversity and/or human health;
   4. emergency measures taken or needed to be taken;
   5. any available information regarding the handling of the organisms and related risk management measures to be applied.

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

4. If necessary, the affect ed 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.

5. The affected Party(ies) may ask for consultations between the concerned states.

PERU

1. Parties should take the necessary precautions inside of their territories, during releases, so as to minimize the occurrence of unintended transboundary movements.

2. Any Party that becomes aware of the occurrence of an unintended transboundary movement of an LMO should immediately inform the competent national authorities of the Parties concerned about th incident so that the necessary action may be taken. For this reason the informing Party should provid data on the type of LMO, the number or volume in question, and if relevant, provide or request the not of origin of the organism in question.

SRI LANKA

1. The Parties shall ensure that in the case of an accident occurring during the transboundary movement of an LMO, or in the case of an accidental/unintended movement within their own territories which may have transboundary effects which are likely to present risks to human health and/or the environment in other Parties, such Parties are immediately informed.

2. In the event of an unintentional transboundary movement of LMOs and/or accident, the exporter or importer shall be required to inform immediately the competent authorities of the States concerned. Th Information shall include, *inter alia*, circumstances of the accident, the identity and numbers or quantities of the living organisms released, other facts necessary to assess the effects of the accident on human and animal health, the environment, the biological diversity and the emergency measures taken or needed to be taken together with any available information regarding the handling of the organisms and information related to risk assessment and management.

SWITZERLAND

1. Each Contracting Party shall, whenever it comes to their knowledge, ensure that, in the case of an unintentional transboundary movement of living modified organisms which are likely to present risks to human health and the environment in other States, those States are immediately provided with all relevant information.

UNITED STATES OF AMERICA

1. 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 th national jurisdiction of the importing Party.

Article 17
EMERGENCY MEASURES

AFRICAN GROUP

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

shall include, inter alia, the circumstances of the accident, the identity and numbers or quantities of th living modified organisms released, other facts necessary to assess the effects of the accident on huma n and animal health, the environment and biological diversity, and the emergency measures taken or needed to be taken.

2. The States concerned shall, where information is provided under paragraph 1 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.

INDIA

1. Parties shall take the necessary measures to ensure that the competent authorities of the State(s) concerned are informed immediately in the event of an accident. The information shall include, *inter alia*, the circumstances of the accident, the identity and numbers of quantities of the living modified organisms released, other facts necessary to assess the effects of the accident on human and animal health, the environment and biological diversity, and the emergency measures taken or needed to b taken.

2. The States concerned shall, where information is provided under paragraph 1 above, ensure that in any emergency the appropriate measures are taken, including immediate alerting of any other State which could be affected by the accident.

MALAYSIA

1. 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 {Risk Management} above to prevent, mitigate or rectify any potential risks to the relevant Parties in case of any unintentional transfer of LMOs, including accidental and emergency cases.

2. Each Party shall, in accordance with its capacity, 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, requisite socio-economic imperatives and the risks to human health and agriculture, and the emergency measures that need to be taken in regard therewith.

PERU

1. In the case of an accident, the insurance company, in collaboration with the competent national authorities, shall take immediate action to avoid possible negative effects of LMOs or products derived from them on the environment or on human health.

2. In the case of an accident during transboundary movement or release of an LMO, th competent authorities of the parties involved shall be informed immediately, and a note of origin of the LMO shall be immediately provided, together with recommendations on risk management.

Article

18

HANDLING TRANSPORT PACKAGING AND LABELLING

AFRICAN GROUP

1. The Parties shall ensure that products, particularly food products incorporating living modified organisms or products thereof, are clearly labelled.

2. The Parties shall ensure that living modified organisms and products thereof which have not been approved for consumption are packaged in such a way as to ensure their complete isolation.

3. The means for transporting living modified organisms and the products thereof shall minimise risks by using the most efficient form of transport with regard to time and distance.

4. The Secretariat shall develop guidelines on good labelling, packaging and transportation practices.

AUSTRALIA/BRAZIL/SRI LANKA

1. Exporting Parties shall ensure that shipments containing living modified organism:
    1. are clearly identified as containing living modified organism;
    2. are handled and packaged in such a way as to prevent accidental release into th environment; and
    3. 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}.

BELARUS

1. The Parties shall ensure safety levels during handling, transport and transit of LMOs. LMOs which have not been approved for use shall be handled and packaged in such a way as to ensure their complete isolation.

2. The Parties shall ensure that food products incorporating LMOs are clearly labelled. Other LMOs shall be labelled if necessary with regard to environmental, health or ethical concerns.

COLOMBIA

1. The secretariat of the Convention on Biological Diversity shall cooperate with the World Customs Organization (WCO) in assigning a universal identification code to the products covered by this Protocol.

2. Each Party which carries out a transboundary movement of an LMO in accordance with articl (LMOs) shall ensure that the product in question is duly encased, packaged, wrapped and labelled, including with its corresponding safety fact sheet, which should contain the elements specified in annex II.

3. The Parties shall ensure that the transboundary movement of LMOs from their territory is effected in accordance with requirements for encasement, packaging, wrapping and labelling not less stringent than those required by their own national legislation.

4. The information contained in the safety fact sheet shall, to the extent possible, be in the language of th receiving Party.

CUBA

1. In order to keep safety levels during transportation, reception, and storage, the Parties shall adopt internationally harmonized and recognized procedures and practices which provide for adequat classification, bottling, and labeling..

2. The Parties taking part in the commerce of Living Modified Organism 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).

INDIA

1. The Parties shall ensure that products in transboundary transfer particularly food products incorporating living modified organisms or products thereof, are clearly labelled, safely packed and transported in accordance with guidelines.

JAPAN

1. Each exporting Contracting Party shall establish appropriate measures for handling, transportation, packaging and transit of LMOs for transboundary transfer according to the standards to be elaborated by the Conference of the Parties to the Protocol.

MALAYSIA

1. The intending country Party shall require that LMOs that are to be subject of a handling, transfer or use be packaged, labelled and transported in conformity with generally accepted and recognised international rules and standards in the field of packaging, labelling and transport, and that due account is taken of relevant internationally recognised practices.

2. The intending country Party shall, where appropriate, take further precautionary measures when

packaging and transporting any LMO to ensure that any risks or harm to other Parties, particularly to the receiving country, is prevented, mitigated or inimised.

3. 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.

MEXICO

1. The transboundary movements of LMOs must be effected in accordance with and in fulfilment of th national law and administrative procedures of the recipient country and/or country of transit. Th development of basic international methods and procedures for packaging and transport of LMOs shall be promoted, taking also into account the needs of developing countries and countries with economies in transition.

NORWAY

1. Each Party shall:
    1. ensure 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.
    2. require that living modified organisms be accompanied by a movement document from th point at which the transfer commences to the point of use.
    3. ensure that all LMOs to be exported are clearly labelled as such. The labell ing shall inform that the movement contains a living modified organism. The labelling shall also inform about the type of living modified organism and the names and addresses of th exporter and importer.

2. Ensure that LMOs to be exported are packaged and transported in accordance with international rules and standards in the field of packaging and transport, particularly in accordance with the UN Recommendations on Transport of Dangerous Goods. The Parties shall aim at developing standards with regard to packaging and transport practices under the Protocol.

PERU

1. Every transboundary movement of an LMO or product derived from it shall be covered by an insurance policy acceptable to the parties involved.

2. In the transport of LMOs or products derived from them, appropriate precautions must be taken to minimize risks during transportation, customs examination and reception.

3. The parties should ensure that export products which are LMOs or products derived from them are clearly labelled, in at least three official languages, one of which should be the language of the importing country.

4. Labelling should meet the following specifications:

   (a) It should be located in a clearly visible spot;

   (b) It should be of a standard size and use internationally accepted symbols;

   (c) It should indicate in three languages (official language of exporting country, official language of importing country and a third official language), that the package contains an LMO or derived product and should be handled with care.

5. The LMOs and products derived from them, which are not yet approved for human or animal consumption, should be packaged and labelled in such a way that it is clear that the LMO is i the process of being evaluated and for that reason it is kept on its own.

SWITZERLAND

1. In order to maintain adequate safety levels during transport, each Contracting Party shall tak appropriate measures to ensure that products containing living modified organisms are appropriately packed and labelled .

UNITED STATES OF AMERICA

1. Each Party shall promote, as appropriate, measures for the appropriate handling, transport, and packaging of LMOs subject to the Article on Advance Informed Agreement.

Article 19
COMPETENT AUTHORITY/FOCAL POINT

AFRICAN GROUP

To facilitate the implementation of this Protocol, each Party shall:

1. Designate or establish a competent authority which shall receive applications and notifications and communicate decisions on living modified organisms and products thereof in accordance with th Advance Informed Agreement procedure set out in Article 4 and 5 and Annex I.

2. Inform the Secretariat and the Biosafety Clearing House within 90 days of the date of the entry into force of this Protocol for it, which agency it has designated as their competent authority.

3. Inform the Secretariat and the Biosafety Clearing House within 30 days of the date of decision, of any changes regarding the designation made by it under paragraph 2 above.

AUSTRALIA

1. Parties shall:

a) designate a Focal point;
b) designate one or more Competent Authorities;
c) inform the Clearing House, within three months of the date of entry into force of the Protocol for them, which agencies have been designated as the Focal Point and the Competent Authority; and
d) inform the Clearing house, within one month of the date of decision, of any changes regarding the abov designations.

BELARUS

1. To facilitate the implementation of this Protocol, each Party shall designate a national competent authority/focal point. This authority/focal point shall be responsible for procedures related to AIA, notification, exchange of information, implementation of emergency measures.

2. Designated national competent authority/focal point should be nominated within 90 days from the dat of ratification of the Protocol. The Secretariat and the Biosafety Clearing Hause (Biosafety Centralised Data Base) shall be informed of it and of any changes regarding the designation within 30 days from the date of decision.

BRAZIL

1. Each Party shall:

a) designate a Focal point;
b) designate a Competent Authority;
c) inform the Clearing House, within three months of the date of entry into force of the Protocol for them which agencies have been designated as the Focal Point and the Competent Authority; and
d) inform the Clearing House within one month of the date of decision of any changes regarding the abov designations.

COLOMBIA

1. Each Party shall designate a national authority which shall be empowered to act on behalf of that Party and to discharge the necessary administrative functions for implementation of the present Protocol.

2. The Parties shall ensure that the designated national authorities have sufficient resources at their disposal for the effective performance of their work.

3. Each Party shall, no later than the date of entry into force of the present Protocol for that Party, notify the secretariat of the Convention on Biological Diversity of the name and address of its designated national authority and shall keep that information up to date.

4. The secretariat shall, without delay, communicate to Parties those notifications which it has received in

implementation of the above paragraph and any change in the information relating to designated national authorities.

CUBA

1.- Each State Party under its constitutional procedures should designate one or more national authorities. When more than one authority be designed, it should assign a specific field for the application of biotechnology. .

2,- The designed national authorities should fulfill, as a minimum, the following responsibilities:

a) To establish appropriate procedures to demand risk assessment of the release proposal of Living Modified Organisms which are likely to have adverse effect on biological diversity.
b) To examine the mechanisms to study and to evaluate risk assessment with the objective of guaranteeing a safe application of Living Modified Organisms to human health and environment.
c) To designate an examination body for risk assessment for all Living Modified Organisms releas proposal into the environment.
ch) To establish mechanisms to facilitate data recording processing and diffusion about local conditions of areas where environment release will be done.
d) To check the right observance of established security conditions as a result of risk evaluation.
e) To establish appropriate procedures of control or mitigation, to finish release and eliminate wastes.
f) To guarantee the necessary confidence of commercial data.
g) To establish mechanisms to inform local communities about the Living Modified Organisms release, given appropriate educational materials.
h) To establish mechanisms for information exchange between countries and to develop national data bases.
i) To present pertinent information to competent international organizations about any negative or unforeseen repercussion on public health or environment related to Living Modified Organism release.
j) To keep a Registry of all activities related to Living Modified Organisms.
k) To receive and to arrange, to present and to evaluate all notification about transboundary movement of Living Modified Organisms.
l) the rest as established by this Protocol
m) Any other assigned by their corresponding governments

EUROPEAN COMMUNITY

1. Each Party shall designate or establish competent authority/ies and/or focal points/s that shall b responsible for the administrative functions required by this Protocol and shall notify this to th Secretariat no later than the date of entry into force of this Protocol for it.

2. Each Party shall also notify relevant data concerning its designated competent authority/ies and/or focal point/s to the Secretariat for inclusion in the Database provided for in Article 20 [on information sharing]. Each party shall also immediately notify the Secretariat of any subsequent changes.

INDIA

1. To facilitate the implementation of this Protocol, each party shall:

(i) designate or establish a competent authority which shall receive notification and communicate decisions on living modified organisms and products thereof in accordance with the advance informed agreement

procedures set out in 4 and 5 Annex I.

(ii) Inform the Secretariat and the Clearing House within 90 days of the date of the entry into force of this Protocol the name of the agency designated as their competent authority.

2. Parties shall ensure that appropriate legal, institutional, and administrative frameworks are in place at the national level within two years after the date of ratification or accession.

JAPAN

Contracting parties shall designate or establish one national focal point and one or more competent authorities for the implementation of the Protocol.

The national focal point shall perform the following tasks:

i. 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;
ii. to collect information on the implementation of the protocol at its national level; and
iii. 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.

(b) The competent authorities shall perform the following tasks:

i. to establish national guidelines and/or regulations for the implementation of the AIA procedures including detailed criteria for risk assessment within their competence;
ii. to receive from exporters applications for the AIA procedures;
iii. to conduct risk assessment;
iv. to take a decision on result of the risk assessment;
v. to inform the exporter with the result of the risk assessment; and
vi. to conduct, if necessary, additional trials, including field trail.

MADAGASCAR

v. The competent national authority will be an officially designated governmental post and not a person. There will only be one competent national authority per country.

vi. The post should be within the Ministry (or agency) in charge of coordinating national biotechnological risk prevention under the Convention on Biological Diversity.

vii. The competent national authority will be the sole interlocutor and will receive requests and notifications from competent national authorities of other countries. It will communicate the decisions on living modified organisms (LMOs) and products thereof in accordance with the prior informed consent procedure under the Protocol.

viii. It shall be up to each country to determine the tasks entrusted to the competent national authority.

ix. The competent national authority shall enter into force on the date of signature of the protocol.

MALAYSIA

1. The Parties shall establish or designate a National Competent Authority (NCA) to serve as the agency to handle any enquiries and proposals for any transfer, handling or use of LMOs pursuant to this Protocol.

2. The Parties shall inform the Secretariat within three months of the entry into force of this Protocol for them which agency they have designated as their competent authority. If there are any changes regarding the designation made by them under paragraph one above, the Parties shall inform th Secretariat within one month of that decision.

3. The National 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.

4. Each Party shall operate the Advance Informed Agreement procedure under Article 4 through th National Competent Authorities designated or established by every Party.

5. The National 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, socio-economic imperatives and the risks to agriculture and human health.

6. The National Competent Authority of the receiving country Party may take into consideration any matter of national interest, including social and ethical matters in carrying out its responsibilities through the National Competent Authority. The National Competent Authority shall in particular b responsible for:

a) receiving all required information, including the risk assessment supplied by the intending country Party or person or entity under its jurisdiction, through the National Competent Authority, prior to such transfer, handling or use.
b) receiving prior notification regarding any intended transfer, handling or use to or within the receiving country Party.
c) making decisions on the transfer, handling or use of the LMO to or within the receiving country.
d) subject to the receiving country Party □ capabilities and capacities, undertaking its own risk assessment and giving its own risk assessment decisions.

MEXICO

1. Each Party shall designate a national office, which should have government support and which will b responsible for the administrative actions required by this Protocol. At the time of ratification of th present Protocol, the name of the focal point should be notified.

NORWAY

To ensure an effective functioning of this Protocol, each Party shall:

1. Designate or establish one or more competent authority(ies) and one focal point. The competent authority/ies shall be responsible for procedures related to Advance Informed Agreement (AIA), notification and information exchange. The competent authority in the State of import shall also b responsible for procedures related to risk assessment and risk management. The focal point, which preferably shall be identical to the competent authority/ies, shall function as the contact point for th Protocol. The focal point shall be responsible for receiving and submitting information provided for in Articles 4, 5 & 6.

2. Inform the Secretariat as soon as possible and no later than the date of the entry into force of th Protocol for the Party in question, which agencies have been designated as its focal point/competent authority(ies). Each Party shall within one month of the dat of decision, inform the Secretariat of any changes regarding the designation made by it.

3. The Secretariat shall forthwith inform the Parties of notifications received under paragraph 2. Th 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.

PERU

1. The competent authority(ies) shall be designated by the State and shall have the following functions:

(a) To approve or turn down applications from exporting countries for the introduction, and release and marketing of living modified organisms and products of modern biotechnology, in accordanc with the Advance Informed Agreement procedure;

(b) Suspension of the clearance granted, in cases where the competent national authority is reasonably satisfied that the importation of such LMOs or products has caused damage or that there has been a change of use of the clearance granted;

(c) To authorize contained use as well as deliberate release, for purposes of research, within the scenario foreseen in national and international legislation on the topic;

(d) To keep the national focal point informed, and also the regional focal point, if there is one;

2. The competent authority shall also have powers to:

(a) Adopt risk assessment criteria, which will ensure that the products introduced, released or commercialized do not cause damage to plant, animal and human health or to the environment in general.

3. The regional focal point, if there is one, shall be designated by the Parties and by consensus.

4. The regional focal point, if there is one, should represent ecological regions common to the Parties.

5. The national or r gional focal point (if there is one) shall be responsible for receiving and sending information on intended or unintended movements of LMOs, accidents due to the transboundary transfer of LMOs, together with any information related to national, regional and global biosafety, maintaining close contact with the secretariat and the Conference of the Parties.

SOUTH AFRICA

To facilitate the implementation of this Protocol, each Party shall

1. Designate and/or establish a competent authority which shall receive notifications, conduct and/or evaluate risk assessments and communicate decisions on LMO's in accordance, with procedures stated in Articles 4, 5 & 13.

2. Inform the Secretariat and the Clearing House within 90 days of the date of entry into force of this Protocol, which agency has been designated as competent authority for that Party .

3. Inform the Secretariat and the Clearing, House within 30 days of the date of decision, of any changes regarding the designation made by it in terms of paragraph 2 above.

SRI LANKA

1. A National Competent Authority shall be designated for the implementation of the Biosafety Protocol as soon as possible.

2. Responsibilities of the designated National Competent Authority/Focal Point shall include, but are not limited to, the following:

a) to receive notification;
b) to transmit information to other Parties and/or the Secretariat and the notifiers;
c) to evaluate risk assessment;
d) to take decisions about notifications under AIA;
e) to transmit decisions on AIA to the notifier and other relevant agencies;
f) 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;
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 undertake risk assessment and give risk management decisions;
i) to be informed immediately in the event of a n adverse effect of the transfer of the LMOs which could affect it.

3. The National 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;

4. Each State shall inform the Biodiversity Convention Secretariat, the agency it has designated as National Competent Authority, as soon as the International Biosafety Protocol enters into force.

SWITZERLAND

1. Each Contracting Party shall designate or establish one national focal point that is authorized to act on its behalf and to be responsible for the administrative functions required by this Protocol.

2. Each Contracting Party shall, no later than the date of entry into force of this Protocol, notify the name and address of its national focal point to the Secretariat for inclusion in the[Biosafety Clearing House] [International safety Database] [Database for international information exchange]. Each Contracting Party shall also immediately notify the Secretariat of any further changes.

3. Each Contracting Party shall ensure that its national focal point has sufficient resources to perform their tasks effectively.

UNITED STATES OF AMERICA

1. Each Party shall designate one or more national authorities that shall serve as its focal point(s) and b authorized to act on its behalf with respect to the functions required by this protocol.

2. Each Party shall, concurrently with the deposit of its instruments of ratification, provide the name and address of its designated national focal point(s) to the Convention on Biological Diversity (CBD) Secretariat. Each Party shall also immediately notify the Secretariat of any subsequent changes. Wher a Party designates more than one national authority, it shall specify the areas of responsibility for each.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2.

Article 20
INFORMATION SHARING/BIOSAFETY CLEARING HOUSE

AFRICAN GROUP

1. The Parties shall facilitate and encourage the collection and exchange of scientific, technical, environmental, socio-economic, commercial and legal information relevant to the implementation of this Protocol. Such information shall be transmitted to the Secretariat, the Biosafety Clearing Hous and other relevant bodies and Parties as the case may be.

~~Biosafety Clearing Hous~~

1. A Biosafety Clearing House shall be established to provide the Parties and, as appropriate th Secretariat, with timely advice and information relating to the implementation of this Protocol. This body shall be composed of recognised experts from developing and developed countries and shall be multidisciplinary. 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 advanc informed agreement. The modalities of establishment of the Biosafety Clearing House shall b considered and decided upon by the Parties at their first meeting.

2. 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, in particular:

a) collect and disseminate to parties information identified in Annex IV and

b)Assist Parties, particularly developing country Parties, when requested, in any of the following or other appropriate matters:

    1. preparing or evaluating risk assessment reports or impact statements;
    2. developing or evaluating risk management schemes and appropriate monitoring programmes, procedures and standards;
    3. preparing emergency plans and other safety measures;
    4. transmitting requests for assistance and relevant information in the event of accidents;
    5. providing information that may be relevant to the settlement of disputes.

3. Each Party shall ensure that timely information pertaining to Biosafety is provided to the Biosafety Clearing House.

AUSTRALIA

1. Parties shall cooperate in sharing information relevant to the safe use, handling and transboundary movement of living modified organisms, on a bilateral and multilateral basis, as appropriate.

2. Parties shall establish a Clearing House for the purpose of promoting and contributing to the sharing of information between Parties. Parties shall make available to the Clearing House information identified in Annex IV.

BELARUS

1. Parties shall provide information through their national competent authorities/focal points to th Biosafety Clearing House/Biosafety Central Data Base to be shared by other Parties/general public. The information provided shall not include confidential data and those ones that can restrict th proprietary rights.

2. Each Party shall ensure that all affected states be timely informed about accidents/unintentional releases associated with LMOs, intended releases of LMOs which can be followed by their transboundary movement, with new information about LMOs under AIA (Art. [ ] ".

BRAZIL

1. Parties shall establish a Clearing House for the purpose of promoting and contributing to the sharing of

information relevant to the safe use, handling and transboundary movement of living modified organisms and products thereof.

2. Parties shall make available to the Clearing House the information identified in Annex IV, *inter alia* :

CANADA

1. Each Party of Import shall make available to the clearing-house mechanism established under Articl 18.3 of the Convention subject to appropriate protection of confidential business information identified in Annex IV:

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

COLOMBIA

1. The mechanism for the exchange of information and cooperation under the Protocol shall be that established by the Convention on Biological Diversity in its Article 18, paragraph 3.

CUBA

1.- The Parties shall cooperate according to their national laws, regulations, and practices and taking particularly into account the needs of the developing countries in order to foster, directly or through th International Registry of Living Modified Organisms and other competent bodies, the research, development, and information exchange on:

a) Most convenient technologies to improve risk confinement, assessment and, management.

b) Useful generic research for risk assessment and management.

c) The transboundary movement of Living Modified Organism and the approvals conferred for trading products having Living Modified Organisms as well as those being prohibited, approved or obtained recently.

d) Adopted legislation on biotechnology safety and national Biosafety mechanisms.

e) Living Modified Organism releases and the unexpected or adverse effects on human health and th environment which have taken place due to them.

f) Technical, scientific, and socio-economic research results, as well as the statistics available on th effects on human health and the environment.

g) Training and study programs and specialized, autochthonous and traditional knowledge.

h) The supervision of Living Modified Organism releases after its commercial use.

i) Groups of experts and advisory bodies

EUROPEAN COMMUNITY

1. A Database for international information exchange shall be established and administered by th Secretariat. Without prejudice to Article 11 [on confidentiality of data], the Database shall contain and provide access to information relevant to the implementation of the Protocol.

2. Without prejudice to Article 11 [on confidentiality of data], each Party shall provide that th Secretariat is informed, for inclusion in the Database, of the information identified in Annex IV:

3. Without prejudice to Article 11 [confidentiality of data], the information shall be accessible to th public.

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

INDIA

1. The Clearing House mechanism under the CBD shall function as the Clearing house mechanism to provide the Parties and, as appropriate the Secretariat, with timely advice and information relating to the implementation of this Protocol.

2. Each Party shall ensure that timely information pertaining to Biosafety is provided to the Clearing House.

3. The Parties shall facilitate and encourage the collection and exchange of scientific, technical, environmental, socio-economic, commercial and legal information relevant to the implementation of this Protocol. Such information shall be transmitted to the Secretariat, the Clearing House and other relevant bodies and Parties as the case may be.

JAPAN

1. The Secretariat of the Protocol shall circulate the information received to all Contracting Parties.

2. The Contracting Parties are encouraged to make available to all interested parties, including other Contracting Parties, regional and int rnational institutions as well as individuals information on th implementation of the Protocol, and the information identified in Annex IV.

MADAGASCAR

1. Information exchange is distinct from the reporting requirement relating to transboundary movements.

2. The information to be submitted to the clearing-house relates to the implementation of the Protocol on the prevention of biotechnological risks.

3. The biotechnological risk clearing-house shall be an integral part of the clearing-house of th Convention on Biological Diversity.

4. The clearing-house shall, together with international databases and the centres of country Parties, serv as a facility for information exchange, for support of the implementation of the Protocol and for th scientific and technological cooperation among Parties.

MALAYSIA

1. Subject to the national laws, regulations and procedures of each Party, and without prejudice to th obligation to provide information under the AIA procedure under Article ( ) {Advance Informed Agreement}, the Parties shall facilitate through a clearing-house mechanism and/or national focal points of each Party, the exchange of information, from all publicly available resources, and fro existing international agencies, organizations and regional networks, 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. In facilitating such exchange of information, patents and other intellectual property rights must be supportive of and must not run counter to this Protocol's objective.

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 applicabl in other countries, including those about national biosafety mechanisms, and approvals given for th transfer, handling and use of LMOs in other countries and for the marketing of products containing LMOs and such other relevant information under Article {Exchange of Information}.

3. Measures should be undertaken to provide for developing country Parties that provide genetic resources, to participate in biotechnology reasearch undertaken in respect of the genetic resources and for the promotion and advance priority access to the results and equitable sharing of benefits arising from biotechnologies based upon genetic resources provided by those countries.

MEXICO

1. The Contracting Parties shall facilitate, through the clearing-house mechanism, the sharing of information from sources that are publicly accessible, including the interchange of results from th technical, scientific, environmental and legal research needed to implement this Protocol, together with the national laws, regulations and norms to be followed by countries of import, taking into account th special needs of developing countries and countries with economies in transition.

NORWAY

1. A Database for information exchange shall be established and administered by the Secretariat. Without prejudice to the provisions in this Protocol concerning confidentiality of data, th Database shall contain and provide access to information relevant for the implementation of this Protocol.

2. Each Party shall provide information identified in Annex IV to the Secretariat for inclusion in th Database.

3. This information shall be accessible to the public.

PERU

1. Parties shall facilitate the mutual sharing of information and also with the secretariat and th Conference of the Parties, although there may be different levels of access to such information.

SOUTH AFRICA

1. The clearing house mechanism of the Convention on Biological Diversity will be the clearing house for this protocol. The functions of the clearing house will be to facilitate access to information regarding:

(i) national procedures for regulation, assessment and risk management ;
(ii) scientific references necessary to the assessment and risk management;
(iii) database on experiments of organisms genetically modified and on commercial products thereof;
(iv) information on transboundary movement and on results of AIA;
(v) dissemination of information on transboundarv movement and use to Parties sharing ecosystems with, or bordering, on, Parties importing or using, LM0's for the first time

SRI LANKA

1. The Parties shall co-operate among themselves in sharing information, developing appropriate technical guidelines and/or codes of practice, and monitoring the effects of risks posed by living modified organisms and products thereof on human and animal health, biological diversity, the environment and socio-economic welfare of societies with a view to promoting the safe management of these organisms and products.

2. The Parties shall facilitate and encourage the collection and exchange of scientific, technical, environmental, socio-economic , commercial and legal information relevant to the implementation of th Protocol. Such information shall be transmitted to the Secretariat, the Biosafety Clearing House and other relevant bodies and parties as the case may be.

3. Information that could be shared is identified , but not limited to, the information listed in Annex IV.

4. An appropriate Biosafety Clearing House mechanism shall be established through the CBD clearing-house mechanism to provide the parties and, as appropriate the Secretariat, with timely advice and information relating to the implementation of the Biosafety protocol. This body shall be composed of recognised experts from developing and developed countries and shall be multidisciplinary. 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.

5. 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 in particular:

(a) collect and disseminate to parties information concerning:
(i) the development, use and transfer of LMOs and products thereof
(ii) methodologies. Techniques, experts, equipment, materials, available results relating to risk assessment and management

(b) assist Parties, particularly developing countries, when requested, in any of the following or other

appropriate matters:

i. preparing or evaluating risk assessment reports or impact statements;
ii. developing or evaluating risk management schemes and appropriate monitoring programmes, procedures and standards;
iii. preparing emergency plans and other safety measures;
iv. transmitting requests for assistance and relevant information in the event of accidents;
v. providing information that may be relevant to the settlement of disputes.

SWITZERLAND

1. Each Contracting Party shall facilitate the collection and exchange of all publicly availabl scientific, technical, environmental and legal information relevant to the implementation of this Protocol taking into account the special needs of developing country and the countries with economies in transition through a [Biosafety Clearing House] [International Safety Database] [Database for international information exchange]. (Note: Biosafety Clearing House: refer to African Group submission)

2. Without prejudice to Article 11 [which address Confidentiality], each Contracting Party shall ensure that the following information is provided to the Secretariat for inclusion in the [Biosafety Clearing House] [International safety Database] [Database for international information exchange]:

    1. information on intentional movement having been subject to Advance Informed Agreement according to Art. 4 and related decision(s)
    2. information on unintentional movements according to Art.16 .

3. A [Biosafety Clearing House] [International Safety Database] [Database for international information exchange] should be established no later than the date of entry into force of this Protocol on the basis of existing international Biosafety Exchange Mechanisms.

UNITED STATES OF AMERICA

1. The Parties shall facilitate the exchange of publicly available information on, and experience with, living modified organisms (LMOs) to enable Parties to make informed decisions related to Biosafety.

2. Each Party shall make available to a centralized database/clearinghouse its domestic laws, regulations, and guidelines applicable to the production, use, and handling of LMOs.

3. Each Party shall make available to a centralized database/clearinghouse publicly available information on risk assessments or environmental reviews generated by the regulatory process.

4. Each Party shall make available publicly available information on its decisions regarding th importation, field testing, or commercial use of any LMO.

Article 21
CAPACITY BUILDING

AFRICAN GROUP

1. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capaciti s in biotechnology and Biosafety.

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 centres for training and capacity building regarding the safe management of living modified organisms or products thereof shall be established.

AUSTRALIA

1. Parties shall cooperate in relation to capacity building for risk assessment, decision making and risk management. Capacity building may include technical assistance, information exchange, training, education and institutional capacity building.

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

BELARUS

Each Party shall strengthen and/or develop human resources and institutional capacities in order to facilitate an effective implementation of the Protocol. 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 are aware of any associated risks and have the means to assess and manage the risks;
d) that states are able to achieve safety when certain LMOs are transferred into and/or to be used in their territories and act adequately in cases of accidental release of LMOs.

BRAZIL

1. Each Party shall strengthen and/or develop human resources and institutional capacities in order to facilitate effective implementation of the Protocol. Such capacity building shall aim to ensure:

a) that national legislation related to Biosafety is developed;
b) that Parties involved in the transfer, handling and use of living modified organisms and/or products thereof, are aware of associated risks and have the means to assess and manage such risks; and
c) that Parties are able to conduct proper risk assessment and management when living modified organisms and/or products thereof are transferred into and/or used in their national territories.

2. Parties shall co-operate to build capacity for risk assessment, decision making and risk management. Capacity building may include technical assistance, information exchange, training, education and institutional strengthening.

3. Capacity building programmes should maximise use of existing mechanisms where possible, including those addressed under the Convention, and should be particularly aimed at developing countries.

4. Tec nical assistance from the private sector should be facilitated and encouraged.

CANADA

1. Each Party shall promote technical and scientific cooperation with other Parties, in particular developing countries, in implementing this Protocol, inter alia, through the development and implementation of national or regional policies. In promoting such cooperation, special attention should be given to the development and strengthening of national and regional capabilities, by means of human resources development and institution building.

2. The financial mechanism established under the Convention will be a source of financial resources for capacity-building to help achieve the purposes of this Protocol, in particular for risk assessment and management.

COLOMBIA

Elements which should be included in the article on national capacity-building:

1. National capacity-building is an essential requirement for the effective implementation of the Protocol;

2. Capacity-building is understood to mean the establishment and/or strengthening, as appropriate, of human or institutional resources, in accordance with the needs and priorities identified by each Party, for:

(a) The management and effective exchange of information relating to compliance with this Protocol;

(b) Risk assessment;

(c) Risk management;

(d) The drafting and adaptation of national legislation for the implementation of the Protocol.

3. National capacity-building should take place, inter alia, through the following:

(a) New and additional financial resources;

(b) Technical assistance and capacity-building;

(c) Transfer of technology related to the scope of this Protocol.

CUBA

1.- The Parties in this Protocol shall create the necessary capacity at local and national levels in correspondence to their possibilities, with the aim to achieve the following objectives:

(i) To strengthen their endogenous capacities to facilitate the implementation of this Protocol and other instruments regarding safety in biotechnology and to develop the corresponding national legislation..

(ii) To identify any risk related to activities of development, use, production and release of Living Modified Organisms and to ~~dispense~~ the means for risk assessment and control to take proper decisions.

(iii) To guarantee safety when Living Modified Organisms are transferred to each country.

(iv) To strengthen the development of policies, facilities, information systems and training in sciences related to safety in biotechnology, including evaluation and risk management techniques, as well as security procedures.

(v) To increase technical knowledge and competence, facilities and resources to evaluate and control risks related to the use of Living Modified Organisms.

2. The Parties will participate in the creation of capacities at regional level in order to jointly tak advantage of the experience accumulated in the survey of risk assessment and in management strategies, contributing with detailed guidelines on national mechanisms of control.

3. The parties will be able to strengthen their national or regional capacities using the financial mechanism, at the request of States Parties that consider it necessary, after assessment by th Secretariat, and intend some of its resources to facilitate technical cooperation, distribute reports and pertinent documents, hold practical courses and training meetings, as well as carrying out other connected activities for the benefit of the Parties being developing countries.

Technical and Scientific Cooperation:

1.- The Parties shall promote international technical and scientific cooperation in the field of handling and use of Living Modified Organisms, where necessary, through the appropriate international a nd national institutions.

2.- The Parties shall promote technical and scientific cooperation with other Parties, in particular developing countries, in implementing national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national capacity , by means of human resourc development and the creation of institutions.

3.- Taking specially into account the needs of the developing countries, the Parties shall cooperate in promoting scientific-technical cooperation led to facilitate participation in this Protocol and its enforcement.

4.- Any Party in 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.

5.- At their first meeting, the Parties shall start deliberations on the means to fulfill the obligations of Paragraphs 1-4 of the present Article, including work plan elaboration in which special attention will be paid to the needs and circumstances of developing countries. The states and regional economic integration organizations not being Parties in the Protocol will be encouraged to participate in the activities specified in such plans.

International registery on Genetically Modified Organisms:

1.- It is established an International Registry on Living Modified Organisms which will be a scientific instrument to record and share data used to assess risks implied by Living Modified Organisms for public health and the environment. This Registry will work closely with the Global Environmental Monitoring System (GEMS) and other UNEP bodies intended to information exchange such as INFOTERRA and th Programme for Environmental Assessment. This Registry will have the following objectives:

(i) Become a global network intended to information exchange on Living Modified Organisms.

(ii) Elaborate data profiles on Living Modified Organisms. Administer a data bank with all aspects related to Living Modified Organisms, including information concerning national policies and regulations applied to these.

(iii) Watch the fulfillment of guidelines elaborated for information exchange on Living Modifies Organisms subject to international trade.

(iv) Provide assistance to developing countries for the establishment of their own national records. Facilitate attainment of the existing information on production, distribution, and elimination of Living Modified Organisms.

(v) Offer training in fields related to control of stated risks and with scientific data use

(vi) Foster scientific research. Issue scientific and technical publications on genetic handling and its end products as well as bulletins intended to provide information on Living Modified Organisms.

(vii) Provide consulting services.

(viii) Detect environmental changes associated to Living Modified Organisms, determine their causes, and communicate research results.

(ix) Identify the gaps in knowledge on the effects of Living Modified Organisms. Elaborate statements on environmental problems related to these.

2.- In the Parties' first meeting, the Registry functions, structure, and location procedures for information exchange and its functional ordinance will be established.

EUROPEAN COMMUNITY

1. The Parties agree that measures for capacity building in the form of information exchange, training, education and institutional capacities, are essential for the effective functioning of the Protocol.

2. Implementation of the measures referred to in paragraph 1 is properly addressed in the general framework of the Convention and through programmes and activities under international organizations

such as UNEP and UNIDO.

INDIA

1. The Parties shall take effective measures to develop and strengthen human resources and institutional capacities in biotechnology and Biosafety, particularly in the developing countries.

2. According to the specific needs of Parties, different regions and sub -regions, activities for training and capacity building for the safe handling and management of living modified organisms or products thereof shall be undertaken with financial assistance provided through the financial mechanisms under the Convention on Biological Diversity (CBD).

MADAGASCAR

1. The prevention of biotechnological risks represents a new domain for many countries and will requir them to strengthen their human, institutional and financial capacities.

2. The Protocol will have to contain provisions relating to the development and strengthening of human resources at different levels: scientists, decision makers and technical implementation staff fro different political, public and private organizations.

3. The Protocol will have to provide for the development and strengthening of national institutions in accordance with the specific needs of different countries for different activities, including for risk assessment and management, the control of LMOs upon entry, upon release and during the observation period.

4. The secretariat, in cooperation with the international clearing-house and national clearing-houses, will organize training programmes, to strengthen national capacities in the area of biosafety. To this end it shall seek the necessary funds for the implementation of these programmes, with a view to ensuring th sound management of LMOs and products thereof.

5. International cooperation shall be sought for the establishment of an information-sharing system and the elaboration of guidelines for the following of the activities implemented to ensure the sound management of biotechnological risks.

MALAYSIA

1. 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.

2. The developed country Parties shall transfer relevant kno -how on fair and most favourable terms including on concessional and preferential terms, in biotechnology and biosafety to developing country Parties.

3. The developed country Parties shall develop such appropriate facilities, training in science related to safety in biotechnology and in the use of risk assessment and risk management techniques for the benefit of developing country Parties and to assist developing country Parties to make their own risk assessment decisions.

4. 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.

MEXICO

1. The Parties shall promote training, cooperation and technical and scientific exchange programmes for the appropriate management of LMOs, together with the necessary collaboration for the preparation of national laws, so that countries, in particular developing countries with rich biological diversity that may be centres of origin and/or present a high level of endemic disease, may achieve the objectives of this Protocol. At the same time, the Parties shall promote international cooperation and th establishment of financial mechanisms to obtain new and additional resources, which will mak possible the implementation of cooperation programmes, including the development of appropriately trained staff.

NORWAY

1. Each Party shall strengthen and/or develop human resources and institutional capacities in order to facilitate an effective implementation of this Protocol. Such measures shall aim to ensure:
    1. that Parties develop and strengthen their capacities to implement this protocol
    2. the development of national legislation related to safe transfer, handling and use of LMOs
    3. the development of procedures for risk assessment and risk management of LMOs.

PERU

1. Each party should organize its own internal system to strengthen institutional capacities in order to fulfil the obligations and mechanisms emanating from the present protocol, and for that reason they should:

    (a) Allocate their own resources to the achievement of these ends;

    (b) Establish regional and subregional mechanisms for the training of human resources and th strengthening of institutional capacities;

    (c) If they are developing countries, negotiate with developed countries regarding possibl collaboration to strengthen their internal capacities for the identification, planning and implementation of their capacity-building programmes.

SRI LANKA

1. Each Party shall strengthen and/or develop human resources and institutional capacities in order to facilitate an effective implementation of the Protocol. Such capacity building shall aim to ensure:
a) that Parties develop and strengthen their capacities to implement the Protocol;
b) that national legislation related to Biosafety is developed;
c) that states involved in the transfer, handling and use of LMOs are aware of any associated risks and have the means to access and manage risks;
d) that states are able to achieve safety when certain LMOs are transferred into and/or to be used in their territories.

2. 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.,

3. 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.

4. Regional or sub-regional centres for training and capacity building regarding the safe management of LMOs or products thereof should be established, according to the specific needs of different regions and sub-regions.

SWITZERLAND

1. The Contracting Parties shall, taking into account in particular the needs of developing countries and countries with economies in transition, cooperate in promoting technical assistance for the development of the infrastructure and necessary capacity to manage living modified organisms for th implementation of this Protocol. Contracting Parties with more advanced Biosafety-regulating programs should provide technical assistance, including training to other Contracting Parties in developing infrastructure and capacity to manage living modified organisms within their countries.

UNITED STATES OF AMERICA

1. The Parties support the aspiration of all importing Parties to perform their own risk assessments.
2. The Parties shall assist each other through information-sharing about LMOs, including through th provision of information to th centralized database.

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

Article 22
PUBLIC AWARENESS / PUBLIC PARTICIPATION

AFRICAN GROUP

1. Each Party shall ensure that adequate information on the use and release of living modified organisms or products thereof is provided to the public.

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, th 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 or products.

AUSTRALIA

1. Parties shall:

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

(b) make available to the public the results of risk assessments for living modified organisms, undertaken for either domestic release or transboundary movement, while respecting the need to protect commercial-in-confidence information.

BELARUS

1. The Parties shall ensure that adequate information on the transfer, handling and use of LMOs is provided to the public.

2. The Parties shall promote and facilitate the development and implementation of educational and public awareness programmes on Biosafety.

3. In some cases (during the AIA procedure, making allowance for LMOs handling, use, marketing) competent authority/focal point may decide that public hearing is to be carried out. The decision to carry out a public hearing shall be publicly announced.

BRAZIL

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

a) endeavour to ensure full public awareness of the issues relevant to the transboundary movements of living modified organisms and products thereof; and
b) make available to the public risk assessment results and decisions concerning the transboundary movement of living modified organisms and products thereof;

2. Parties are encouraged to facilitate public participation in risk assessment decisions.

CANADA

1. With respect to the safe transfer, handling and use of living modified organisms, specifically

focusing on transboundary movement, each Party shall:

a) promote and encourage understanding of the importance of, and the measures required for, such safe transfer, handling and use; and,

b) co-operate, as appropriate, with other States and international organizations in developing public awareness material on these topics.

CUBA

1.- The Parties shall stipulate public participation by allowing access to information on which decisions ar 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..

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

INDIA

1. The Parties shall promote and encourage understanding of the importance of safety in use, handling and management of living modified organisms and their products.

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

JAPAN

1. The Contracting Parties shall take appropriate measures to enhance public awareness of and/or public participation in the implementation of the Protocol.

MALAYSIA

1. Subject to relevant national legislation, Parties shall endeavour, and shall procure the industry and researchers in this regard, 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. Acceptance of biotechnology products will be enhanced if the information is disclosed, in particular to the community where any transfer, handling, release or use will occur.

2. Parties shall promote and facilitate, in accordance with national legislation and within their respectiv capacities, the development and implementation of educational, both formal and informal, and public awareness programmes on biosafety.

MEXICO

1. The Parties shall take appropriate measures to ensure that the general public may have adequate access

to information relating to the utilization of this Protocol, while respecting confidential commercial information.

2. The Parties shall promote and facilitate, in accordance with their national laws and respectiv capacities, the development of educational programmes for public awareness-raising in respect of safety and biotechnology.

NORWAY

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 of the Convention.

2. The Parties shall apply Article 14(1) of the Convention with regard to public participation.

PERU

1. Both the public and private sectors should play an active role in creating public awareness and sharing information regarding th implications of LMO release and the use of products derived from them, through educational programmes at all levels of organized society.

2. In decision-making in regard to the release or commercialization of LMOs, public opinion should b taken into account, particularly the views of those people likely to be more affected by the release of LMOs or products derived from them

SRI LANKA

1. The Protocol shall include a provision on public participation on compliance with the Protocol.

2. The Parties shall ensur that adequate information on the safe transfer, handling and the use of LMOs is provided to the public.

3. 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 with their respective capacities, th development and implementation of educational, both formal and informal, and public awareness programmes on safety in biotechnology.

4. Each Party shall ensure, in accordance with its national laws and r gulations, provide the public which is likely to be affected by any activity or product involving LMOs, an opportunity for public hearings in the process of approving the release, transfer or use, contained or otherwise, of such LMOs or products thereof.

SWITZERLAND

1. Each Contracting Party shall take appropriate measures to ensure to the extent practicable, that th public has appropriate access to information related to the implementation of this Protocol, whilst respecting confidential commercial information.

2. Each Contracting Party shall promote and facilitate, as appropriate and in accordance with national laws and regulations, and within their respective capacities, the development of educational public awareness program on safety in biotechnology.

Annex I

INFORMATION REQUIRED IN ORDER TO OBTAIN ADVANCE INFORMED AGREEMENT

AFRICAN GROUP

1. The exporter of living modified organisms or products thereof shall provide the competent authorities of the States concerned with the following information in order to obtain advance informed agreement in accordance with the above mentioned provisions:

a) Names and addresses of the exporter and the importer
b) A complete risk assessment report on the living modified organism or the product thereof in accordanc with the risk assessment parameters stated in the protocol
c) Number or quantity of organisms or products to be transferred or volume of culture and physical for
d) The step 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
e) The applicable laws, procedures and guidelines of the State of export
f) Any requirements to manage risks and to ensure safe handling and use, and methods for safe disposal and appropriate emergency procedures in case of accidents.
g) Intended dates of transfer
h) Intended means of transport
i) Information relating to insuranc
j) Declaration by the exporter that the information is correct

Information to be provided inter alia

(a) the living modified organism:
its taxonomy, ecology and reproductive behaviour;
if genetically modified, information on its donor, recipient and vector organism, the gene(s) introduced, including marker genes, stability of the introduced genes and risk of transfer of those to other organisms, methods of managing unintended release, and methods of use;
if the organism is not genetically modified, information on whether it is known to exist in present day nature or not, methods of using it, and methods of managing any unintended release.

(b) The product of living modified organism:
information on methods of using it, whether it is a novel chemical, or one which occurs in nature, the living modified organism which produced it as referred to in (a) above, and management methods in case of accidents.

AUSTRALIA

1. Name and address of exporter
2. Name and address of importer
3. Taxonomic identification of living modified organis
4. Taxonomic identification of donor organis
5. Nature of introduced trait
6. Intended date of transfer of living modified organis
7. Quantity of living modified organisms to be transferred in shipment
8. Center of origin of the organism that has been modified
9. Any other information considered relevant by the exporter.

BRAZIL

i. name and full address of the exporter;
ii. name and full address of the importer;
iii. taxonomic identification of the living modified organism;
iv. taxonomic identification of the donor organism;
v. centre of origin of the organism that has been modified and areas with high genetic diversity relevant to the living modified organism;
vi. complete scientific description of the introduced trait, including methodology used for transformation;
vii. physical form of the living modified organism or product thereof;
viii. intended use of the living modified organism or product thereof in the territory of the importing Party;
ix. intended date of transfer of the living modified organism or product; means of transport and point of disembarkation;
x. brief history of the living modified organism or product thereof and its uses in other countries;
xi. quantity of the living modified organism or product thereof to be transferred in shipment; and
xii. any other information considered relevant by the exporter.

CANADA

The notification referred in Article 1(1) regarding LMOs subject to AIA shall include the following:

a) the name of the exporter and importer
b) information about the LMO, including source and characteristics
c) available information about the potential adverse effects of the LMO on the conservation and sustainable use of biological diversity, including within the Party of import;
d) intended use; and,
e) available information about any notification to other governments regarding the import or development of the living modified organism, and the purpose thereof.

COLOMBIA

1. Information relating to the organism.

1.1 Characteristics of the parent organism:

(a) Name or identity of the organism (taxonomic classification, phenotype and genotyp

characteristics);

(b) Pathogenicity, toxicity and allergenicity for humans and, where appropriate, for other species;

(c) Natural habitat and geographical origin of the organism (its distribution and effect on th environment);

(d) Mechanisms used by the organism to survive, to multiply and to spread (in th environment);

(e) Means by which genetic material is transferred to other organisms;

(f) Centres of origin of the organism.

1.2 Vector characteristics:

(a) Name or identity of the organism (taxonomic classification, phenotype and genotyp characteristics);

(b) Pathogenicity, toxicity and allergenicity for hu ans and, where appropriate, for other species;

(c) Natural habitat and geographical origin of the organism (its distribution and effect on th environment?);

(d) Mechanisms used by the organism to survive, to multiply and to spread (in th environment?);

(e) Means by which genetic material is transferred to other organisms;

(f) Mobilization frequency or capacity of the vector to transfer to other organisms;

(g) Factors which could influence the capacity of the vector to establish itself in other hosts;

(h) Current state (complete, partial or disarmed plasmid).

1.3 Characteristics of the host organism:

(a) Name or identity of the organism (taxonomic classification, phenotype and genotyp characteristics);

(b) Pathogenicity, toxicity and allergenicity for humans and, where appropriate, for other species;

(c) Mechanism for survival, persistence and competitiveness and dissemination in th environment and other relevant interactions;

(d) Capacity for transferring genetic material and potential dissemination routes;

(e) Methods for detecting the organism in the environment and for detecting the transfer of donated nucleic acid;

(f) Potential of the organism to affect ecosystem conditions;

(g) Description of the product or products of the gene or genes inserted and, wher appropriate, of the stability of the change;

(h) Activity/manifestation of the insertion.

2. Information relating to the planned use.

2.1 Confined conditions:

(a) The number or quantity of organisms to be used;

(b) The scale of operation;

(c) The proposed confinement measures, including verification and validation of their operation;

(d) Information on the control of wastes;

(e) Information relating to prior uses;

(f) Measures for protection of staff;

(g) Contingency measures;

(h) Description of the biosafety methods and procedures.

2.2 Intended releases:

(a) Purpose and scale of the release;

(b) Description and geographical location of the release;

(c) Method and frequency of the release;

(d) Measures to control wastes;

(e) Information relating to prior uses;

(f) Proximity to sources of water or residential areas;

(g) Contingency plans.

3. Relevant information derived from any previous releases.

4. Risk assessments carried out on the LMOs in question.

5. Name and address of the requesting organization, this being understood to be the individual or body corporate interested in the transboundary movement.

CUBA

INFORMATION REQUIRED IN CASE OF COMMERCIALITY NOTIFICATION.

A) Besides the information specified in Annex II, the following shall be notified in the product commerciality notification:

1. Product name and that of the GMOs it contains.

2. Manufacturer or distributor's name and address in the country of origin.

3. Product specificity, exact product conditions, including, when pertinent, the environmental or geographic zone type for which the product is appropriate.

4. Foreseen use type: industry, agriculture and specialized activities, public consumption in general.

B) Besides the information presented in Item A, the following shall be provided, when pertinent, in conformity with Article s 16 and 18 of the Present Protocol.

1. Measures to be adopted in case of non-intentional release or undue use.

2. Specific introductions or recommendations for storage and handling.

3. Estimate production or importation in the country.

4. Propose packing. It should be adequate so as to avoid non-intentional release of GMOs during storage or further phases.

5. Proposed labeling. It should include, at least summarizedly, the information referred to in Items A.1; A.2; A.3; B.1 and B.2

CUBA

I.- GENERAL INFORMATION.

A.- Name and address of the notifier.
B.- Information on personnel and training.

1- 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;
2- Information on training and qualifications of personnel involved in carrying out the release.

II. INFORMATION RELATING TO THE GMO.

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

1. scientific name;
2. taxonomy;
3. other names(usual name, strain name, cultivar name, etc.);
4. phenotypic and genetic markers;
5. degree of relatedness between donor and recipient or between parental organisms;
6. description of identification and detection techniques;
7. sensitivity, reability (in quantitative terms) and specificity of detection and identification techniques;
8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts;
9. potential for genetic transfer and exchange with other organisms;
10. verification of the genetic stability of the organisms and factors affecting it;
11. pathological, ecological and physiological traits:
a) classification of hazard according to existing rules concerning the protectio n of human health and/or th environment;
b generation time in natural ecosystems, sexual and asexual reproductive cycle;
c) information on survival, including seasonability and the ability to form survival structure e.g.: seeds, spores or sclerotia;
d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possibl vectors, host range including non-target organism. Possible activation of latent viruses (porviruses). Ability to colonize other organisms;
e) antibiotic resistance, and potential use of these antibiotics in human and domestic organisms of prophylaxis and therapy;
f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. nature of indigenous vectors:
a) sequence;

b) frequency of mobilization;
c) specificity;
d) presence of genes which confer resistance.
13. History of previous genetic modifications.

B.- Characteristic 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 GMO and to make the introduced vector and insert function in the GMO;
3 frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;
4. information on the degree to which the vectors is limited to the DNA required to perform the intended function.

C.- Characteristic of the modified organism:

1. Information relating to the genetic modification:
a) methods used for the modification;
b) methods used to construc and introduce the insert(s) into the recipient or to delete a sequence;
c) description of the insert and/or vector construction;
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) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
b) structure and mouth of any vector and/or donor nucleic acid remaining in the final construction of th modified organisms;
c) stability of the organism in terms of genetic traits;
d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;
e) activity of the expressed protein(s);
f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;
g) sensitivity, reability (in quantitative terms) and specificity of detection and identification techniques;
h) history of previous releases or uses of the GMO;
i) health considerations:

- toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;
product hazards;
- comparison of the modified organis to the donor, recipient or (where appropriate) parental organis regarding pathogenicity;
- capacity for colonization;
- if the organism is pathogenic to humans who are immunocompetent:
  - diseases caused and mechanism of pathogenicity including invasivens and virulence,
  - communicability,
  - infective dose,

- host range, possibility of alteration,
- possibility of survival outside of human host,
- 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 deliberated, including e 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 b used for the releases;
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 GMOs at the end the experiment;
11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B.- Information on the environment (both on the site and the wider environment):

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 biotypes or protected areas;
4. size of local population;
5. economic activities of local populations which are based on the natural resource of the area;
6. distance to closest areas protected for drinking water and/or env ironmental purpose;
7. climatic characteristic 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 th environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT.

A.- Characteristic affecting survival, multiplication 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, etc.);
3. sensitivity to specific agents.

B.- Interactions with the environment:

1. predicted habitat of the GMOs;
2. studies of the behavior and characteristics of the GMOs 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 into organisms in affected ecosystems;
b) post-release transfer of genetic material from indigenous organisms to the GMOs;
4. likelihood of post-release selection leading to the expression of unexpected and/or undesirabl e traits in the modified organism;
5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal of genetic material, Methods to verify genetic 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 GMOs could be disseminated.

C. Potential environmental impact:

1. po ential for excessive population increase in the environment;
2. competitive advantage of the GMOs 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 GMOs and the target organism;
5. identification and description of non-target organisms which may be effected unwittingly;
6. likelihood of post-release shifts in biological interactions 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 EMERGENC RESPONSE PLANS.

A. Monitoring techniques:

1. methods for tracking the GMOs, and for monitoring their effects;
2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, wher 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. duration and frequency of the monitoring.

B. Release Control.

1.- Methods and procedures to avoid or minimize the dissemination of GMOs out of the release place or th zone foreseen for their use.
2.- Methods or procedures to protect the already mentioned place from non-authorized people's entrance.
3.- Methods and procedures to prevent other organisms from penetrating in that place.

C. Refuse Treatment.

1.- Type of resume produced.
2. Foreseen refuse volume.
3. Possible risks.
4.- Proposed treatment description.

D. Action plans in case of emergencies.

1. GMO control methods and procedures in case of unexpected dissemination.
2. Decontamination methods for affected zones, for instance, GMO eradication.
3. Elimination or sanitation methods for pl ants, animal soil, etc. exposed to the organisms during dissemination or thereafter.
4. Isolation methods for the zone affected by dissemination.
5. Protection plans for human health and the environment in case an undesirable effect is produced.

INDIA

The exporter of living modified organisms or products thereof shall provide the competent authorities of th States concerned with the following information in order to obtain advance informed agreement:

1. names and addresses of the exporter and the import r
2. a complete risk assessment report on the living modified organism or the product thereof in accordanc with the risk assessment parameters as stated in Annex [ ] of the Protocol.
3. Number or quantity of organisms or products to be transferred or volume of culture and physical for
4. the step reached in the testing and observation of the living modified organism or the product thereof according to the legal or administrative requirements of the State of export
5. the applicable laws, procedures and guidelines of the State of export
6. any requirements to manage risk and to ensure safe handling and use, and methods for safe disposal and appropriate emergency procedures in case of accidents
7. intended dates of transfer
8. intended means of transport
9. information relating to insuranc
10. declaration by the exporter that the information is correct.

NORWAY

a) name and address of exporting company/institution
b) name and address of receiving company/institution
c) origin, name and taxonomic status of recipient organis
d) description of all traits introduced or modified and characteristics of the organis
e) purpose of the genetic modification
f) the risk assessment carried out by the exporter on possible adverse effects on human health and th conservation and sustainable use of biological diversity, including as far as possible the conditions in th 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) intended dates of transfer
h) number of organisms to be transferred or volume or culture and physical stat
i) any relevant requirements to ensure safe handling, storage, subsequent transport and us
j) intended dates of transfer/movement/release/activity
k) methods for safe disposal and contingency plans in case of accidents/unintended movements
l) intended use of the organis
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 labeling of the LMO

PERU

1. The export application should accompanied by documents that indicate:

(a) A clear description of the characteristics of the LMO or product being exported;

(b) Assessment of the risks to human health and the environment that could derive from th importation and use of the organism or product;

(c) The conditions for handling and release of the organism or product;

(d) Data showing the result of other releases carried out in the originating and other countries;

(e) Previous importation clearances or refusals.

2. The competent authority of the importing country shall require the exporter to submit the "note of origin" of the LMO or its derived product, in which information is contained on:

(a) The living modified organism:

(i) Its taxonomy, ecology and reproductive behaviour;

(ii) Information on the gene or genes' donor organism, the gene recipient, the vector organism, the genes introduced including marker genes, the stability of th introduced genes and the risks of transfer of these to other organisms, methods of managing unintended release and methods of use;

(b) The product of living modified organisms: Information on methods of using it, whether it is a novel product or one which occurs in nature, the living modified organism which produced it as referred in (a) above and management methods in case of accidents.

SOUTH AFRICA

1. The Competent Authoritv of the State of export shall supply the following information to the competent authority of the State of Import, prior to the first transfer of LMOs:

i) name and address of exporting company/institution
ii) name and address of recieving company/institution
iii) origin, name and taxonomic status of relevant donor and recipient organisms and characteristics of recipient organisms
iv) centres of origin and diversity
v) description of all traits introduced or modified
vi) purpose of the genetic modification and stability of introduced genetic
vii) material
viii) the result(s) of an appropriate risk assessments carried out, including a summary of risks to human health and the environment
ix) intended dates of transfer
x) number of organisms, or volume and physical state of culture, to betransferred
xi) any relevant requirements to ensure safe handling, storage, subsequent transport and us
xii) methods for safe disposal and suitable procedures in case of accidents
xiii) intended use of the organis
xiv) information on similar previous releases
xv) any differences between the environment of the exporting country and the environment into which th organism is to be released.

SRI LANKA

1. The exporter of LMOs or products thereof shall provide the Competent Authority of the recipient Party with the following information in order to obtain AIA in accordance with Article [ ]:

a) names and addresses of the exporter and the importer;
b) a complete risk assessment report on the LMO or the products thereof in accordance with the risk assessment parameters as stated in Annex [ ] of the Protocol;
c) number, quantity, volume or of organism or products thereof to be transferred and their physical form;
d) the safety standards reached in the testing and observation of the LMO or the products thereof according to the legal or administrative requirements of the Party of export;
e) the applicable laws, procedures, guidelines of the Party of Export;
f) any requirements to manag risks and to ensure safe handling and use, and methods for safe disposal and appropriate emergency procedures in case of accidents;
g) intended dates of transfer;
h) intended means of transport;
i) information relating to insurance, liabilities and compensation;
j) certification by the Competent Authority or the accredited agency of the Party of export that th information provided is correct.

SWITZERLAND

a) name and address of exporting user;
b) name and address of importing user;

c) origin, name and taxonomic status of r cipient organisms;
d) description of the traits introduced or modified and characteristics of the organism;
e) summary of the assessment of risks to human health and the environment;
f) intended dates of transfer;
g) number of organisms to be transferred or volume of culture and physical form;
h) any requirements to ensure safe handling, storage, subsequent transport and use;
i) methods for safe disposal and suitable procedures in case of accidents;
j) intended use of the organism;
k) information on relevant previous releases (reference is made to paragraph 47 of the UNEP Technical Guidelines for Safety in Biotechnology)

UNITED STATES OF AMERICA

1. The notification shall include the following information:

a) the name and address of the importer;
b) the taxonomic name and common name of the recipient organism;
c) a description of the traits modified or introduced including the taxonomic status of the donor organis and the function of the introduced DNA (if known);
d) the characteristics of the LMO;
e) known and available assessments that may have been generated by the regulatory process with respect to the LMO;
f) any relevant requirements to ensure safe storage, transport, and use; and
g) any applicable methods for safe disposal and procedures for accidents.

Annex II

Risk Assessment Parameters

AFRICAN GROUP

The user shall carry out an assessment prior to the use and release of living modified organisms or products thereof 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:

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

    a) Scientific name and taxonomy;
    b) Strain, cultivar or other name;
    c) Species it is related to and degree of relatedness;
    d) The degree of relatedness between the donor and recipient organisms, or between parental organisms;
    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) Description of identification and detection techniques for the organisms, and the sensitivities of these techniques;
    j) Geographic distribution and natural habitats off organisms including information on natural predators, prey, parasites, competitors, symbionats and hosts;
    k) Climatic characteristics of original habitats;
    l) Ability of the organisms to survive and colonise the environment to which release ,is intended or otherwise;
    m) Genetic stability of the organisms, and factors affecting the stability;
    n) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;
    o) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;
    p) Pathogenicity to humans or animals, if any;
    q) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;
    r) Known allogenicity and/or toxicity of biochemical and metabolic products;
    s) 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 c oding 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:

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 n ed 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 th unmodified organism;
j) Probability of vertical or horizontal gene transfer to other species;
k) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;
l) Allogencities, toxicities, pathogenicities and unintended effects;
m) Autecology of the living modified organism compared with that of the unmodified organism;
n) Susceptibility of the living modified organism to diseases and pests compared with th unmodified organism;
o) Detailed information on past uses including results on all experiments leading to previous releases.

4.1 Resuscitated organism:

a) Scientific name and taxonomy;
b) Identity of nearest species and their characteristics which are of relevance to the intended use;
c) Site at which it was found;
d) Methods used for resuscitation;
e) Purpose of introducing the organism and benefits, if any;
f) Impacts on human and animal health and the environment;
g) Measures for encountering adverse impacts;
h) Length of time the organism has been in use;
i) Genetic stability;
j) Likelihood of gene transfer to other organisms;
k) Fossil and living nearest relative species;
l) Biological and biochemical differences from related living species;
m) Information on previous uses since resuscitation.

4.2 DNA sequences from fossils or from resuscitated organisms:

a) Scientific name and taxonomy of the species whether resuscitated or a fossil;
b) Site of origin of the fossil;
c) Site of the gene in the resuscitated genome, if known;
d) Base sequence of the extracted gene;
e) Method used in extracting the gene;
f) Function of the gene, if known;
g) Purpose of use and benefits, if any;
h) Environment in which it lived before fossilisation;
i) Fossil species related to the species from which the gene was taken;
j) Living species related to the species from which the gene was taken.

5. 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:

1. Capacity for colonisation;
2. If the living modified organism is pathogenic to humans or animals the following information is required:
    1. diseases caused and mechanism of pathogenicity, including invasiveness and virulence, and property of virulence;
    2. communicability;
    3. infective dose;
    4. host range and possibilities of alteration;
    5. ability to survive outside of the human or ani al host;
    6. the existence of vectors or other means of transmission;
    7. biological stability;
    8. allergenicity;
    9. availability of appropriate therapies.

6. 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 th 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 biochemical 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.

7. 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 th introduction of the living modified organisms or products thereof;
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.

AUSTRALIA

(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) impact on centres of origin and areas with high genetic diversity relevant to the living modified organism;
(e) risk assessment techniques developed by relevant international organisations.

BELARUS

1. The assessment of the risks associated with a transfer, handling, use and release of LMOs shall b based on

a) The characteristics of the LMO, including:
i. the recipient (host) organism ;
ii. the donor organism(s), vector(s) used;
iii. the genetic structure of DNA insert, encoded trait(s);
iv. the centre of origin of recipient and donor organisms.

b) The intended use, i.e. the specific application of the contained use or deliberate release or placing on th market, including the intended scale.
c) The characteristics of the potential rec iving environment.
d) The socio-economic considerations in the country.
f) ris -benefit analysis of the LMO.

Minimum standards on the risk assessment procedure is described in "UNEP International Technical Guidelines for Safety in Biotechnology".

BRAZIL

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 or product thereof 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 or product thereof on human health;

f) risk assessment techniques developed by relevant international organisations; and

g) details of risk assessments completed elsewhere, as appropriate.

INDIA

The user shall carry out an assessment prior to the use and release of living modified organisms or products thereof 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:

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

a) scientific name and taxonomy;
b) strain, cultivar or other name;
c) species it is related to and degree of relatedness;
d) the degree of relatedness between the donor and recipient organisms, or between the parental organisms;
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) description of identification and detection techniques for the organisms, and the sensitivities of thes techniques;
j) geographic distribution and natural habitats of the organisms including information on natural predators, prey, parasites, competitors, symbionts, and hosts;
k) climatic characteristics of original habitats;
l) ability of the organisms to survive and colonise the environment to which release is intended or otherwise;
m) genetic stability of the organisms, and factors affecting the stability;
n) the presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;
o) the potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;
p) pathogenicity to humans or animals, if any;
q) if pathogenic, their virulence, infectivity, toxicity and modes of transmission;
r) known allogenicity and/or toxicity of biochemcial and metabolic products;
s) availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

2. Characteristics 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 marker gene(s);
c) ability of the vector(s) to mobilise and transfer genes by integration and methods for determining th presence of the vector(s);
d) history of prior genetic manipulation, whether the donor or r cipient 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 organism:

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;
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 method for constructing inserts and to introduce them into the recipient organism;
e) whether introduced gene(s) integrated or extrachromosomal;
f) number of insert(s) and its/their structure(s), for example, the copy number whether in tandem or other types of repeats;
g) product(s) 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 organisms compared with the unmodified organism;
j) probability of vertical or horizontal gene transfer to other species;
k) probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;
l) allogenicities, toxicities, pathogenicitie and unintended effects;
m) autecology of the living modified organism compared with that of the unmodified organism;
n) susceptibility of the living modified organism to discuss and pests compared with the unmodified organism;
o) detailed information on past uses including results on all experiments leading to previous releases.

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

5. 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.

6. 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 th 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) 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) possibl interactions between the living modified organism and other organisms in the ecosystem which might be affected by accidental releases;
g) known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, being a vector of pathogenes, 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.

7. Socio-economic considerations.

MALAYSIA

1. In assessing risk for a proposed release, a multidiciplinary approach is demed necessary.

2. It also requires a team of experts specific to the type of release experiments i.e. a panel reviewing release of transgenci plants may differ in member composition to that reviewing release of organisms for biological control.

3. The different fields of expertise to be considered when selcting an expert panel should include, as appropriate:

a) ecosystem health (soil/water), function of each ecosystem in which the organismn will be released or to which it mught spread
b) soil foodweb interactions
c) nutirient cycling
d) population genetics
e) taxonomy

f) agronomy/seed scienc
g) entomology
h) microbiology
i) marine biology
j) pathology
k) veterinary
l) process engineering
m) food safety
n) social science and economics

4. The objective of a risk asssessment is to enable evaluation of possible harm or likehood of it occuring during a release experiment. Wherever possible, information should cover expected probabilities of events occuring and the magnitude of their effects.

5. For contained uses, parameters of assessment can include:

a) number or volume of organisms to be used
b) sclae of the operation
c) levels of containment
d) procedure for waste management
e) procedure for accidents and unexpected events
f) information from previous relevant uses where appropriat

6. Release experiments of transgenic plants: Apart form the general principles, other specific factors that should be taken into consideration can include:

a) size of release (strat with small scale release prior to large scale field trials and production);
b) effects of transgenic products (primary and secondary) on pollinators and where possible non-target organisms (Assessment of risk on pollinators should be considred for new crop traits on a cas -by-case basis);
c) effects of secondary transfer of transgenic to wild relatives (assessment depends on the propensity of th transgenic plant or interfertile relative to become weeds in an agricultural system);
d) transfer by hybridization and introgression of transgenes from crops to wild-type species (assessment should include data on the probability of introgression into casual populations).

7. Release experiments of transgenic animals: Apart from the general principles, other specific factors that should be taken into conisderation can include:

a) effect of the modified trait on physiological behaviour and reproduction of the transgenic animal;
b) possibility of the inserted sequence to cross hybridize with feral population and subsequent effect on agriculture and the environment;
c) if the organism is to be consumed as food or for animal feed, assessment should include production of new metabolities or toxins that may be hazardous to other organisms within the release ecological habitat at the site of release;
d) potential transmission of genetic material from GMOs to other species by means other than reproduction;
e) movement of GMOs into other ecological systems.

8. Release of GMOs for biological control: Apart from compliance with the general principles, othe 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.

9. Release experiment of GMO for bioremediati on: 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.

NORWAY

INFORMATION RELATING TO THE LMO:

Characteristics of the organism from which the LMO is derive :

1. The relevant biological, physiological and genetic and environmental characteristics of th recipient/parental/host organism include, as appropriate:

a) the name and identity of the organism;
b) pathogenicity, toxicity and allergenicity (in the case of micro-organisms, it should be noted that there ar internationally accepted classification lists for human pathogens. Similar lists exist at national level for plant and animal pathogens in some countries);
c) the natural habitat and the geographic origin of the organism, its distribution and its role in th environment;
d) mechanisms by which the organism survives, multiplies and disseminates in the environment;
e) means for transfer of genetic material to other organisms.

Characteristics of the organism(s) from which nucleic acids are obtained (the donor):

1. The relevant characteristics include, in particular, pathogenicity, toxicity and allergenicity.

Characteristics of the vector:

a) identity, origin, natural habitat, and the relevant safety characteristics of the vector;
b) the frequency at which the vector is mobilised or can transfer itself to other organisms;
c) factors which would influence the ability of the vector to become established in other hosts.

Characteristics of the inserted (the insert) or deleted nucleic acid:

a) functions coded by the inserted or deleted nucleic acid, including any residual vector;
b) information on the expression of the inserted or deleted nucl ic acid and the activity of the gen product(s).

Characteristics of the LMO:

1. The LMO should be compared with the organism from which it is derived, examining, wher relevant the following points:

a) pathogenecity, toxicity and allergenicity to humans and other organisms (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);
b) survival, persistence, competitive abilities and dissemination in the environment or other relevant interactions;
c) capacity to transfer genetic material and the ways in which this might occur;
d) methods for detecting the organism in the environment and for detecting the transfer of the donated nucleic acid;
e) functions which might affect its ecological range;
f) characterisation of the product(s) of the inserted gene(s) and, where appropriate, the stability of th modification.

INFORMATION RELATING TO THE INTENDED USE

1. The amount of information required will vary with the characteristics of the organism and the intended use, frequency and the scale of the use. In the context of biosafety it is also relevant to compere th intended use of the LMO with traditional use of similar not modified organisms to detect whether new use, in new geographical or climatic regions, changed farming, forestry or aquaculture practice etc. will have any possible effect on biodiversity.

2. For contained uses, this shall include:

a) number or volume of organisms to be used;
b) scale of the operation;
c) proposed containment measures, including verification of their functioning;
d) training and supervision of personnel carrying out the work;
e) plans for waste management;
f) plans for safety of the health of personnel;
g) plans for handling accidents and unexpected events;
h) relevant information from previous uses.

3. For deliberate releases, this shall include:

a) purpose and scale of the release;
b) geographical description and location of the release;
c) proximity to residences and human activities;
d) method and frequency of release;
e) training and supervision of personnel carrying out the work;
f) likelihood of transboundary movement;
g) time and duration of the release;
h) expected environmental conditions during the release;
i) proposed risk-management measures including verification of their functioning;
j) subsequent treatment of the site and plans for waste management;
k) plans for handling accidents and unexpected events/disasters;

l) relevant information from any previous releases.
m) new or changed use or practice compared to similar not modified organisms;
n) long-term and secondary effects on conservation and sustainable use of biological diversity or human health

CHARACTERISTICS OF THE POTENTIAL RECEIVING ENVIRONMENT

1. The potential for an organism to cause harm is related to the environments into which it may b released, its interaction with other organisms and its intended or unintended use. Relevant information shall include:

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

PERU

1. The competent authority for this purpose shall:

(a) Request the exporter and the person responsible for the intended release to provid information in respect of the type of organism or product to be imported and which is specified in th corresponding annex.

(b) Consult other public and private institutions or persons qualified in the field regarding th risk attached to the proposed releas .

(c) Facilitate public access to information about the proposed deliberate release.

(d) Carry out as many tests and inspections as may be necessary.

(e) Require observation of the LMO at least during a period proportional to its vital cycle or reproductive period, before it is used as planned.

SRI LANKA

1. Characteristics of the living modified organism and its parental organisms:

i. scientific name and taxonomy including strain, cultivar or variety;
ii. 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;
iii. the description of the modifications made and traits introduced including methods using gen technology;
iv. the function of the genetic modifications and/or the new insert, including any marker genes;
v. purpose of the modification and intended use in relation to need or benefit;
vi. whether introduced genes integrated or extrachromosomal;
vii. number of inserts and other structures, for example, the copy number whether in tandem or other types of repeats;
viii. products of the transferred genes, levels of expression and methods for measuring expression;
ix. stability of the introduced genes in terms of expression and integration;
x. biochemical and metabolic differences of the LMO compared with those of the unmodified organisms;
xi. nature, host range and the genetic stability of the vectors used;
xii. probability of vertical or horizontal gene transfer to other species including wild and naturalised relatives;
xiii. probability of inserts or transferred genes to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;
xiv. allogenicities, toxicities, pathogenicities and any unintended effects;
xv. if pathogenic, their virulence, infectivity, invasiveness, toxicity and mode of transmission;
xvi. host range of the LMO and mutability;
xvii. ability to survive outside the human and animal hosts, any secondary hosts, resting and survival stages;
xviii. information on appropriate therapies against pathogenicity, allergenicity and toxicity;
xix. Autecology of the LMO compared with that of the unmodified organism;
xx. susceptibility of the LMO to diseases and pests as compared to that of the unmodified organism;
xxi. detailed information on past uses including results on all experiments leading to previous releases;
xxii. ability of the organism to survive and colonise the environment to which release in intended or otherwise.

2. Environmental Considerations: Information on the LMO, the donor and recipient organisms as well as the vectors in relation to:

i. factors affecting the survival, reproduction and spread of the LMO in the environment;
ii. available techniques for detection, identification and monitoring of the LMO and transmission of genes from the LMO to other organisms;
iii. known and predicted habitats/ecosystems of the LMO;
iv. possible interactions between the LMO and other organisms in the ecosystem which might be affected by accidental release;
v. possible involvement in biogeochemical processes;
vi. effects on agriculture, th environment and human and animal health;
vii. proposed risk management measures including verification of their functioning and availability of methods for decontamination of the landscape in case of accidental releases;
viii. scale, method, frequency, time and duration of release;
ix. likelihood of transboundary movement.

3. Socio-economic Considerations:

i. possible threats to biological diversity, traditional farming and indigenous technologies and sustainabl agriculture;
ii. possible effects which are antagonistic to the social, cultural, ethical and religious values of communities from the use or release of the LMO or products thereof.

ANNEX III

RISK MANAGEMENT SCHEMES

AFRICAN GROUP

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.

1..Imported products of living modified organisms used for human or animal health (e.g. antibodies, drugs and hormon s):

a) Observation to ensure that changes in food habitats, 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 living modified organism for human and animal health:

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

3. Imported living modified organism for contained use:

a) The products of living modified organisms will be treated as in 1;
b) Experiments will be made in complete laboratory containment to determine : (i) longevity of th living modified organism in cases of unintended release in the premises and in the surrounding environment, and (ii) genetic transfer into other micro-organism and implications thereof on human and animal health and the environment.
c) Methods for counteracting adverse impacts resulting from unintended releases should b specified.

4. Products of living modified organisms made locally:

a) Trial on experimental animals will be made when the product of the living modified organism is intended to be used on humans;
b) In all other cases, trials will be made on species for which the product of the living modified organism has been designed.

5. Living 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 th vector introduced or of other genes through the agency of the vector to the living modified organism or to other species which will be found in association with the living modified

organism to ensure that virulence is not acquired by the living 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 living modified organism has been made;
e) Statistically valid trials in conditions in which the vaccinated individuals live in their communities.

6. Imported plant or microbial living modified organis for release:

a) The reports from releases in areas other then the State of import shall be thoroughly evaluated by the national Biosafety Committee. Particular emphasis shall be given to whether th 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 hav 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 living modified organism, the health of th organism within the area of limited release, the biological diversity and the ecology of the area;
e) Nationally approved limited filed releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

7. Imported animal living 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 th 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 gen 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 living 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 living modified organism, when required, will b carried out in complete containment;
c) Observations aimed at understanding the nature of the living modified organism, shall b carried out in complete containment;
d) Experiments with the soil, soil micro-organism, plant and animal species, under th environmental conditions of the area of intended release, will be carried out in complet containment;
e) Complete observations of the interactions of the living 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 living modified micro-organisms may be used on an experimental basis, otherwise they shall be destroyed;

f) The product from the living 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 living 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 living modified organisms or its successor shall provide annual reports to the competent authority.

9. Animal living 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 an observations on the living modified organism will be carried out under complete containment;
d) The living 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 trnasgeneic animal and those of its micro-organisms especially in the context of gene transfer and those of th 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 living modified organisms, its micro-organisms focusing on gene transfer, and the ecology of th microbial, plant and animal communities in the area, again inclkud8ing gene transfer;
f) If the animal is intended to yield a product, the regulation of the product will follow th procedure in item 4;
g) The monitoring of the spread and behaviour of any released animal living modified organis 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 organism carried out under completely contained laboratory conditions and continuing in th development of living modified organisms or products thereof 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 imported living modified organism or products thereof shall be subject to approval by the National Biosafety Committee. All final approval for the use of living modified organisms or products thereof 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 living modified organisms in question or th product thereof 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 living modified organism or the product thereof 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 living modified organism or products thereof shall be monitored appropriately and emergency plans to prevent escape and accident shall always be in place.

INDIA

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.

1. Imported products of living modified organisms used for human or animal health (e.g. antibodies, drugs and hormones):

a) observation to ensure that changes in food habitats, nutrition and other factors that could conceivabl 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 human or animals, as appropriate, in areas other than the State of import.

2. Imported microbial living 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, sinc some spilling is inevitable.

3. Imported living modified organisms for contained us :

a) the products of living modified organis s shall be treated as in 1;
b) experiments will be made in complete laboratory containment to determine: (i) longevity of the living 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;
c) methods for counteracting adverse impacts resulting from unintended releases should be specified.

4. Imported plant or microbial living modified organis for releas :

a) the reports from releases in areas other than the State of import shall be thoroughly evaluated by a designated authority. Particular emphasis shall be given to whether the applicable regulations in th previous release have been adequate to ensure safety;
b) if it is decided that the previous release mechanisms have been rigorous enough, observations shall b 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;
c) the observations will include the health of the living modified organism, the health of the organis within the area of limited release, and the biological diversity and the ecology of the area;
d) nationally approved limited field releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

5. Imported animal living modified organism for release:

a) the reports from releases in areas other than the State of import shall be thoroughly evaluated by a designated authority. Particular emphasis shall be given to whether the applicable regulations in th previous release have been adequate to ensure safety;
b) if it is decided that the regulations used in the previous release have been rigorous enough, then observations shall be made in complete containment in the expected ambient climatic, nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers;
c) when the results have met the stated requirements, then a trial release may be authorised with adequat emergency plans put in place to deal with cases of escape.

6. General requirements:

a) All trials, experiments or observations specified in all the above cases (1-5) 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.

b) Once approval from the appropriate designated authority is obtained at the completion of the final stag of the trials, experiments or observations, the living modified organism in question or the product thereof can be employed for its intended use. The appropriate designated authority shall notify its decision in writing to the competent authority.

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

d) The release of living modified organisms or products thereof shall be monitored, appropriate and emergency plans to prevent escape and accident shall always be in place.

NORWAY

General Precautions

1. Appropriate information and training is provided for those involved in handling the organisms;
2. Monitoring procedures are applied in such a way that appropriate measures can be taken in case of unexpected effects during or after the release;
3. The dissemination of the released organisms and/or gene flow from the released organisms ar controlled;
4. Controlling access to the release site.

For Plants

1. Applying reproductive isolation, by:

    1. spatial separation;
    2. temporal separation: use of plants that will flower either earlier or later than plants of nearby reproductively compatible species;
    3. biological prevention of flowering (e.g. by omitting vernalisation);
    4. removal of the male or female reproductive structures;
    5. bagging of flowers
    6. making use of sterility.

2. Controlling the persistence or reproductive structures structures such as propagules or seeds.
3. Destroying volunteer plants after harvest; control of volunteers nay be necessary during longer periods, depending on the species.

For Animals

1. Confining by appropriate means such as fences, filters, islands, ponds;
2. Applying reproductive isolation by using sterile animals;
3. Isolation from feral animals of the same species.
4. Controlling the persistence or dispersal of reproductive structures such as larvae or eggs.

For micro-organisms

1. Using organisms with impaired ability to grow or persist in the environment;
2. Minimising gene transfer by:
    1. Using organisms that do not contain known self-transmissible mobilizable or transposabl genetic elements;
    2. ensuring that introduced traits are stably located on the chromosome.

3. 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

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

AFRICAN GROUP

Collect and disseminate to parties information concerning:

1. the development, use and transfer of living modified organisms and products thereof;
2. methodologies, techniques, experts, equipment, materials, available results of research relating to the response to unintended releases of living modified organisms and which could be used in the event of accidents or emergencies.

AUSTRALIA

1. Collect and disseminate to parties information concerning

a) all living modified organisms which have been subject to bans or restrictions in that Party;

b) all risk assessments and import decisions relating to living modified organisms, including the relevant timeframes;

c) national risk management procedures for use and handling of living modified organisms;

d) any unintentional transboundary movements of living modified organisms, and;

e) any unintentional domestic releases of living modified organisms which could result in unintentional transboundary movements of living modified organisms.

BELARUS

1. The Parties shall facilitate and encourage the collection and exchange of information relevant to th implementation of this Protocol. This information shall includ *inter alia*:

a) designations of competent authorities/focal points and changes in such designations;
b) national requirements/legislation, frameworks and guidelines on biosafety;
c) national decisions/reviews about LMOs contained uses, releases, marketing and transboundary transfers;
d) general matters relevant to risk assessment/ anagement associated with LMOs;
e) information on accidental/unintentional movements of LMOs and biosafety measures implemented in that cases;
f) list of national experts, advisory bodies, training workshops/programmes;
g) other relevant information.

BRAZIL

1. Parties shall make available to the Clearing House information *inter alia* on:

a) national risk management procedures for use and handling of living modified organisms and products thereof;
b) national institutional framework for monitoring and compliance within their territories;
c) all risk assessments and import decisions relating to living modified organisms and products thereof, including the relevant timeframes;
d) all living modified organisms and products thereof which have been subject to bans or restrictions by that Party;
e) any unintentional transboundary movements of living modified organisms;
f) any unintentional domestic releases of living modified organisms which could result in unintentional transboundary movements of living modified organisms; and
g) any incidents of uninformed, unauthorized or otherwise illicit transboundary movements of living modified organisms or products thereof.

CANADA

Reporting for Risk Assessment and Management

1. The Party of import shall provide to the clearing-house mechanism in a timely fashion notice of each allowance or prohibition made under Article 2, including any conditions forming part of the decision, and the reasons provided under Article 2.3.

Parties will also provid

a) information to assist other Parties in decision-making under the Protocol with respect to its national laws, regulations, guidelines, codes of practice and administrative procedures for th safe transfer, handling and use of living modified organisms;

b) any other information regarding living modified organisms that the Party considers would be of benefit to other Parties and to the public, including information with respect to risk assessment and management, and other scientific information; and,

c) 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.

COLOMBIA

1. This mechanism shall include, ~~inter alia~~, the following information:

(a) Information on measures adopted by the national legislation of the countries;

(b) Information on decisions adopted by the countries with regard to transboundary movement of LMOs;

(c) Information on accidental or unintended movements of LMOs, including contingency or mitigation plans to be used in such event;

(d) Information relating to the appropriate assessment and management of risks;

(e) Information on the implementation of the PIC procedure, including simplified procedures and bilateral, multilateral and regional agreements;

(f) Updated information on the designated national authorities for the purposes of this Protocol.

EUROPEAN COMMUNITY

Information Exchang

1. relevant data of designated competent authorities and focal points;
2. the text of any decision on a notification of an intentional transboundary movement and th summary of the risk assessment;
3. a summary of any notified unintentional transboundary movements which are likely to hav significant adverse effects in another Party or non-Party on the conservation and sustainable use of biological diversity, taking also into account risks to human health;
4. the text of decisions taken pursuant to Article ( ) [safeguard clause];
5. general description of products consisting of or containing LMOs having received consent by a Party or Parties for placing on the market;
6. information concerning its biosafety regulatory framework on LMOs;
7. a summary of any methods and plans for monitoring of LMOs

JAPAN

I. Information to be submitted ot the Secretariat of the Protocol

1. The Contracting Parties shall provide the Secretariat of the Protocol with the following information:

(a) National regulatory framework for the implementation of the Protocol, including:
(i) names, addresses and telecommunication numbers of the national focal point and the competent authorities;
(ii) national guidelines and/or regulations for the implementation of the Protocol, including information required for the AIA procedures and for risk assessment
(iii) if any bilateral, regional and multinational agreements or arrangements as well as unilateral declarations on the exemption and/or the simplification of the AIA procedures.

(b) Periodical report on the implementation of the AIA procedures, including statistics.

MADAGASCAR

1. The biosafety clearing-house shall assist Parties on an as-required basis including in the following:

a) Preparing and processing risk assessment reports and impacts studies relating to human and animal health, the environment, biological diversity and social and economic welfare by providing scientific and technical data on LMOs and on the potential risks of their introduction;

b) Supporting the drafting of legislative texts;

c) Providing assistance in emergencies;

d) Developing programmes and procedures for risk management;

e) Preparing minimum standards;

f) Preparing advanced informed agreement documents;

g) Settling disputes between Parties.

NORWAY

1. Each Party shall provide information to the Secretariat for inclusion in the Database of:

    a) designated competent authority/ies and focal point
    b) information about national legislation for the implementation of the Protocol
    c) decisions made under the AIA procedure and related risk assessments
    d) declarations on simple notifications with regard to subsequent movements of LMOs
    e) information on research and co-operation in biotechnology
    f) the amount of LMOs exported, category, characteristics, states of import etc.
    g) information on accidental/unintended movements
    h) any other relevant information.

PERU

1. The competent national authority or the national focal point or the regional focal point, if there is one, shall be responsible for coordinating information related to:

    (a) Development, use and transfer of LMOs or products derived from them;

    (b) Methodologies, techniques, experts, equipment, materials and results of research related to the response to unintended releases of LMOs, to be used in the case of accidents or emergency situations;

    (c) Release of LMOs to the market;

    (d) Information on national laws of the country parties;

    (e) Information referring to transboundary movements of LMOs;

(f) Information on mechanisms adopted by the parties for the implementation of the protocol;

(g) Information on the available statistics regarding the effects of the release of LMOs on human health and the environment;

(h) Information on decisions taken by the country parties in relation to the movements of living modified organisms;

(i) Information on domestic releases of LMOs;

(j) Information on banned, approved and recently developed LMOs;

(k) Information on post-commercial monitoring of LMO release;

(l) A list of experts in biosafety.

SRI LANKA

Information that could be shared
a) information relevant to proper risk assessment and risk management;
b) information on accidental/unintentional movement of LMOs which have adverse impact on th environment and human health;
c) information on LMOs released on the market;
d) information on national legislation in countries;
e) information regarding transboundary movement of LMOs;
f) the number of LMOs exported/imported, categories, characteristics, etc.;
g) information available on effects on human health and environment;
h) information on decisions taken by countries in relation to movement of LMOs;
i) information on codes of practice and guidelines related to the transboundary movement of LMOs;
j) information on the implementation of the AI
k) information on domestic releases of LMOs;
l) information on prohibited, approved and newly developed LMOs;
m) information on monitoring post-commercial release of LMOs;
n) lists of experts and training workshops/programmes;
o) lists of advisory bodies.

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