

DRAFT DOCUMENT FOR DISCUSSION ONLY

A MANUAL ON THE PROTECTION CONFIDENTIAL BUSINESS INFORMATION IN UGANDA

Meaning of terms in this manual

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

"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;

Preface

This manual aims at providing a transparent system for identifying and protecting confidential information while at the same time providing a mechanism for informing the general public about those basic elements of information in an application that are not to be kept confidential in Uganda.

The manual therefore establishes procedures whereby, following a dialogue between the notifier and the authorities, certain information can be agreed to be confidential, following a request from the notifier and if there is verifiable justification.

It is important to note from the start that information cannot be automatically considered or accepted as confidential, and in practice in most cases it is expected that little information will be of a confidential nature.

This guidance is intended to assist in the understanding and implementation of the Cartagena Protocol provision. It is however not by any means intended to be an authoritative interpretation of the Cartagena Protocol or the Biosafety regulations.

Introduction

This manual provides guidance to those rules and procedures that apply to the protection of confidential business information in Uganda in accordance with the Cartagena Protocol on biosafety. The rationale for such protection of confidential business information (CBI) is that information provided to Competent Authority (CA) in Uganda during AIA, or other procedures, is likely to include proprietary commercial information that require protection. Proprietary information in the context of Ugandan biosafety regulations includes but not limited to:

- Trade secrets,
- Commercially valuable data,
- Information to be published in scientific journals.

It is considered to be the applicant's obligation to indicate and verifiably justify which information in an application for authorisation for contained use, transboundary movement or other uses shall be treated and respected by Ugandan authorities as confidential business information.

Definition of Confidential Business Information

In the case of GMOs, confidential information is likely to be related to modern biotechnology techniques used in the production of the GMOs and other relevant information of a commercially sensitive nature.

In accordance with Article 21(1), of the Cartagena Protocol on Biosafety, the CA in Uganda is required to identify and treat as confidential information provided by the notifier upon request by the notifier. This may include, for example, certain information provided in accordance with Annex I, or subsequently upon request by the CA during the AIA procedure.

Basically, Article 21 aims at:

- allowing for identification and justification for confidential information,
- Decision and consultation before final disclosure,
- Protecting confidential information from outside in same manner as domestic information.

Thus, where the CA so requests, the notifier must provide reasons or justification as to why the information should be treated as confidential. The implication of Article 21(1) is that the CA would not be able to make available to others, for example to the public, the information provided. On the contrary, it would be under an obligation to take steps to ensure that the confidentiality of the information in question is protected.

In addition, the CA shall not divulge to third parties any confidential information notified or exchanged and shall protect intellectual property rights relating to the data received. Furthermore, the notifier is required to give justification for the information that has been identified as requiring confidential treatment.

Scope of non-Confidential Business Information

Information treated as non-confidential shall be defined as provided for in Article 21(6) of the Cartagena protocol. Accordingly, the following information shall not be considered confidential.

- a) The name and address of the notifier which may be a name and address of the applicant, the manufacturer, producer or distributor, if applicable;
- b) A general description of the living modified organism or organisms which may include 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;
- c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health/animal health if applicable; and
- d) Any methods and plans for emergency response. Including 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.

The NBC however may from time to time identify additional categories of information which the CA will not treat as confidential. For example, the following have been identified as non confidential information in previous cases:

- purpose of the release and location of release.
- The evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.
- a summary of the environmental and -if applicable- the socio-economic risk and impact assessment;

Review of relevant laws on Confidentiality in Uganda

(STILL UNDER REVIEW)

Procedure for disclosing Confidential Business Information to the CA in Uganda

Confidential business information shall be divulged to the Executive Secretary of the Uganda National Council for Science and Technology who is also the head of the CA in Uganda during disclosure of an application during AIA, intentional transboundary movements of GMOs under Article 17, or on GMO-FFPs under Article 11. The disclosure shall:

- specify the basic procedure for ensuring protection of confidential information provided under the procedures of the Protocol,
- address the situations where the CA and the notifier disagree as to whether particular information should be treated as confidential or not, and where the notifier decides to withdraw a notification,.
- set out a general obligation to protect confidential information received under the Protocol, and
- specify categories of information which shall not be considered confidential.

While Article 21 allows certain information to be treated as confidential, it does not require information concerning GMOs to be treated as confidential as a general rule. Rather, it is up to the provider of the information (the notifier) to specify the information which it considers should be treated as confidential and then to consult with the Party of import.

Upon receiving the information considered confidential, the Executive Secretary of the Uganda National Council for Science and Technology shall discuss the information with the Chairman and members of the of the NBC who are on oath to protect the information.

Procedure for initiating consultations on the nature of confidential business information

Where the notifier identifies information that should be treated as confidential, but the CA considers that the information in question does not qualify for such treatment, the CA through the NBC shall consult with the notifier. However the final decision on confidentiality rests with the CA.

If the request by the notifier is considered unjustified, then the notifier must be informed before the information is disclosed. The decision by the CA refusing confidential treatment does not need to give reasons unless the notifier so requests. However, although the CA takes the final decision, it must allow for consultation with the notifier and also for internal review of its decisions refusing confidential treatment.

In addition the CA and NBC in Uganda shall not be free to disclose information which it has decided is not subject to confidentiality. Under the circumstances, the CA shall notify its decision to the notifier before the information can be disclosed so that the notifier has an opportunity to consult and to have the decision reviewed ahead of any disclosure. If the consultation and review do not resolve the issue, the consequences of continued disagreement between the notifier and the CA in Uganda to whether particular information should be treated as confidential shall be addressed as provided for in 21(5) of the protocol.

Internal Procedures for the protection of confidential business information

The procedures that the CA shall use to protect confidential information will be done in accordance with the provisions of the biosafety regulations. The CA in addition shall set up adequate procedures to this effect so as to prevent disclosure or the commercial use of confidential information.

In addition, there shall be "non-discrimination" between imported and domestically produced GMOs in relation to confidentiality, i.e. applying the same level of protection for all GMOs .

Unauthorised use of confidential Information for commercial purposes

While such information will need to be made available to the CA through the notification procedure the Protocol forbids the commercial use of that information by the CA unless written consent from the notifier or legal owner of the proprietary information. This shall be upheld at all times.

Confidentiality of commercial and industrial information in situations of a withdrawn a notification

Withdraw of a notification made to the CA may occur when a proposed transboundary movement is not going ahead for a variety of reasons, including the possibility that the notifier and the CA have been unable to agree on which "commercial and industrial information, including research and development information", as well as more generally to "information" should be treated as confidential. In such circumstances, the CA is not free to use or disclose the disputed information and it must respect the confidentiality of the information, even if it is of the view that confidential treatment has not been justified by the notifier.