A MANUAL ON TRANSBOUNDARY MOVEMENT OF GMO'S INTO UGANDA

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For NFRD

Meaning of terms in this manual

For the purpose of this manual and unless the context otherwise indicates:

"organism" shall mean any biological entity, including micro-organisms, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;

"Genetically modified organism" (GMO) shall mean an organism, including micro-organisms, in which the genetic material has been altered by means of in vitro culture and/or recombinant nucleic acid technology in a way that does not occur naturally;

“authorisation” shall mean the authorisation, in writing, of an activity involving LMO(s) by the National Biosafety Committee;

“application” shall mean the appropriate presentation of the requisite information, as specified in respective regulations, to the National Biosafety Committee, for the authorisation of respective activities involving GMO(s);

"applicant" shall mean any natural or legal person, nominated within a public or private institution or company, submitting the application to the National Biosafety Committee;

“import” shall mean the intentional transboundary movement of GMO(s) into the territory of Namibia, for a purpose to be specified;

“export” shall mean the intentional transboundary movement of GMO(s) out of the territory of Uganda, for a purpose to be specified;

“transit” shall mean the intentional transboundary movement of GMO(s) through the territory of Uganda, avoiding any intentional release, use, disposal or handling of GMO(s) within Uganda;

“spillage” shall mean any unintentional release of GMOs during transport through or into the territory of Uganda;

“transport supervisor” shall mean the person directly responsible for all operations directly associated with the transport and transit of GMO(s);

Preface

The development and production *of* GMO's and their products from developed countries is not only rapidly increasing but they are already starting to move over national territories for trading. Some of the recipient countries for these products do not have adequate measures to protect them form the potential adverse effects *of* GMO's to the environment and the human health. For the prevention *of* such potential risks the international society has exerted many efforts to prepare measures to mitigate possible negative impacts. The most representative of these measures is found the 'The Cartagena Protocol on Biosafety (hereinafter "Protocol")' that was adopted in January of 2000.

The Cartagena Protocol on Biosafety is an international agreement that aims to contribute to the safe transport, handling and use of living modified organisms (GMO'S) derived from modem biotechnology. It attempts to achieve a balance between the free flow of goods in international trade and the conservation and sustainable use of biological diversity, by regulating the movement of GMO's from one country to another.

The *Biosafety Protocol* reflects growing public concerns about the potential risks of biotechnology. While many countries with modern biotechnology industries do have domestic legislation, there were previously no binding agreements to address GMO's that cross national borders because of trade or accidental releases. The aim of the Protocol is to ensure that companies receiving shipments have both the opportunity and the capacity to assess the risks attached to products of modern biotechnology.

Under the Protocol, exporters are required to label GMO's intended for introduction into the environment and to indicate that they "may contain living modified organisms". Moreover, countries are conferred with the right to restrict the import of GMO foods, and the decision is left up to each importing country. The government of Uganda is expected to indicate whether or not it is willing to accept imports of agricultural commodities that include GMO's by communicating their decision to the world community via an Internet-based Biosafety Clearing House (BCH).

The establishment of biosafety protocol has increased pressure on Uganda to formulate guidelines and build capacity to regulate development and transboundary movement of GMOs. As a signatory to the Protocol, Uganda has taken preliminary steps to implement the protocol. It has designated a national focal point and competent authority and established the National Biosafety Committee (NBC). Much preparatory work is under way to ensure that mechanisms and instruments are in place for implementation of the Protocol and this manual is an attempt to do this.

This manual is one such attempt and is aimed at offering guidance towards the effective operationalisation of the established regulatory and administrative system to enable adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (GMO's) resulting from modern biotechnology, with a specific focus on transboundary movements in Uganda and meet the obligation foreseen under the Cartagena Protocol.

INTRODUCTION

The Cartagena Protocol is the global legal instrument for the regulation of transboundary movement, handling and use of so called 'Living Modified Organisms' (LMO's). The term GMO's which is used in this manual has the same meaning as the term LMO. Other terms, such as 'transgenic organisms', 'genetically engineered organisms', 'organisms with novel traits', which are commonly used in various parts of the world and in various regulatory systems, basically have the same meaning as well.

In case of a transboundary movement of GMO's, which are intended for *an* intentional introduction into the environment in the importing country, a so called' Advance Informed Agreement' (AIA)-Procedure has to be followed, which allows the importing country to undertake a full risk assessment and make a decision on the basis of a notification which has to include the relevant data.

GMO's which are intended for direct use such as food, feed or for processing in Uganda (GMO'S-FFPs), or which are basically agricultural commodities including GMO's, may be subject to a somewhat lighter procedure: If Uganda approves GMO'S-FFPs, and they are going to be exported, it has to notify this to Biosafety Clearing House (BCH) which is a global information exchange mechanism for biosafety. It is designed as a powerful internet-based system with a central component at the Secretariat of the CBD (which is the Secretariat to the Cartagena Protocol as well) and decentralised components (in the Parties).

Transboundary movement

In its traditional sense the term transboundary movement means "any movement of hazardous wastes or other wastes from an area under the national jurisdiction of one State [meaning "any land, marine area or airspace within which a State exercises administrative and regulatory responsibility in accordance with international law in regard to the protection of human health or the environment"] to or through an area under the national jurisdiction of any State, provided at least two States are involved in the movement." (1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, and 1991 Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Waste Within Africa).

Transboundary movement of GMO's therefore, means the movement of a living modified organism from one party to another, however, transboundary movements extends to movement between parties and non-parties to the Cartagena Protocol.

Uganda is richly endowment of resources. The country has a great variety of landscape and vegetation. There are semi arid areas in the Southwest and northeast and rain forests in the west and some parts of the central. The remainder of the landscape is savanna and swamps. The country is also rich in wild life, which inhabits six national parks, 12 game reserves 14 controlled hunting areas and 8 game sanctuaries. Ten major forest reserves are also wildlife protection areas. The above information has important impacts for biosafety considerations that the country has to adopt. Uganda's proximity to the Vavilonian centre where several crop origins in Ethiopia makes the risks posed by genetic engineering to the biodiversity of crops very real. On the other hand the favourable climate and weather regimes in Uganda make invasion by alien species very easy. As a landlocked country, issues of transboundary movement of GMO's will be very crucial and therefore, the issue of the AIA needs to be internalised by policy makers and implementers. Against this background, there is a growing population, which has exerted a lot of pressure on land resources. Consequently, government has adopted decentralization, privatisation, and trade liberalization as key policies for socio-economic development. Government programmes like the PMA are emphasizing modernization of Agriculture where Government is also pushing for increased food production through biotechnology. Biotechnological research on Bananas and cassava is being undertaken in collaboration local institutions and partner institutions developed countries to ensure national food security and poverty eradication.

Many countries, particularly developed countries, have legislation regulating various aspects of genetically modified organisms. Although the Cartagena Protocol addresses the issue of transboundary movement of GMO's between parties to the protocol, there are no binding agreements that regulate movement of GMO's across national borders especially for movement between parties and non-parties to the Cartagena Protocol.

Importation of GMO's resulting from modern biotechnology into a country is generally considered within the scope of the provisions regulating the release of GMO's into a country's environment. In most countries, national biosafety regulations apply to locally produced GMO's to be released within a country's environment and to imported ones. These requirements include the need for a permit, authorisation or

consent for the introduction of GMO's. Thus both local manufacturers and importers of GMO's are also subject to other regulatory provisions regarding inter alia site inspection, accidents, liability, offences and penalties.

The Biosafety Protocol negotiated under the auspices of the Convention on Biological Diversity aimed at regulating the transboundary movement, handling and use of GMO's derived from modem biotechnology that may have an impact on conservation and the sustainable use of biodiversity. The development of a Biosafety Protocol was driven by the recognition that biotechnology, although potentially beneficial, raises concern that the new genetic combinations derived from modem biotechnology could manifest themselves in ways that could be risky to the environment.

Uganda was an active participant in these negotiations, which were concluded in January 2000 in Montreal.

1. Scope of this manual

The manual provides guidance to those rules that apply to the "transboundary movement, transit, handling and use of all GMOs that may have adverse effects on conservation and sustainable use of biological diversity in Uganda. *Just like in* article 5 of the *protocol this manual does not cover products derived from GMOs nor pharmaceuticals for humans, these are addressed by other relevant international agreements. Also as derived from article 6 of the Protocol, this manual does not cover* GMOs destined for contained use. The relevant articles of the Cartagena relating to TBM of GMOs into Uganda which is covered by this manual include:

- Article 5 Exemptions from the protocol of TBM of certain pharmaceuticals for human use
- Article 6 Exemptions from AIA procedure of transit TBM and TBM of GMOs destined for contained use
- *Article 7 Application of the AIA procedure*
- Article 8 Notifications
- Article 9 Acknowledgement of receipt
- Article 10 Decision procedures
- Article 11(4)-(9) Procedure for GMOs intended for use as food /feed/ processing
- Article 12 Review of decisions
- Article 12 Simplified procedure
- Article 14 Bilateral/regional/multilateral agreements/ arrangements on TBM
- Article 15 (2),(3) Risk assessments for TBM
- Article 17 Unintentional TBM
- Article 18 (1), (2) Handling, transport, [packaging and identication of GMO for TBM

- Article 21(1), (2), (4)-(6) Confidential information
- Article 24 (1) TBM with non parties
- Article 25 Illegal TBM

2. Application of the AIA procedure in the TBM

Advance informed agreement requires that before the first initial transboundary movement of GMOs into Uganda, that Uganda:

- is notified of the proposed TBM
- receives information about the GMO and its proposed use;
- is given an opportunity to decide whether or not to allow the import of the GMO and upon what conditions (if any).

1. It is a requirement of the national biosafety regulations that application for authorisation of transport and transit of GMO(s) be subjected to the AIA procedure. This procedure requires that all applications for TBM of GMOS reveal:

- General information including full addresses of the applicant, information on the port of entry, route of transport, date and duration of transport.
- Name and address of the transport supervisor;
- Name, address and contact of the party sending the transport, conducting the transport and accepting the transport,
- Contact address of the responsible regulatory authorities outside Uganda, if applicable,
- Date of transport and port of entry,
- Route and temporal and spatial details of the transport,
- Volume, weight or number of GMO(s),
- Vehicle(s) used for transport and proposed packaging and labelling;

2. A technical dossier providing detailed information on the transport, whether in transit or destined to Uganda including:
   - Details on the GMO(s) to be transported, including packaging;
   - A description of the conditions of transport and containment, i.e. vehicle, volume or quantity;
   - Details on measures foreseen in order to prevent unintentional release of the GMO(s) into the environment;
   - Details on measures or methods for unique identification, including labelling and accompanying documents.

3. A technical dossier providing information on:
   - the GMO(s), including details on purpose, genetic modification and a short assessment of potential risks if unintentionally released within Uganda,
   - respective references and original papers on assessments carried out, recommendations made or conditions imposed by another regulatory authority,
   - measures and strategies envisaged or established in order to prevent any unintentional release of the GMO(s) into the environment during transport and transit;
   - instructions on handling, transport, labelling and proposed use of the GMO(s);
   - instructions on measures to be taken in case of spillage;
   - a certified procedure and technique, allowing the effective, reliable and unique identification of the GMO, including an indication of limitations and costs.

4. A summary, containing all relevant information on the GMO(s) with respect to the risk assessment and respective recommendations made, or conditions imposed by, the relevant regulatory authority of the country of export.

3. Notification of a TBM

In accordance with Article 8 of the Cartagena protocol which addresses and accords guidance on this first step in the AIA procedure. Accordingly, the applicantor exporter has the legal obligation to ensure that Uganda receives notification of the proposed TBM of the GMO.

The notification is made in hard and electronic copies to the Executive Secretary
Uganda National Council for Science and Technology which is the competent authority at the following address:

The Executive Secretary
Uganda National Council for Science and Technology
P.O Box 6884
Kampala
Uganda
Tel: 256 41 250499
Fax: 256 41 234579
Email: uncst@starcom.co.ug

The notification must contain at a minimum, the information specified in annex 1 of the protocol. This information is also a legal requirement under the biosafety regulations of Uganda.

4. Acknowledgement of receipt of a notification of a TBM

In accordance with article 9 of the Cartagena Protocol the Executive Secretary of the UNCST is required to acknowledge receipt of a notification in writing to the notifier within 90 days of its receipt. The acknowledgement will state:

- The date of receipt of the TBM application.
- Whether the notification contains the information referred to in article 8.
- Whether or not UNCST will proceed according to the domestic regulatory framework.
- Next steps after the notification

It is important to note that if UNCST fails to acknowledge receipt of a notification within the 90-day deadline its consent to the proposed TBM will not be implied.

5. Decision procedure of a TBM

In accordance with article 10 of the Cartagena Protocol the Competent Authority at UNCST is required to take a decision notification in writing to the notifier within a maximum of 270 days of its receipt of the notification to:

- Approve the first transboundary movement of a GMO through the territory of Uganda with or without conditions.
- Prohibit the import;
- Request additional relevant information
- Inform the notifier that the period of 270 days is extended by a defined period of time.

6. Procedure for GMO TBMs intended for use as food/feed/processing

Article 11(4)-(9) spells out obligations for Uganda that are for GMOs intended for use as food/feed/processing. Accordingly, Uganda has several options:

- In accordance with subarticle 4, of the CBP, Uganda may take a decision on an import of a GMO intended for use as food/feed/processing in accordance with its regulations;

- In accordance with subarticle 5 of the CBP, Uganda may make available to the BCH copies of its national laws, regulations and guidelines applicable to the import of GMO intended for use as food/feed/processing in accordance with its regulations

- In accordance with subarticle 7 of the CBP, Uganda may declare that its failure to make a decision does not imply its consent or refusal to the import of a GMO intended for use as food/feed/processing.

- In accordance with subarticle 9 of the CBP, Uganda may indicate its needs for financial or technical assistance and capacity building with respect to GMOs intended for use as food/feed/processing.

7. Review of decisions of a TBM

In accordance with Article 12, the changing state of knowledge about a given GMO and its potential impacts on biological diversity and human health may influnce a decision being taken. It provides for the review on decisions on imports, of GMOS in light of new information or circumstances. The review of such a decision can be initiate d by:

- Party of import (Uganda)
- Party of export
- Notifier

8. Simplified procedure of a TBM

The Competent Authority may provided that adequate measures are applied to ensure the safe intentional transboundary movement of GMOs utilize Article 13 of the CBP which obliges parties to:

- Approve and inform BCH of intentional transboundary movement of GMO at the same time as the movement is notified to the Competent Authority
- Inform the BCH of imports that are exempted from the AIA

9. Bilateral/regional/multilateral agreements/arrangements on TBM

Situations will arise where Uganda and other part(y) ies to the protocol may conclude or intend to conclude an agreement or arrangement on the TBM of a GMO that is more specific than the protocol and addresses the issues in more detail and is adjusted to he countries particular situation or needs. This is addressed in Article 14 of the CBP. Under these circumstances, such arrangements and agreements must be :

- Consistent with the objectives of the Protocol.
- Should not result in inm a lower level of protection than that provided by the Protocol.

10. Risk assessments for TBM

The competent Authority in Uganda is charged with the authority to ensure that risk assessments for the TBM of GMOs are carried out and form the basiss for reaching decisions on proposed imports of GMOs that are subject to the protocols AIA procedure. The Competent Authority may perform the RA or may require the exported to do so as provided for in Article 15 (2). Under the circumstances, the CA will be expected to:

- Define the requirements of the RA
- Appoint well qualified individuals to do the RA
- Meet the requirements for public disclosure

Also in accordance to article 15(3), the cost of the RA will be the responsibility of the notifier.

Handling, transport, [packaging and identification of GMO for TBM
Article 18 (1), (2)

The Cartagena Protocol requires that the Party of import inform the Party of export on the respective rights and obligations under the Biosafety Regulations for Uganda, especially on the requirements for authorisation, labelling and accompanying documentation.

Persons, transporting GMO(s) within the scope of the national regulations, within Uganda should take into consideration:

- climatic conditions;
- infrastructure;
- transport conditions;
- technical capacities;
- existing practises;
- any other regulation applicable to the subject of the transport

The application should also demonstrate that the transport or transit does not represent any significant risk to human health or the Ugandan environment. The application should show that measures are efficient to minimise or prevent any unintentional release or potential abuse of the GMO(s) during transit. In addition, the application should also demonstrate that certified techniques and methods are available to identify or trace the GMO(s) in case an unintentional release occurs

The applicant should therefore ensure that the authorisation for transit and the accompanying documents requested under Ugandan Regulations accompany the transport at any time and shall be made available to any official, upon request. These documents should not substitute any other document necessary under any other regulation (i.e. transport documents for goods, whether hazardous or not).

Documentation and Labelling of transboundary GMOs
Any transport and transport in transit of GMO(s) in Uganda should be clearly labelled "*Contains Genetically Modified Organisms*". Such labelling should accompanying documents for all GMOS in transit through Uganda. The import of GMO-samples or GMOs in minor quantities and for research purposes only, and for which no authorisation is required should be labelled "*biological sample, genetically modified – for research purposes only*".

The accompanying documentation for transport and transport in transit of GMO(s) according to Uganda regulations should be clearly printed, in an appropriate style and in English language and shall inform:

- the importer that he/she receives LMO(s);
- the border control and customs on the port of entry and/or leave, route of transport, and date/duration of transport;
- on the conditions of transport and containment, including volume or quantity and measures to prevent or minimise unintentional and unauthorised release of LMO(s);
- those involved in transport on what to do in case of spillage or accidents;
- a summary, containing all relevant information on the LMO(s) with respect to the risk assessment and respective recommendations made, or conditions imposed by, the relevant regulatory authority of the country of export.

The accompanying documentation should also contain, in addition, a technical paper on the certified method or procedure for the unique identification of the LMO(s). The accompanying documents shall not affect or substitute any other required documentation, including:

- import permits;
- customs declaration;
- phytosanitary and sanitary documents;

- any other document, applicable to the subject and procedure of transport.
- on the expenses of the transporting institution.

Confidential information of a TBM
Article 21(1), (2), (4)-(6)

Handling confidential business information for transboundary movement of GMOs
The Cartagena Protocol on biosafety states provides for the applicant to identify information that is to be treated as confidential. Article 21 states that the Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons upon request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure. It furthermore states that "Each Party shall protect confidential information received under this Protocol, Each party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms. The Protocol thus:

- Allow for identification and justification for confidential information;
- Decision and consultation before final disclosure;
- Protects confidential information in same manner as domestic information

Proprietary information in the context of Ugandan biosafety regulations include
Trade secrets

- Commercially valuable data
- Information to be published in scientific journals
- The applicant should therefore indicate and verifiably justify which information in an application for authorisation for transboundary movement shall be treated and respected by Ugandan authorities as confidential business information.

Notwithstanding the above, the following information is not considered confidential business information:

- name and address of the applicant, the manufacturer, producer or distributor, if applicable;
- a general description of the GMO(s), products containing GMO(s) or GMO-derived products, including brand-name(s) and proposed packaging and labelling conditions, if applicable;
- a general description of the genetic modification and the modified trait;
- a summary of the environmental and -if applicable- the socio-economic risk and impact assessment;
- a summary of the assessment of the potential risk and impact on human and animal health, if applicable;
- a summary on plans and strategies for monitoring, emergency response, waste treatment and disposal as well as measures and techniques for sampling, detection and identification of the GMO.

Illegal TBM
Any person transporting GMOs in transit is liable for any damage, which may arise, from the transport or any unintentional or unauthorised release during the transport. In case of an unintentional or unauthorised release is detected, the Executive Secretary, Uganda National Council for Science and Technology, upon consultation with NBC, may decide on procedures and measures to contain the spread of the respective GMO and restore the site of unintentional or unauthorised release

Functions of the National Biosafety Committee in processing a GMO transboundary notification application

The role of the National Biosafety Committee is to will examine the application received from the executive secretary, Uganda National Council for Science and Technology and this includes examining the conformity of the application with the requirements specified in Biosafety Regulations of Uganda. This examination should not take more than 10 working days. If any modifications occur, the applicant shall immediately inform the Executive Secretary of the Council about any significant modification of technical or organisational measures, relevant to the transboundary movement.

Fees and costs involved in the in transboundary movement of GMOs

The Minister responsible for Science and Technology requires compensation for the administrative activities and procedure involved in the review of an application for authorisation of the contained use, intentional release, transit and placing on the market of GMOs. Documents and information on an application, in addition to those already provided by the Executive Secretary, Uganda National Council for Science and Technology, to the public and interested or affected parties, are made available at the applicants costs for their reproduction and posting. In addition, all further costs involved in monitoring, organising public hearings or inviting independent reviews are borne to the applicant, though the applicant has been informed in advance. The Minister responsible for Science and Technology may consider to share the expenses for monitoring, public hearings or independent reviews, if the activity in question is in the public interest or is carried out by a public institution or organisation.

Applicable fees for transboundary movement of GMOs into Uganda

Item	Fee in US$
Application fee	200
Permission to Transport or Transit of GMOs through Uganda	500
Application Processing Fees	1000
Permission to use country facilities for the contained use of GMOs in transist	500
Permit fee	200

Fee exemptions

Complex applications or combined applications for authorisation may require an expanded administrative process and review, for which the Executive Secretary of the Uganda National Council for Science and Technology may determine a fee of up to five times higher than described above.

The Executive Secretary of the Uganda National Council for Science and Technology may upon consultation with the responsible Minister, decide, whether an activity for which an authorisation is requested, is in the interest of the public. In this case, the applicant may receive a remission or reduction of fees. Also, public or governmental institutions may receive a remission of fees.