THE REPUBLIC OF UGANDA

## Uganda National Council for Science and Technology

# National Biosafety Committee

## Standard Operating Procedures




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## Uganda National Council for Science and Technology

# National Biosafety Committee

## Standard Operating Procedures

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# A. Introduction

The process of modernizing agriculture or improving health and preserving the environment inevitably involves the application of novel biotechnologies including genetic engineering of crops to increase yield and enhance their nutritional qualities, developing new biopharmaceuticals, and pollution sensitive green technologies. The generation, development and application of these biotechnologies have biosafety implications, which must be carefully managed to ensure that the process and final products are safe for human consumption and the environment. It is for this reason and purpose that the National Biosafety Committee (NBC) was established in 1996.

The NBC is an independent technical committee established under Section 5 (e) of the Uganda National Council for Science and Technology Act (Cap 209). It is one of several biosafety mechanisms that government has put in place to facilitate the testing and development of potentially useful genetically engineered organisms. These Standard Operating Procedures (SOPs) guide the NBC so that it is effective and consistent in its work.

# B. Purpose

The purpose of these SOPs is to establish uniform procedures for the NBC to review applications for research and product development involving genetically engineered plants as well as applications for use of genetically engineered organisms or their associated products. The NBC is a mechanism to evaluate and provide advice on the safety of work involving genetically engineered organisms and associated products in Uganda. The NBC may deviate from these SOPs when necessary to address unexpected or unique problems that may occur in the course of their work. These SOPs may not contravene any existing policies, laws, and guidelines regulating research and general release of genetically engineered plants, other genetically engineered organisms or products thereof.

# C. Scope

These SOPs apply to all persons and organizations who engage with the NBC for the purpose of research and general release of a genetically engineered organism and its associated products. They also apply to members and staff of the NBC.

# D. Establishment of the NBC

## 1. Responsibility of the NBC

The main responsibility of the NBC is to ensure that research, product development, general release of genetically engineered organisms are done in a manner that is safe to humans and the environment. The NBC serves to protect individuals, the community and the environment from potential risks of genetic engineering, while at the same time, facilitate the beneficial utilization of the technology.

## 2. Terms of reference for the NBC

The specific terms of reference for the NBC are as follows:

a. Conduct initial and continuing review of applications for projects involving genetically engineered organisms or intended for research, product development or general release;

b. Carry out inspections on projects involving genetically engineered organisms;

c. Educate the public on biosafety procedures;

d. Liaise with biosafety regulatory bodies of other countries in matters of trans-boundary movement of genetically engineered organisms and their associated products;

e. Advise the UNCST on any other biosafety related matters including public comments on specific biotechnology products.

f.

## 3. Composition of the NBC

The NBC may be composed of members drawn from diverse fields of science and technology including, but not limited to, science, engineering, agriculture, medicine, environment, industry, trade, law and social sciences. Members are usually drawn from universities, government ministries and agencies, private sector, and civil society. Members of the NBC should be sufficiently qualified and must have the necessary expertise and competence. The NBC comprises of a Chairperson, Vice Chairperson and nine members. When necessary, the NBC may co-opt a member for a specified period of time. The co-opted member shall be selected based on their expertise in the area of interest.

## 4. Appointment of NBC Members

Members of the NBC are appointed by the Uganda National Council for Science and Technology (UNCST). The appointment includes appointment of the Chairperson. The Vice Chairperson is elected by members from among the members. Members are appointed on their individual merit, but with due consideration of the sectors they come from. A member of the NBC is appointed to serve for four (4) years, and is eligible for reappointment. A member serving a renewed term of office goes through the same process as if they were being appointed for the first time.

## 5. Resignation and replacement of NBC member

A member of the NBC may resign at any time, upon giving a two months written notice to the Executive Secretary of the UNCST. A member of the NBC may also be replaced when the UNCST is satisfied that the member can no longer discharge his/her duties due to infirmity of the body or mind, and for misconduct or misbehaviour.

# E. NBC Secretariat

## 1. Location

The Secretariat of the NBC is provided within the Unit at UNCST responsible for research oversight and regulatory affairs. Staffs of UNCST at the level of Science Officer and above are assigned to service the NBC.

## 2. Functions

The functions of the NBC Secretariat are:

a. Inform and advise applicants and new NBC members of applicable regulations, guidelines, processes and procedures;

b. Maintain active communication with applicants, ensuring timely and complete submission of applications for NBC review and feedback on the review process;

c. Organize meetings of the NBC, including the distribution of relevant documentation to members, scheduling the meetings, and ensuring the quorum;

d. Take minutes at all NBC meetings;

e. Follow-up with tasks that the NBC requests the applicants to perform such as progress reports, final reports, corrective actions, amendment of the approved protocols, etc.

f. Liaise with the NBC Chairperson on preparation of annual reports of NBC activities;

g. Liaise with the Chairperson, on matters that may be handled in an expedited fashion;

h. Ensure proper keeping of records, including maintaining applications, approved protocols, and all correspondences in relation to NBC activities;

i. Facilitate access to literature and educational programmes useful to the members of NBC.

j. Update information about NBC membership, including declarations of potential conflicts of interest.

The Secretariat may be assigned additional functions as need may arise.

# F. Meetings of the NBC

## 1. Convening Meetings

Meetings of the NBC are scheduled at least once every two months throughout the year. The Secretariat in close collaboration with the Chairperson will schedule meetings of the NBC, and give members at least two weeks' notice.

## 2. Agendas

NBC meeting agendas are set by the NBC Chairperson with the assistance of the Secretariat. Any member of the NBC may request a topic be placed on an upcoming agenda. Standing items on the agenda include prayer, communication from chairperson, opportunity to disclose conflict of interest, report from the NBC Secretariat, review of minutes of previous meeting, matters arising and the substantive subject(s) for the meeting.

## 3. Quorum

Quorum for the NBC meetings consists of at least 50% of the total number of Committee members. Co-opted members are not counted as part of the quorum.

## 4. Voting

Decisions of the NBC shall be by consensus, and if consensus cannot be achieved, by a two thirds majority vote of the members present. The voting procedure involves a motion, a second of the motion and a vote seeking a simple majority of the members present. Co-opted members

do not vote. Members may participate by electronic means such as conference calling, and may vote in this way, provided they have access to materials being discussed at the meeting.

### 5. Minutes

The minutes of NBC meetings will reflect the date, time, and place of the meeting, individuals in attendance, whether minutes of the prior meeting were approved, all approved motions, and the time of adjournment. Regarding discussions of applications, the content of NBC minutes will include the name of the applicant, the name of the agent, discussion of the risk assessment by the NBC, and the biosafety level assigned to the work by the NBC. Trade secret information, confidential business information, and specific information the disclosure of which would directly compromise national security will be redacted in the minutes. Draft minutes of the previous NBC meeting are included in the next agenda packet for review by committee members. NBC members are asked for any comments or changes to the minutes after which a formal motion may be made, seconded, and discussed, followed by a vote on approval of the minutes. Approved NBC minutes, which are kept as a permanent record of committee business, are available to the public upon request.

## G. Conflict of Interest

A member of the NBC may not be involved (except to provide information) in the review or approval of an application in which he/she has been or expects to be engaged or has a direct financial interest. NBC members are expected to recuse themselves from the review and approval of applications in which they expect to be engaged or in which they have a direct financial interest. A committee member will not be assigned to review an application if a conflict of interest has been identified. At each meeting committee members will be given an opportunity to identify any conflicts of interest pertaining to items on the agenda.

# H. Confidentiality

NBC members shall protect all information given to them in confidence in the course of their work, including Confidential Business (or proprietary) Information. Members shall be requested to sign a confidentiality agreement on appointment to the NBC. No member of the NBC shall use information provided to them in the course of their work in the committee for personal gain.

# I. Payments to NBC members

Members of the NBC shall be entitled to reimbursement for reasonable expenses incurred during discharge of their official NBC duties. Such reimbursement shall cover meals, travel, and accommodation in accordance with UNCST financial policy and manual. NBC members shall be paid a transport and facilitation allowance determined in accordance with the UNCST financial policy and manual for every meeting attended.

# J. Review Process

## 1. Receiving an application

Members of the NBC shall receive complete applications and documents at least 14 calendar days prior to the convened NBC meeting. Applications must be made using UNCST standard application forms available at www.uncst.go.ug. The application and documents may be in hard copy or sent electronically. The NBC Secretariat shall ensure that application and documents for NBC review are screened for completeness; and shall inform the applicant within five working days of the status of their application.

## 2. Reviewing applications

The Secretariat, in close collaboration with the Chairperson, assigns an application or document to three NBC members as primary, secondary and tertiary reviewers. During the meeting, these reviewers are given the first opportunity to make comments on the application or document,

and then the other committee members. Applicants may be may be invited to present their protocols at the convened NBC meetings. Where the expertise may not exist within the NBC, an application or document may be sent to an external person/consultant who may be co-opted to the NBC for a specific period of time. The expert shall submit comments in writing, and may also be requested to attend an NBC meeting. Where the application involves a general release, or whenever necessary, the NBC may elicit public comments on the application. Public comments shall be received within 30 days from the date the application is published for comments.

## 3. Duration of review

The NBC shall make a decision on a complete application within 90 and 270 days from the date it is received at the NBC Secretariat in the case of field trials and general release respectively, except for expedited review.

## 4. Expedited review

The NBC may review an application or document in an expedited fashion provided that:

a. NBC or similar body in another country or group of countries with comparable ecosystems has previously reviewed and approved the application in question;

b. The application in question is exempt from review by international or regional protocols;

The NBC secretariat in close collaboration with the Chairperson determines whether an application or document qualifies for expedited review. If it does, the Chairperson may undertake the review and may assign one or two members of the committee to review the application or document within seven working days. The expedited review process takes no more than 21 working days.

## 5. NBC Decisions

The NBC decisions on an application shall be communicated in a decision document (Appendix 1). The decision document contains a summary of the question, the decision, and the rationale for the decision. It also describes the project, the process of assessment and decision, safety and other concerns raised, risk mitigation procedures addressing the concerns, terms and conditions and dates of authorization (for approvals), or reasons for rejection(s). Confidential Business Information or other confidential information is not included in the decision document. The decision document is also used to in reporting to the Biosafety Clearing House in the case of genetically engineered organisms. Decision documents will be submitted to UNCST not later than seven days from the date of NBC meeting at which the decision was made. The decision document is used by UNCST to prepare an approval or authorization letter (Appendix 2). This letter will act as the Authorization Permit. No project involving genetically engineered organism shall commence without the authorization permit. The duration of the permits is for three years, subject to annual review. When the three years elapse and the project is not ended, the permit may be renewed upon submission of a satisfactory progress report.

## 6. Appeal against NBC Decision

An applicant who is dissatisfied with the decision of the NBC may appeal to the Chairperson of the UNCST. The Chairperson of UNCST shall convene a Panel to consider the appeal.

# K. Elements of Review

In general, NBC review of applications involving genetically engineered organisms is intended to 1) prevent the escape of novel gene from the experimental site; 2) prevent a genetically engineered organism from being consumed by humans or livestock, and 3) prevent genetically engineered organism from establishing and persisting in the environment.

In particular, the NBC shall, among other things, review the following elements in an application: qualification and competence of the applicant; adequacy of resources for the project; suitability of facilities; characteristics of genetic construct; characteristics of the recipient organism, plant species or the environment; potential environmental risks; and safety for food and feed.

# L. Fees

## 1. NBC Review Fees

The review fees for applications submitted to the NBC are indicated in below. The fees are determined by the UNCST and are subject to review any time. The review fees must be paid prior to review of the application by the NBC. Applications whose fees are not paid shall not be included in the agenda for NBC meeting. The review fee is non-refundable.

| | Fees in US Dollars | | |
|---|---|---|---|
| **Nature/ Category of review** | **Laboratory Experiments*** | **Field Trials** | **General Release** |
| Initial Review | 1,300 | 1,800 | 5,000 |
| Continuing Review/ Annual Renewal | 400 | 700 | N/A |
| Amendment | 300 | 500 | N/A |

*Laboratory experiments which are eligible for payment of fees shall be determined on a case by case basis by the Competent Authority.

## 2. Inspection Fees

Routine inspection by designated agents or inspectors is undertaken to ensure compliance with approval conditions. Fees for inspection are charged on a cost-recovery basis for each official inspection required by the NBC, and shall be paid to the UNCST basing on UNCST financial policy and manual.

# M. Linkage between NBC and Institutional Biosafety Committees

An Institutional Biosafety Committee (IBC) is established at an organization where the project involving genetic modification takes place. The responsibility of the IBC is to provide on-going oversight and guidance for scientists at the organizational level on all matters relating to safety measures in place to support genetic engineering work. An IBC shall endorse an application before it is submitted to the NBC. The NBC shall require an IBC letter of endorsement as evidence that the application has been reviewed and endorsed by the IBC. It is the responsibility of the applicant to secure an IBC endorsement and forward it along with the application to the NBC. Decisions of the NBC shall be copied to the relevant IBC. At the end of each calendar year, the IBC shall make a formal report of its activities during the year to the NBC. The report shall be due on 31st January every year. The format for the report is included in Appendix 3.

# N. Annual Reports to UNCST

At the end of each calendar year, the IBC shall make a formal report of its activities during the year to the UNCST. The report shall be due on 31st January every year. The format for the report is included in Appendix 4.

# O. Records Keeping

## 1. NBC filing system

The NBC maintains a hard copy folder for each application securely at the NBC secretariat. The folder contains a reference number, project document, reviewer's comments, copies of approval letters and other correspondence, inspection reports, and e-mails related to the applicant's work. The folder is kept at the NBC secretariat for a period of at least five years after completion of the project.

### 2. NBC database

The NBC secretariat maintains an electronic database of all applications submitted for NBC review.

### 3. NBC meeting materials

The NBC maintains records of the past meetings of the NBC. The meeting files contain the

agenda, the agenda enclosures and handouts, and a copy of the approved minutes for that particular meeting.

## P. Inspections by NBC

The NBC may carry out scheduled and unannounced inspections of facilities. Inspectors may be NBC members, UNCST staff or designated inspectors from other agencies, e.g. the Phyto-sanitary and Plant Health Inspectorate. An inspection schedule shall be drawn up by the NBC secretariat. The NBC shall assign an inspector for each project, as and when necessary. Inspection reports shall be made to the NBC within five working days of completing the inspection. The applicant shall meet the cost of scheduled inspections.

## Q. Emergency situations

Certain situations may require immediate action such as accidental release of a genetically engineered plant. The applicant shall report any situation involving genetic engineering that poses a threat to human health and the environment to the NBC Secretariat within 24 hours. Note: accidental release of a genetically engineered organism or product does not in itself necessarily constitute non-compliance, but does require prompt reporting to the NBC. In addressing the emergency, the NBC Chairperson is first notified, who then determines whether a full NBC meeting is required to resolve the issue.

# R. Non-compliance

## 1. Evaluating non-compliance

In situations where non-compliance is identified or reported, the NBC shall evaluate whether the situation represents "significant problems with or violations of the approval terms and conditions". In this case, the NBC secretariat will provide a summary to the NBC which describes the situation; the individual(s) involved, and proposed corrective actions. The NBC will review the situation and make a recommendation about corrective actions. The NBC may appoint members of the NBC to form a sub-committee to carry out the evaluation.

## 2. Outcomes for the Applicant

Depending upon the severity and nature of the non-compliance, certain actions may be taken. For example, the NBC may:

a. Notify the head of the organization hosting the project;

b. Summon the Applicant to appear before the NBC;

c. Modify approval terms and conditions;

d. Recommend education, training or mentoring;

e. Increase the frequency of inspections;

f. Suspend or terminate the project;

g. Apply other appropriate sanctions including fines and restoration measures.

# S. Training of NBC members

New NBC members are oriented to the committee through discussion with the NBC chairperson and the NBC Secretariat. Background materials regarding the functioning of the NBC are provided including a copy of any relevant national biosafety regulation or guidelines. NBC members





and staff are encouraged to attend refresher courses, professional development conferences on biosafety and related matters.

# T. Guidance Documents

## 1. Preparation of Guidance Documents

The NBC may develop guidance documents to assist in the submission and review of applications. Upon development and approval of a guidance document, the NBC secretary assigns an appropriate version number and effective date to the document, converts the document it to pdf format, and places it on the official website of the UNCST. Previous versions shall be withdrawn from the website, unless needed for on-going activities. Changes introduced by a new version of the guidance document shall be implementing by the applicants as soon as possible. Guidance in these documents may change without notice, and the requirements described may be altered or superseded by official guidance issued by the UNCST, such as the terms and conditions of authorization for a particular trial. Applicants and others should consult the guidance documents, as well as all relevant guidelines, SOPs, biology documents, and other published guidance in preparation and planning for any activities involving regulated organisms or substances.

## 2. Biology Documents

The NBC encourages applicants to use biology documents prepared from authentic sources. For example, crop biology documents are published from time to time by various bodies including regulatory authorities, and are also available from sources such as the Organization for Economic Cooperation and Development (OECD) and the United States Department of Agriculture. Applicants are encouraged to use these published biology documents to complete the relevant portions of the application, provided that local conditions are adequately addressed in the documents cited. Where an adequate published document or relevant information does not exist, the applicant may be required to

prepare and submit a crop biology document along with the application. Currently, the NBC prefers use of the OECD format for crop biology documents.

## U. Review of SOPs

These SOPs may be reviewed at any time by the UNCST or upon a written request from the NBC. Once a written request is received, the NBC Secretariat conducts an evaluation of the areas to be reviewed. The review may be done jointly by the NBC, or a consultant may be hired as appropriate. The revised draft is discussed by the NBC at a scheduled meeting and accordingly approved and endorsed by the Executive Secretary of UNCST.

# APPENDICES

## Appendix 1. NBC Decision Document

| NATIONAL BIOSAFETY COMMITTEE |
| --- |
| DECISION DOCUMENT |
| File Reference Number: |
| In regard to Application by [*name of applicant*] for: *[Title of project].*<br>*[Brief project summary including goals and objectives]*<br>*[Date application was received; dates when NBC meetings were held to review the application, and vote taken on the application]* |
| RISK ASSESSMENT UNDERTAKEN: |
| *[Summarize NBC deliberations on the risk assessment. Mention resources that were used or referred to]* |
| RECOMMENDED CONFINEMENT AND/OR RISK MITIGATION MEASURES: |
| *[List the confinement or risk mitigation measures recommended by the NBC]* |
| OTHER ISSUES TO BE CONSIDERED: |
| *[Mention any other issues identified which the Applicant must take into account.]* |

| DECISION |
| --- |
| The NBC, having conducted a thorough assessment, having considered the safety issues, risk mitigation options available, and other concerns identified, has [approved/rejected] the application. |
| TERMS AND CONDITIONS |
| The activities authorized shall be carried out in accordance with Terms and Conditions described below: |
| REASONS FOR REJECTING THE APPLICATION: |
| *[Indicate reasons for NBC's rejection of the application]* |
| AUTHORIZATION |
| |
| Signature, Chairperson of the NBC Date |
| |
| Signature, Secretary of the NBC Date |

| | |
| --- | --- |
| Original: File<br><br>Copies: -UNCST Executive Secretary<br>-Biosafety Clearing House<br>-Applicant | For further information, contact:<br>*[Contact details of NBC]* |

## Appendix 2. Format for Authorization Letter/Permit

A letter of Authorization [LOA] is issued by UNCST for each project approved, which serves as the official permit for the project. As such, a copy of the LOA must be included in the trial documents, and be available for inspection by Biosafety Inspectors or other authorized agents. The LOA lists the Terms and Conditions applicable to the trial, and is the governing document for conduct of the trial.

## Appendix 3. Form for Annual Report of the IBC

The annual report of the IBC will include information regarding the following: The composition of the IBC, including member qualifications/ expertise, member roles in the IBC among others; Details of all IBC activities during the reporting period; A list of projects under IBC supervision; Anticipated or Planned activities for the following year.

## Appendix 4. Format for Annual Report of the NBC

The annual report of the NBC will include information regarding the following: The composition of the NBC, including member qualifications/ expertise, member roles in the NBC among others; Details of all NBC activities during the reporting period, and a list of projects under NBC supervision;

## Appendix 5: The role of the NBC in reviewing applications involving bio-hazardous substances

The NBC has additional responsibility of reviewing application involving bio-hazardous substances such as virulent strains of pathogens or regulated exotic bio-agents. These generally fall under the risk group three and four of human etiologic agents (USDHHS/NIH 2002), and risk group three of phytopathogenic agents (Flanders Interuniversity Institute for Biotechnologies, 2002) or later versions. In reviewing such applications involving bio hazardous substances, the NBC shall apply the same standards and procedures as outlined in these SOPs. IBCs also have a responsibility to advise or notify the NBC of activities involving regulated bio-agents; and shall also be required to endorse any such application prior to NBC review.

# Acknowledgement

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## NOTES

# NOTES





